

KidneyNews

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Dialysis Centers Adapt to Evolving COVID-19 Outbreak

Maintaining patient care, reducing transmission are priorities

By Bridget M. Kuehn



Dialysis centers across the country are taking extraordinary measures to ensure the safety of patients and staff during the Coronavirus Disease-2019 (COVID-19) pandemic. The team at Seattle's Northwest Kidney Centers found itself on the leading edge of that effort when they learned that one of their dialysis patients was the first US fatality.

"Our guiding principles were first and foremost to ensure that patients are coming to dialysis," said Suzanne Watnick, MD, Chief Medical Officer, Northwest Kidney Centers.

Watnick and Elizabeth McNamara, Vice-President of Patient Care Services and Chief Nursing Officer, shared their experiences during a webcast hosted by ASN's Nephrologists Transforming Dialysis Safety (NTDS) initiative. They were joined in the call by leaders from NTDS and Shannon Novosad, MD, MPH, a medical officer with the Dialysis Safety Team in the Centers for Disease Control and Prevention's (CDC) Division of Health Care Quality Promotion. ASN has also teamed up with the CDC to create a COVID-19 Response Team that meets weekly. The team published its first set of recommendations in the

Clinical Journal of the American Society of Nephrology and expects to issue frequent updates. It is all part of an ongoing effort by leaders in nephrology to help keep clinicians abreast of the latest information in the rapidly evolving pandemic.

"It's a challenge being on the forefront of an evolving pandemic," McNamara said. "That's what I told the staff: 'What we said yesterday might change today. What we said two hours ago might change, and it's not because we have wrong information. It's because we're finding out new information, so we have to stay facile. We have to be able to adapt.'"

Evolving US response

Given how much the COVID-19 outbreak has evolved since it was declared a pandemic by the World Health Organization on March 9, 2020, Novosad said it is critical for dialysis centers to plan ahead for what may come next.

Watnick said they immediately began coordinating their efforts with the CDC and local public health authorities to facilitate their response and crafted a letter to patients notifying them of the patient death and the pre-

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Proteinuria After AKI Predicts Kidney Disease Progression, Study Suggests

For hospitalized patients with acute kidney injury (AKI), postdischarge measurement of albuminuria may improve the ability to identify patients at higher subsequent risk of progressive kidney disease, according to a prospective, multicenter cohort study reported in the March issue of *JAMA Internal Medicine*.

Patients with an episode of AKI are at high risk of rapidly declining kidney function. New approaches are needed to identify those patients at highest risk of kidney disease progression.

Doubling of the urine albumin-to-creatinine ratio (UACR) after hospital discharge is associated with a 1.5-

fold increase in the odds of kidney disease progression, according to the report by the Assessment, Serial Evaluation, and Subsequent Sequelae in Acute Kidney Injury (ASSESS-AKI) investigators. The lead author is Chi-yuan Hsu, MD, MSc, chief of the division of nephrology at the University of California, San Francisco.

"Proteinuria level is a valuable risk-stratification tool in the post-AKI period," Hsu and coauthors write. "These results suggest there should be more widespread and routine quantification of proteinuria after hospitalized AKI."

The researchers analyzed data on 1,538 hospitalized

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Our coverage continues inside with recommendations for dialysis facilities and perspectives from physicians on the ground



Policy Update

Improving quality measures and a much-needed update to healthcare interoperability



AKI!Now

This new ASN initiative promotes excellence in preventing and treating AKI with a goal of improving long-term outcomes





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Proteinuria After AKI

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adults from the ASSESS-AKI Study. Patients were enrolled 3 months after discharge from four North American clinical centers, representing a range of hospital settings. During their hospital stay, 769 patients had an episode of AKI, defined as a relative increase of at least 50%, or 0.3 mg/dL in serum creatinine (SCr), compared to the most recent outpatient measurement (7 days to 1 year before admission). The patients were 519 men and 250 women, mean age 63.7 years; 15.2% were black. Median duration of the AKI episode was 2 days.

Patients in the AKI cohort were matched to 769 adults without AKI at index hospitalization. Both groups made an outpatient research study visit 3 months after hospital discharge. At this visit, mean estimated glomerular filtration rate (eGFR) was 65.7 mL/min/1.73 m² in the AKI group, compared to 72.7 mL/min/1.73 m² in patients without AKI. For AKI patients, the mean peak SCr value was 2.46 mg/mL.

At the study visit, patients also underwent random urine UACR measurement, with median values of 21 mg/g in the AKI group and 11 mg/g in patients without AKI. Patients with an episode of AKI were more likely to have UACR values between 30 and 300 mg/g (microalbuminuria), 27.4% versus 19.4%; as well as over 300 mg/g (macroalbuminuria), 15.5% versus 6.5%.

Data analysis focused on potential predictors of subsequent kidney disease progression, including proteinuria, eGFR, and a range of clinical and demographic variables. Progressive kidney disease was defined as halving of estimated eGFR or diagnosis of kidney failure.

Higher UACR linked to increased odds of kidney disease progression

Median follow-up was 4.7 years. During this time, kidney disease progression occurred in 138 patients: a rate of 9.0%. Fifty-eight of the patients with progressive disease were diagnosed with kidney failure. Of the 138 patients, 97 were in the AKI group.

Patients with higher UACR at the 3-month postdischarge visit were significantly more likely to have kidney disease progression: hazard ratio 1.53 for each doubling of UACR.

“The performance of postdischarge UACR was better in patients who experienced AKI than in patients discharged without AKI,” Hsu and coauthors write. C statistics were 0.82 versus 0.70, respectively.

Post-AKI eGFR was also a predictor of kidney disease progression: HR 1.50 per each decrease of 10 mL/min/1.73 m². However, the C statistic of 0.77 was lower than the corresponding C statistic for post-AKI UACR (again 0.82). In a comprehensive model incorporating clinical risk factors, discrimination for predicting kidney disease progression was greater in patients who had AKI than in those who did not: C statistic 0.85 versus 0.76.

In the overall ASSESS-AKI population—after accounting for UACR, eGFR, and traditional CKD risk factors—neither the presence nor severity of AKI was independently associated with kidney disease progression. But UACR remained a significant, independent risk factor, as did eGFR. The findings are consistent with previous studies (such as James et al., 2017) suggesting that AKI stage is less important than kidney function at discharge.



Patients with higher UACR at the 3-month postdischarge visit were significantly more likely to have kidney disease progression.

Call for more routine quantification of proteinuria after hospitalized AKI

Two recent reports have reported increases in proteinuria after AKI, “potentially reflecting residual renal parenchymal injury,” according to Hsu and coauthors. In a VA study, Parr et al. (2018) found that AKI patients were more likely to have 1+ or greater proteinuria in the year after discharge, compared to matched controls without AKI. Another report by Hsu and colleagues (2019), based on analysis of the prospective ASSESS-AKI and CRIC cohorts, concluded that “an episode of hospitalized AKI was

independently associated with a 9% increase in the urine protein-to-creatinine ratio.”

The new results provide evidence that measuring proteinuria after AKI can help predict subsequent loss of kidney function—even more strongly than post-AKI eGFR. “[O]nce post-AKI proteinuria, post-AKI eGFR, and other known CKD risk factors are taken into account, patients who experience AKI during hospitalization have similar renal prognoses compared with hospitalized patients who did not experience AKI,” Hsu and colleagues write. The authors note some important strengths of their prospective cohort study, including rigorous measurement of proteinuria about 90 days after hospital discharge. They note that their findings are consistent with Healthy People 2020 objectives to increase the proportion of hospitalized patients with AKI who undergo follow-up renal assessment within 6 months after discharge.

Previous studies of renal outcomes have focused on SCr, but proteinuria is not commonly assessed. “Our findings demonstrate that proteinuria after AKI carries important prognostic information not conveyed by serum creatinine alone and that clinicians should not be falsely reassured by the latter,” Hsu and colleagues write.

Because proteinuria is itself a potentially modifiable risk factor, treatments to reduce proteinuria—including blood pressure control and angiotensin converting enzyme inhibitors or angiotensin receptor blockers—might lower the risk of adverse outcomes after AKI. Several recent studies have suggested benefits of ACE-I or ARB therapy for patients with AKI, many of whom also have other indications, although these medications “appear to be underutilized” after AKI, according to the authors.

Overall, the findings add evidence that “increased proteinuria (and decreased eGFR) [are] potentially key steps in the causal pathway linking AKI to CKD.” The ASSESS-AKI investigators conclude: “Our results suggest there should be more widespread and routine quantification of proteinuria after hospitalized AKI, perhaps similar to how patients with diabetes mellitus undergo screening for proteinuria.” ■

The paper discussed in this article is:

1. Hsu CY, et al. Post-acute kidney injury proteinuria and subsequent kidney disease progression: The Assessment, Serial Evaluation, and Subsequent Sequelae in Acute Kidney Injury (ASSESS-AKI) Study. *JAMA Intern Med* 2020; 180:402–410.

Other papers mentioned:

1. James MT, et al. Derivation and external validation of prediction models for advanced chronic kidney disease following acute kidney injury. *JAMA* 2017; 318:1787–1797.
2. Parr SK, et al. Acute kidney injury is a risk factor for subsequent proteinuria. *Kidney Int* 2018; 93:460–469.
3. Hsu CY, et al. Impact of acute kidney injury on urinary protein excretion: analysis of two prospective cohorts (ASSESS-AKI and CRIC). *J Am Soc Nephrol* 2019; 30:1271–1281.



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Dialysis Centers Adapt

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cautions they would be taking.

“We wanted to be transparent and felt they had the right to know,” McNamara said. Staff were trained in droplet precautions and protocols to follow for patients with suspected or confirmed cases, patients were screened for potential symptoms, and strict protocols for regular disinfection of all surfaces were enacted.

Alan Kliger, MD, chair of NTDS, noted that older patients, particularly those older than 80 years, and those with chronic conditions like heart disease, lung disease, and diabetes appear to have the greatest risk of dying. Although data are limited, he noted that patients with kidney disease are expected to be at higher risk.

“Kidney care patients typically have multiple chronic conditions, which make them a vulnerable population in general, and it’s no different in this situation,” said Jeff Giullian, chief medical officer for DaVita, in an e-mail interview. “The safety of patients is our top priority, which is why we’ve been actively educating both patients and clinicians on the importance of maintaining discipline with infection control practices and the CDC’s established best practices for helping prevent exposure to this and other diseases.”

Communication with patients is critical, Kovosad emphasized. This should include basic information about COVID-19 through posters, letters, or staff talking points. Patients should know what symptoms to look for such as fever, cough, sore throat, and muscle aches. They should also be educated about the precautions being taken to protect them and how they can help, for example, by using cough etiquette or proper handwashing.

“It helps patients take an active role in staying healthy and it also helps a number of procedures that clinics will be implementing, such as screening,” she said.

Communication with staff and transparency about procedures and policies is also vital, Kovosad said. Staff need to be kept up to date on how to keep themselves and patients safe. They must be trained in the use of protective equipment and have easy access to it and receptacles for disposal. She also said dialysis centers should ensure sick leave policies are “non-punitive and flexible” and that staff know what they are.

“It’s important that healthcare personnel understand they can be a source of infection both to other patients and fellow staff members and they shouldn’t report to work when ill,” she said. If they develop symptoms at work, they should immediately don a mask, inform their supervisor, and leave the treatment area. During times of community transmission or when infected patients are in the facility, they may also want to check their temperature regularly.

Multidisciplinary cooperation and planning are also key. Giullian said DaVita established domestic and international task forces in January, made up of people who specialize in emergency management, infection control, and supply chain management and communications. They’ve also been working closely with the CDC, ASN, Kidney Community Rapid Response, and other providers, he said.

“What many people don’t know is how connected and supportive providers in the kidney care community are of one another in times of need,” he said. “Establishing and engaging proactively and consistently with these organizations helps all of us better support our patients.”

One step that all facilities should take now is an inventory of their personal protective equipment and preparing to have supplies conveniently available, Kovosad said.

“If your facility is concerned about a potential or imminent shortage of [personal protective equipment], definitely contact your state or local health department,” she said. “They are in the best position to help you troubleshoot through temporary shortages.”

“We worked closely with our vendors and distributors to secure supplies of medications, dialysis disposables, and

personal protective equipment,” Giullian said.

Facilities should also develop triage protocols, for example, having symptomatic patients call ahead. Symptomatic patients should wear masks while in the facility, be kept at least six feet from other patients, and be dialyzed at the end of a row or in a private room with the door closed, if available, Kovosad said. If a center has numerous symptomatic patients, they may wish to begin cohorting them and the staff who treat them, for example, dialyzing them on the last shift to allow for disinfection.

When a patient is diagnosed with COVID-19, the local public health department should be notified immediately, she said. These patients, or those with suspected cases, should be treated in a separate room, but negative air pressure is not currently recommended, she noted.

“We can provide dialysis to patients with COVID-19,” Watnick emphasized. “We have an obligation as a community to provide it so our patients are receiving the safest and most effective care.”

Watnick offered reassuring advice to other centers about the outbreak. She emphasized following the latest science and working in collaboration with the CDC and local public health authorities. She also emphasized the role centers can play in helping to reassure staff and patients. Watnick noted that their centers are in daily communication with staff, including having daily conference calls to field questions.

“There’s a lot of fear, a lot of anxiety, not only for our

There’s a lot of fear, a lot of anxiety, not only for our patients, but also for our staff and the community in general. . . . But . . . centers can provide reassurance, be transparent, communicate well, and provide as much support as possible for patients, the dialysis staff, and the medical staff.

patients, but also for our staff and the community in general,” Watnick said. But she said centers can provide reassurance, be transparent, communicate well, and provide as much support as possible for patients, the dialysis staff, and the medical staff.

International perspectives

While some US dialysis centers are still bracing for the effects of COVID-19, their colleagues in other parts of the world are offering advice and early data about what to expect. In a recent overview of the data, Vivekanand Jha, MBBS, MD, DM, PhD, President of the International Society of Nephrology and Executive Director of the George Institute for Global Health in Newtown, Australia, highlighted the data so far on the potential kidney effects of COVID-19.

“The data is limited essentially to people who present to hospitals and are admitted afterward—individuals who have a more advanced COVID infection,” he cautioned.

Among people admitted to hospitals with the infection, more than half had some kidney involvement such as proteinuria and a smaller proportion also had a decline in the filtration function of the kidneys, Jha noted. In an unreviewed manuscript published on the preprint server medRxiv, Yiqiong Ma, of the department of nephrology at Renmin Hospital of Wuhan University in China, described the experience of one dialysis center in Wuhan where the virus originated. Between January 14, 2020, and February 17, 2020, 37 of the center’s 230 hemodialysis

patients and 4 of its 33 staff were diagnosed with COVID-19. Seven patients died during that period, including 6 with COVID-19. The COVID-19-infected dialysis patients had a different immunologic profile than other patients infected with the virus. The dialysis patients had fewer lymphocytes and fewer inflammatory cytokines.

The Chinese Society of Nephrology and the Taiwan Society of Nephrology have leveraged their countries’ experience on the leading edge of the pandemic to develop guidelines for dialysis centers around the globe. A summary of the guidelines was included in Jha’s paper. Among the recommendations are screening patients at the door, separating staff during lunch breaks, appropriate protective gear for staff, protective gear for transport personnel, and cohorting patients and staff to avoid cross-contamination. Communication was also emphasized.

Most dialysis centers around the world are adapting on the fly. Jha said the unprecedented scale of the pandemic makes it a unique situation compared to the previous outbreaks of the related SARS and MERS viruses.

“Dialysis units are developing their own practices for containment,” Jha said. The key, he said, is to ensure uninterrupted access to dialysis including for those with COVID-19 infections. He also argued for judicious use of protective gear in the face of potential shortages, “just to make sure that we maintain a sense of balance as we deal with this condition.”

Kliger, the lead author of the COVID-19 Response Team’s recommendations, echoed the call for a steady response through the pandemic.

We are witnessing a response to a pandemic that we have never seen before,” Kliger wrote. “Such unprecedented steps create anxiety and uncertainty in us all.”

But he noted that most people with COVID-19 infections develop mild symptoms and survive without complications. Children seem to do well. Elderly and high-risk people must think carefully about how to protect themselves.

Our best strategy to stop viral transmission is frequent hand hygiene, social distancing, avoiding contact with infected people, and if we develop symptoms, self-quarantine, use cough/sneeze etiquette, wash surfaces with disinfecting spray or wipes and keep informed about best practices from the CDC and local health departments. ■

Suggested Reading

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2. Kliger A and Siberzweig J. Mitigating Risk of COVID-19 in Dialysis Facilities. *CJASN*. March 16, 2020. <https://doi.org/10.2215/CJN.03340320>
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ASN Seeks Policy Changes to Aid Kidney Care During COVID-19 Pandemic

By Bridget M. Kuehn

The ASN is working closely with the US government to ensure the safety and health of the more than 37 million Americans living with kidney diseases during the COVID-19 pandemic.

On March 18, 2020, ASN President Anupam Agarwal, MD, FASN, and leaders from 15 other professional medical societies met by phone with President Donald Trump to stress the unique challenges of caring for patients during the pandemic. The more than 500,000 US patients on dialysis and the 222,000 with kidney transplants are among those most vulnerable to the spread of COVID-19.

Other leaders of the US COVID-19 response team participating in the call included Vice President Mike Pence, US Department of Health and Human Services (HHS) Secretary Alex Azar, US Centers for Disease Control and Prevention Director Robert Redfield, MD, Centers for Medicare & Medicaid Services Administrator Seema Verma, and Coronavirus Response Coordinator Ambassador Deborah Birx, MD.

During the call, Dr. Agarwal expressed ASN's commitment to working with the vice president and his task force, partners within the federal agencies, and congressional representatives to ensure the unique needs of kidney patients are met during the pandemic. He explained that testing and personal protective equipment shortages are felt acutely by dialysis and transplant patients and by

healthcare professionals.

ASN submitted a letter to HHS Secretary Azar asking him to prioritize COVID-19 testing for dialysis and transplant patients and for both living and deceased donors. ASN also requested several temporary policy changes during the pandemic, including a pause in Quality Assessment and Performance Improvement (QAPI) requirements that mandate home patients receive routine testing at dialysis centers and a temporary suspension of the QAPI reporting requirement.

Already, the Medicare program has relaxed its rules for telehealth visits to reduce the need for patients to leave their homes for care. The decision was strongly supported by ASN. The change will allow nephrologists, other physicians, nurse practitioners, clinical psychologists, and licensed social workers to provide telehealth to any home. Services may include office visits, mental health counseling, and preventive screening.

"During the COVID-19 national emergency, covered health care providers subject to the HIPAA Rules may seek to communicate with patients, and provide telehealth services, through remote communications technologies," according to the Office for Civil Rights (OCR). To facilitate this, the OCR will "exercise discretion" and not enforce HIPAA restrictions that had previously limited which technologies could be used for the duration of the COVID-19 public health emergency. ■



COVID-19 Response Team Recommendations for Dialysis Facilities

The ASN, working in conjunction with the Centers for Disease Control and Prevention (CDC) has put together recommendations for dialysis facilities on managing the COVID-19 pandemic. A brief summary of each recommendation is available here:

- All patients should be screened for symptoms on arrival. Symptomatic patients should be advised to call ahead. Those with symptoms or at risk because of likely exposure to COVID-19 should wear a mask while in the facility.
- Patients with suspected or confirmed COVID-19 should be isolated. A separate room with a closed door (not a room used for hepatitis B positive patients) should be used if available. Or patients may be cohorted in a shift, at a facility, or if no other option exists, at the end of a row with a mask at least six feet from other patients.
- Patients should be instructed on mask use, cough etiquette, and proper tissue disposal.
- Dialysis staff should employ standard contact and droplet precautions, including isolation gowns, gloves, masks, and eye shields or goggles. Protective gear must be used judiciously in the face of shortages.
- Routine disinfection of surfaces and equipment should be used.
- Public health officials should be notified promptly of possible COVID-19 cases.
- Review online guidance from the CDC and ASN frequently. Recommendations are likely to be updated frequently.

Source: Kliger A and Siberzweig J. Mitigating risk of COVID-19 in dialysis facilities. *Clin J Am Soc Neph* March 16, 2020. <https://doi.org/10.2215/CJN.03340320>

AKI Is a 'Risk Multiplier' for Complications After Hip Replacement

Patients who develop acute kidney injury (AKI) after primary total hip arthroplasty (THA) are at increased risk for adverse outcomes, including complications and death, reports a study in *Arthritis Research & Therapy*.

On analysis of the US National Inpatient Sample from 1998 to 2014, the researchers identified a cohort of 4.1 million primary THAs. Of these, approximately 61,000 developed AKI: a rate of 1.5%. The primary outcome of interest was the rate of complications (including infection and revision arthroplasty) and mortality associated with AKI after THA. Healthcare utilization and transfusion were analyzed as secondary outcomes.

With adjustment for age, gender, race, income, underlying diagnosis, comorbidity, and insurance status, the risk of all primary outcomes was significantly higher for patients with AKI after THA. Associated odds ratios (ORs) were 2.34 for implant infection and 2.54 for revision surgery. AKI was also associated with a large increase in mortality risk: OR 8.52.

Secondary outcomes also showed significant AKI-associated increases in transfusion, OR 2.46; total hospital charges above the median, OR 2.29; discharge to a rehabilitation facility, OR 2.11; and hospital stay longer than 3 days, OR 4.34. Overall, AKI after primary THA

was associated with a 2.3 to 2.5 relative risk of in-hospital complications, a 3.5-day longer hospital stay, and \$37,000 excess mean hospital charges.

The analysis of nationwide data highlights elevated risks of complications and death and increased healthcare utilization and costs for patients with AKI after THA. Further studies are needed to determine the mechanisms of and potentially modifiable risk factors for AKI in patients undergoing hip replacement surgery [Singh J, Cleveland JD. Acute kidney injury after primary total hip arthroplasty: a risk multiplier for complication, mortality, and healthcare utilization. *Arthritis Res Ther* 2020; 22:31]. ■

Notes from the Field: COVID-19 in Washington State

Kidney News interviewed Katherine R. Tuttle, MD, FASN, FACP, FNKF, about her experience on the ground during the outbreak of COVID-19 in Washington state. Dr. Tuttle is executive director for research, Providence Health Care, professor of medicine, University of Washington, and co-principal Investigator, Institute of Translational Health Sciences, in Spokane, WA.

Washington state is the epicenter of the COVID-19 outbreak in the United States. What is the situation on the ground?

This is very serious. Every nephrologist here at Providence Health Care is essentially on-call 24/7. I am personally covering the Special Pathogen Unit (SPU) at Providence Sacred Heart Medical Center.

Demand exceeds capacity for dialysis, ventilation, and other acute care services in some Seattle area hospitals, and Spokane is about two weeks behind Seattle. We are currently at greater than 90% capacity for hemodialysis and CRRT, even though our facility is a state-of-the-art 720-bed quaternary medical center, the sixth largest west of the Mississippi River.

We are developing an acute peritoneal dialysis program for extra capacity, something that hasn't been done here since the 1980s.

The actual rate of AKI is also a major problem.



Tell us more about your medical center.

Providence Sacred Heart Medical Center has one of only a few SPUs in the US. The SPUs are sites conducting the National Institute of Allergy and Infectious Diseases/National Institutes of Health-sponsored clinical trial of remdesivir, and possibly other antiviral agents, for COVID-19. The research unit that I oversee is responsible for running the trial here. We are having patients with COVID-19 flown in from cruise ships and elsewhere to have access to the study treatment. Dialysis patients are being severely affected, and we are very concerned about workforce and resources to meet the needs.

What else can you tell us about the shortage of dialysis care?

We have not yet had to deny dialysis care here in Spokane. In places where capacity is already inadequate, basically, older people with severe illness and various comorbidities are not being dialyzed. They are put on comfort care.

With input from expert clinicians and bioethicists, we are now trying to develop criteria for patients to receive acute dialysis. We have not seen this in modern times. This harkens back to the early dialysis experience in the 1960s when Dr. Belding Scribner led the Seattle program. They also had to make very difficult decisions, but under totally different circumstances.

How would you encapsulate the current situation among those in the healthcare profession?

It's physically, mentally, and spiritually exhausting.

We are looking back to the 1918 Spanish flu for guid-

ance, including the comparison between how Philadelphia and St. Louis handled it. We are essentially no further along in dealing with a viral pandemic than we were then.

This is a national emergency, and this is where we need to put all our attention. It's like a bomb dropped with viruses instead of nuclear radioactive particles. In hospitals, this is battleground medicine.

What advice would you give those in facilities that have not yet seen many patients with COVID-19?

- Get ready for a lot of AKI. We don't know the number because we don't know the denominator, but be aware that if you are admitting lots of COVID-19 patients, you will have AKI.
- Plan ahead because you will need human capacity, dialysis machines, CRRT, fluids, catheters. Do an environmental scan of your resources.
- Plan for acute PD because you can use it if you run out of resources for hemodialysis and CRRT. My staff were like deer in the headlights when I brought up PD: "I've heard of it, but I haven't done it." I myself haven't put a PD catheter in a patient in over 20 years. At our facility, all elective surgeries have been canceled indefinitely. Surgeons won't be too busy during this time, so they will help with access for acute PD and with vascular access.
- And, finally, share your story. Right now, we need to be sharing our lived experience through these notes from the field. We're flying the airplane while we are still building it, and all together, we need to do the best we can to share our experiences until we have the time to sit down, analyze the data, and write the papers. ■

COVID-19: A Letter from Austria

By Gert Mayer

The COVID-19 situation in Austria is still developing. Looking at the numbers from Northern Italy, it replicates the pace there (increase in confirmed cases of 1.5 times each day). Tyrol is a "red zone"; everyone with typical symptoms is a suspected case. The government has taken rigorous actions, closing down borders and public life. People not needed for public service (like medical personnel) or other basic aspects of life (supermarket employees, etc.) are not allowed to leave home, with the exception of buying food.

Nephrology is a sensitive specialty because people with kidney diseases are very vulnerable. We have reduced outpatient clinic work, and we have closed our renal transplant program and all elective surgery.

From an organizational point of view, the current critical aspects, especially for the care of people on dialysis, are the following:

1. Organize dialysis: We try to set up "clean" units and

concentrate patients with symptoms and those who have tested positive in special wards. Because this is not possible everywhere, several other ways to separate patients who test positive from the others within a unit are discussed (currently we prefer special shifts in dedicated rooms rather than dedicated rooms only). Patients absolutely stay in their shift and we are making individual plans for patients who need dialysis more frequently (e.g., postoperative trauma individuals).

2. Secure the supply of materials and make conscious decisions on using them to obtain maximum benefit.
3. Keep our staff healthy: This is a special concern. Next to the regular prophylaxis measures, we form teams (nurses and doctors) who work together over a period of time to avoid one individual's positive test leading to isolation of everyone. We reduce face-to-face meetings and use video conference whenever possible to secure communication. Col-

leagues not needed for patient care are sent home and we are starting to train students and doctors to handle dialysis machines.

Some final pieces of advice:

- Prepare as soon as possible. The clearer the instructions are from the leading authorities from the very beginning, the more comfortable everybody is.
- Communicate and coordinate with colleagues from other hospitals; smart solutions can also come up through others.
- Uncertainty and fear exist already and should not be increased further by conflicting orders.

Austrian nephrology will do whatever it takes to protect our patients. ■

Gert Mayer is head of the Department of Internal Medicine IV (Nephrology and Hypertension), Innsbruck, Austria, and is a member of the Kidney News Editorial Board.

The Role of Journals in Dissemination of COVID-19 Information

By Michael Allon

In a matter of just a few weeks, COVID-19, a viral illness that none of us have previously heard of, has evolved into a global pandemic of a magnitude not encountered in over 100 years. As of March 20, 2020, there have been over 200,000 infections documented worldwide with nearly 9000 deaths. The number of infections in the US topped 14,000, and is expected to rise substantially as more tests are performed. Over 200 deaths have been reported.

COVID-19 has overwhelmed the healthcare systems in China, Korea, Italy, and Iran, and is growing in scope elsewhere at an alarming rate. It has prompted widespread and unprecedented measures to slow its spread, with mass social distancing or even virtual lockdowns, including cancellation of large meetings, closing of schools, hotels, restaurants, movie theaters, bars, gyms, or any other place where people congregate; mass cancellation of flights; closing of national borders; unprecedented quarantines; and major economic upheavals. In addition to measures taken to limit COVID-19 spread, there have been ongoing efforts to provide rapid testing for large populations, evaluate therapeutic antiviral agents, and develop vaccines.

As nephrologists, we have a particular interest in managing dialysis patients infected by COVID-19. At present, there are approximately 450,000 hemodialysis patients in the US, each of whom undergoes thrice weekly outpatient dialysis sessions, typically lasting 3–4 hours. These patients are at increased risk of experiencing serious complications, including respiratory failure and death, due to their older age and multiple co-morbidities. In fact, the first two deaths from COVID-19 in the US were in dialysis patients in Seattle. In addition, these patients are dialyzed in close proximity to other patients thrice weekly, increasing their likelihood of becoming infected.

There are many vexing practical issues that nephrologists need to learn. How should we screen dialysis outpatients for COVID-19 infection? What precautions should be implemented in dialysis patients with suspected COVID-19 infection? What happens if the infection is confirmed? What are the mechanics of dialyzing such patients in the hospital? How will we dialyze hospitalized patients with COVID-19 infection who develop acute kidney injury requiring renal replacement therapy?

There is already a high patient-to-nurse ratio in US hemodialysis units. What happens if the dialysis staff becomes infected and there are insufficient nurses or dialysis technicians to provide the dialysis sessions? What happens if many nephrologists and advanced practitioners are quarantined due to COVID-19 infection and not available to oversee the medical care of dialysis patients? Can we see home or in-center dialysis patients via telemedicine, rather than requiring them to come for face-to-face visits with providers?

There are several evidence-based, reliable, and informative sources of online information on COVID-19, including those disseminated by the NIH, CDC, and NTDS. However, I am extremely concerned about the dissemination of er-

roneous and even dangerous information on social media (<https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/2019-novel-coronavirus-myth-versus-fact>). Some of the recent myths disseminated include: swallowing or gargling with bleach can protect against COVID-19; a vaccine is already available; COVID-19 was deliberately created and released; buying products from China will cause COVID-19; and a face mask will protect you from being infected with COVID-19.

Clearly, we have much to learn, and the learning curve will be steep. American nephrologists will benefit by learning from the experiences of nephrologists in countries that have already seen a greater share of COVID-19 infections.

Clearly, we have much to learn, and the learning curve will be steep. American nephrologists will benefit by learning from the experiences of nephrologists in countries that have already seen a greater share of COVID-19 infections.

It is the responsibility of nephrology journals to rapidly disseminate the relevant public information. While we want to ensure that such publications are available in a short time frame, we also want to ensure that the published data are reliable and accurate. The peer review process can be expedited by having such papers reviewed in-house, rather than sending them out to external reviewers. Ideally, e-publications should be available within 48 hours of the manuscript being accepted for publication. It is critical that such papers be made available as open access publications, even by journals that typically require a subscription. *JASN*, *CJASN*, and *Kidney360* have already committed to provide all COVID-19 publications as open access. This will ensure that healthcare professionals across the world can access this information at no cost and with no delay.

We also have a responsibility to help educate dialysis patients and their families, as well as dialysis staff. While we do not want to needlessly duplicate information disseminated by other organizations, COVID-19 information specific to dialysis patients has not been addressed by them. The nephrology journals can facilitate sharing of this information by providing a lay summary of COVID-19 related publications. ■

Michael Allon, MD, is professor of medicine at the University of Alabama at Birmingham, where he serves as the Associate Director for Clinical Affairs and the Medical Director of Dialysis Operations in the Division of Nephrology.



Only one calcimimetic lowers and maintains key sHPT lab values with IV administration you control¹

Not an actual Parsabiv™ vial.
The displayed vial is for illustrative purposes only.

Indication

Parsabiv™ (etelcalcetide) is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Limitations of Use:

Parsabiv™ has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.

Important Safety Information

Contraindication: Parsabiv™ is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including pruritic rash, urticaria, and face edema, have occurred.

Hypocalcemia: Parsabiv™ lowers serum calcium and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias if they develop hypocalcemia due to Parsabiv™. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv™.

Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to Parsabiv™. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv™.

Concurrent administration of Parsabiv™ with another oral calcimimetic could result in severe, life-threatening hypocalcemia. Patients switching from cinacalcet to Parsabiv™ should discontinue cinacalcet for at least 7 days prior to initiating Parsabiv™. Closely monitor corrected serum calcium in patients receiving Parsabiv™ and concomitant therapies known to lower serum calcium.

Measure corrected serum calcium prior to initiation of Parsabiv™. Do not initiate in patients if the corrected serum calcium is less than the lower limit of normal. Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with Parsabiv™. Measure PTH 4 weeks after initiation or dose adjustment of Parsabiv™. Once the maintenance dose has been established, measure PTH per clinical practice.

Worsening Heart Failure: In Parsabiv™ clinical studies, cases of hypotension, congestive heart failure, and decreased myocardial performance have been reported. Closely monitor patients treated with Parsabiv™ for worsening signs and symptoms of heart failure.

Upper Gastrointestinal Bleeding: In clinical studies, 2 patients treated with Parsabiv™ in 1253 patient years of exposure had upper gastrointestinal (GI) bleeding at the time of death. The exact cause of GI bleeding in these patients is unknown and there were too few cases to determine whether these cases were related to Parsabiv™.

Patients with risk factors for upper GI bleeding, such as known gastritis, esophagitis, ulcers or severe vomiting, may be at increased risk for GI bleeding with Parsabiv™. Monitor patients for worsening of common Parsabiv™ GI adverse reactions and for signs and symptoms of GI bleeding and ulcerations during Parsabiv™ therapy.

Adynamic Bone: Adynamic bone may develop if PTH levels are chronically suppressed.

Adverse Reactions: In clinical trials of patients with secondary HPT comparing Parsabiv™ to placebo, the most common adverse reactions were blood calcium decreased (64% vs. 10%), muscle spasms (12% vs. 7%), diarrhea (11% vs. 9%), nausea (11% vs. 6%), vomiting (9% vs. 5%), headache (8% vs. 6%), hypocalcemia (7% vs. 0.2%), and paresthesia (6% vs. 1%).

Please see Brief Summary of full Prescribing Information on adjacent page.

IV = intravenous; sHPT = secondary hyperparathyroidism; PTH = parathyroid hormone; P = phosphate; cCa = corrected calcium.

Reference: 1. Parsabiv™ (etelcalcetide) prescribing information, Amgen.

 **Parsabiv™**
(etelcalcetide) Injection for
intravenous use
2.5mg/0.5mL | 5mg/1mL | 10mg/2mL

BRIEF SUMMARY OF PRESCRIBING INFORMATION



Please see package insert for full Prescribing Information.

INDICATIONS AND USAGE

PARSABIV is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Limitations of Use:

PARSABIV has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with chronic kidney disease who are not on hemodialysis and is not recommended for use in these populations.

CONTRAINDICATIONS

Hypersensitivity

PARSABIV is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including pruritic rash, urticaria, and face edema, have occurred with PARSABIV [see Adverse Reactions (6.1) in PARSABIV full prescribing information].

WARNINGS AND PRECAUTIONS

Hypocalcemia

PARSABIV lowers serum calcium [see Adverse Reactions (6.1) in PARSABIV full prescribing information] and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause paresthesias, myalgias, muscle spasms, seizures, QT interval prolongation, and ventricular arrhythmia.

QT Interval Prolongation and Ventricular Arrhythmia

In the combined placebo-controlled studies, more patients treated with PARSABIV experienced a maximum increase from baseline of greater than 60 msec in the QTcF interval (0% placebo versus 1.2% PARSABIV). In these studies, the incidence of a maximum post-baseline predialysis QTcF > 500 msec in the placebo and PARSABIV groups was 1.9% and 4.8%, respectively [see Adverse Reactions (6.1) in PARSABIV full prescribing information]. Patients with congenital long QT syndrome, history of QT interval prolongation, family history of long QT syndrome or sudden cardiac death, and other conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias if they develop hypocalcemia due to PARSABIV. Closely monitor corrected serum calcium and QT interval in patients at risk receiving PARSABIV.

Seizures

Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to PARSABIV. Monitor corrected serum calcium in patients with seizure disorders receiving PARSABIV.

Concurrent administration of PARSABIV with another oral calcium-sensing receptor agonist could result in severe, life-threatening hypocalcemia. Patients switching from cinacalcet to PARSABIV should discontinue cinacalcet for at least 7 days prior to initiating PARSABIV [see Dosage and Administration (2.4) in PARSABIV full prescribing information]. Closely monitor corrected serum calcium in patients receiving PARSABIV and concomitant therapies known to lower serum calcium.

Measure corrected serum calcium prior to initiation of PARSABIV. Do not initiate in patients if the corrected serum calcium is less than the lower limit of normal. Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with PARSABIV [see Dosage and Administration (2.2) in PARSABIV full prescribing information]. Educate patients on the symptoms of hypocalcemia, and advise them to contact a healthcare provider if they occur.

If corrected serum calcium falls below the lower limit of normal or symptoms of hypocalcemia develop, start or increase calcium supplementation (including calcium, calcium-containing phosphate binders, and/or vitamin D sterols or increases in dialysate calcium concentration). PARSABIV dose reduction or discontinuation of PARSABIV may be necessary [see Dosage and Administration (2.2) in PARSABIV full prescribing information].

Worsening Heart Failure

In clinical studies with PARSABIV, cases of hypotension, congestive heart failure, and decreased myocardial performance have been reported. In clinical studies, heart failure requiring hospitalization occurred in 2% of PARSABIV-treated patients and 1% of placebo-treated patients. Reductions in corrected serum calcium may be associated with congestive heart failure, however, a causal relationship to PARSABIV could not be completely excluded. Closely monitor patients treated with PARSABIV for worsening signs and symptoms of heart failure.

Upper Gastrointestinal Bleeding

In clinical studies, two patients treated with PARSABIV in 1253 patient-years of exposure had upper gastrointestinal (GI) bleeding noted at the time of death while no patient in the control groups in 384 patient-years of exposure had upper GI bleeding noted at the time of death. The exact cause of GI bleeding in these patients is unknown, and there were too few cases to determine whether these cases were related to PARSABIV.

Patients with risk factors for upper GI bleeding (such as known gastritis, esophagitis, ulcers, or severe vomiting) may be at increased risk for GI bleeding while receiving PARSABIV treatment. Monitor patients for worsening of common GI adverse reactions of nausea and vomiting associated with PARSABIV [see Adverse Reactions (6.1) in PARSABIV full prescribing information] and for signs and symptoms of GI bleeding and ulcerations during PARSABIV therapy. Promptly evaluate and treat any suspected GI bleeding.

Adynamic Bone

Adynamic bone may develop if PTH levels are chronically suppressed. If PTH levels decrease below the recommended target range, the dose of vitamin D sterols and/or PARSABIV should be reduced or therapy discontinued. After discontinuation, resume therapy at a lower dose to maintain PTH levels in the target range [see Dosage and Administration (2.1) in PARSABIV full prescribing information].

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Hypocalcemia [see Warnings and Precautions (5.1) in PARSABIV full prescribing information]
- Worsening Heart Failure [see Warnings and Precautions (5.2) in PARSABIV full prescribing information]
- Upper Gastrointestinal Bleeding [see Warnings and Precautions (5.3) in PARSABIV full prescribing information]
- Adynamic Bone [see Warnings and Precautions (5.4) in PARSABIV full prescribing information]

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The data in Table 2 are derived from two placebo-controlled clinical studies in patients with chronic kidney disease and secondary hyperparathyroidism on hemodialysis. The data reflect exposure of 503 patients to PARSABIV with a mean duration of exposure to PARSABIV of 23.6 weeks. The mean age of patients was approximately 58 years, and 60% of the patients were male. Of the total patients, 67% were Caucasian, 28% were Black or African American, 2.6% were Asian, 1.2% were Native Hawaiian or Other Pacific Islander, and 1.6% were categorized as Other.

Table 2 shows common adverse reactions associated with the use of PARSABIV in the pool of placebo-controlled studies. These adverse reactions occurred more commonly on PARSABIV than on placebo and were reported in at least 5% of patients treated with PARSABIV.

Table 2: Adverse Reactions Reported in ≥ 5% of PARSABIV-Treated Patients

Adverse Reaction*	Placebo (N = 513)	PARSABIV (N = 503)
Blood calcium decreased ^a	10%	64%
Muscle spasms	7%	12%
Diarrhea	9%	11%
Nausea	6%	11%
Vomiting	5%	9%
Headache	6%	8%
Hypocalcemia ^b	0.2%	7%
Paresthesia ^c	1%	6%
*Included adverse reactions reported with at least 1% greater incidence in the PARSABIV group compared to the placebo group		
^a Asymptomatic reductions in calcium below 7.5 mg/dL or clinically significant asymptomatic reductions in corrected serum calcium between 7.5 and < 8.3 mg/dL (that required medical management)		
^b Symptomatic reductions in corrected serum calcium < 8.3 mg/dL		
^c Paresthesia includes preferred terms of paresthesia and hypoesthesia		

Other adverse reactions associated with the use of PARSABIV but reported in < 5% of patients in the PARSABIV group in the two placebo-controlled clinical studies were:

- Hyperkalemia: 3% and 4% for placebo and PARSABIV, respectively.
- Hospitalization for Heart Failure: 1% and 2% for placebo and PARSABIV, respectively.
- Myalgia: 0.2% and 2% for placebo and PARSABIV, respectively.
- Hypophosphatemia: 0.2% and 1% for placebo and PARSABIV, respectively.

Description of Selected Adverse Reactions

Hypocalcemia

In the combined placebo-controlled studies, a higher proportion of patients on PARSABIV developed at least one corrected serum calcium value below 7.0 mg/dL (7.6% PARSABIV, 3.1% placebo), below 7.5 mg/dL (27% PARSABIV, 5.5% placebo), and below 8.3 mg/dL (79% PARSABIV, 19% placebo). In the combined placebo-controlled studies, 1% of patients in the PARSABIV group and 0% of patients in the placebo group discontinued treatment due to an adverse reaction attributed to a low corrected serum calcium.

Hypophosphatemia

In the combined placebo-controlled studies, 18% of patients treated with PARSABIV and 8.2% of patients treated with placebo had at least one measured phosphorus level below the lower normal limit (i.e., 2.2 mg/dL).

QTc Interval Prolongation Secondary to Hypocalcemia

In the combined placebo-controlled studies, more patients treated with PARSABIV experienced a maximum increase from baseline of greater than 60 msec in the QTcF interval (0% placebo versus 1.2% PARSABIV). The patient incidence of maximum post-baseline predialysis QTcF > 500 msec in the placebo and PARSABIV groups was 1.9% and 4.8%, respectively.

Hypersensitivity

In the combined placebo-controlled studies, the subject incidence of adverse reactions potentially related to hypersensitivity was 4.4% in the PARSABIV group and 3.7% in the placebo group. Hypersensitivity reactions in the PARSABIV group were pruritic rash, urticaria, and face edema.

Immunogenicity

As with all peptide therapeutics, there is potential for immunogenicity. The detection of anti-drug binding antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to etelcalcetide with the incidence of antibodies to other products may be misleading.

In clinical studies, 7.1% (71 out of 995) of patients with secondary hyperparathyroidism treated with PARSABIV for up to 6 months tested positive for binding anti-etelcalcetide antibodies. Fifty-seven out of 71 had pre-existing anti-etelcalcetide antibodies.

No evidence of altered pharmacokinetic profile, clinical response, or safety profile was associated with pre-existing or developing anti-etelcalcetide antibodies. If formation of anti-etelcalcetide binding antibodies with a clinically significant effect is suspected, contact Amgen at 1-800-77-AMGEN (1-800-772-6436) to discuss antibody testing.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no available data on the use of PARSABIV in pregnant women. In animal reproduction studies, effects were seen at doses associated with maternal toxicity that included hypocalcemia. In a pre- and post-natal study in rats administered etelcalcetide during organogenesis through delivery and weaning, there was a slight increase in perinatal pup mortality, delay in parturition, and transient effects on pup growth at exposures 1.8 times the human exposure for the clinical dose of 15 mg three times per week. There was no effect on sexual maturation, neurobehavioral, or reproductive function in the rat offspring. In embryo-fetal studies, when rats and rabbits were administered etelcalcetide during organogenesis, reduced fetal growth was observed at exposures 2.7 and 7 times exposures for the clinical dose, respectively.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

There were no effects on embryo-fetal development in Sprague-Dawley rats when etelcalcetide was dosed at 0.75, 1.5, and 3 mg/kg/day by the intravenous route during organogenesis (pre-mating to gestation day 17) at exposures up to 1.8 times human exposures at the clinical dose of 15 mg three times per week based on AUC. No effects on embryo-fetal development were observed in New Zealand White rabbits at doses of etelcalcetide of 0.375, 0.75, and 1.5 mg/kg by the intravenous route (gestation day 7 to 19), representing up to 4.3 times human exposures based on AUC. In separate studies at higher doses of 4.5 mg/kg in rats (gestation days 6 to 17) and 2.25 mg/kg in rabbits (gestation days 7 to 20), representing 2.7 and 7 fold clinical exposures, respectively, there was reduced fetal growth associated with maternal toxicities of hypocalcemia, tremoring, and reductions in body weight and food consumption.

In a pre- and post-natal development study in Sprague-Dawley rats administered etelcalcetide at 0.75, 1.5, and 3 mg/kg/day by the intravenous route (gestation day 7 to lactation day 20), there was a slight increase in perinatal pup mortality, delay in parturition, and transient reductions in post-natal growth at 3 mg/kg/day (representing 1.8-fold human exposures at the clinical dose of 15 mg three times per week based on AUC), associated with maternal toxicities of hypocalcemia, tremoring, and reductions in body weight and food consumption. There were no effects on sexual maturation, neurobehavioral, or reproductive function at up to 3 mg/kg/day, representing exposures up to 1.8-fold human exposure based on AUC.

Lactation

Risk Summary

There are no data regarding the presence of PARSABIV in human milk or effects on the breastfed infant or on milk production. Studies in rats showed [¹⁴C]-etelcalcetide was present in the milk at concentrations similar to plasma. Because of the potential for PARSABIV to cause adverse effects in breastfed infants including hypocalcemia, advise women that use of PARSABIV is not recommended while breastfeeding.

Data

Presence in milk was assessed following a single intravenous dose of [¹⁴C]-etelcalcetide in lactating rats at maternal exposures similar to the exposure at the human clinical dose of 15 mg three times per week. [¹⁴C]-etelcalcetide-derived radioactivity was present in milk at levels similar to plasma.

Pediatric Use

The safety and efficacy of PARSABIV have not been established in pediatric patients.

Geriatric Use

Of the 503 patients in placebo-controlled studies who received PARSABIV, 177 patients (35.2%) were ≥ 65 years old and 72 patients (14%) were ≥ 75 years old.

No clinically significant differences in safety or efficacy were observed between patients ≥ 65 years and younger patients (≥ 18 and < 65 years old). No differences in plasma concentrations of etelcalcetide were observed between patients ≥ 65 years and younger patients (≥ 18 and < 65 years old).

OVERDOSAGE

There is no clinical experience with PARSABIV overdosage. Overdosage of PARSABIV may lead to hypocalcemia with or without clinical symptoms and may require treatment. Although PARSABIV is cleared by dialysis, hemodialysis has not been studied as a treatment for PARSABIV overdosage. In the event of overdosage, corrected serum calcium should be checked and patients should be monitored for symptoms of hypocalcemia, and appropriate measures should be taken *[see Warnings and Precautions (5.1) in PARSABIV full prescribing information]*.

AMGEN[®]

PARSABIV[™] (etelcalcetide)

Manufactured for:

KAI Pharmaceuticals, Inc., a wholly owned subsidiary of Amgen, Inc.

One Amgen Center Drive

Thousand Oaks, California 91320-1799

Patent: <http://pat.amgen.com/Parsabiv/>

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Laying a Foundation for Improving Quality Measures for Kidney Care

By Nicole Fauteux

Quality measures can be powerful tools for leveraging performance improvement, but only if they are based on reliable evidence, feasible to implement, and attributable to the providers being measured. Quality measures should also capture clinically relevant outcomes and other aspects of care that matter to patients.

Since the introduction of value-based care, quality measures have multiplied, but far too frequently, they fall short of these standards. This deficiency undermines the value of quality measurement, and not just for kidney care. In 2018, the American College of Physicians (ACP) Performance Measurement Committee determined that only 37% of the national measures being used to evaluate ambulatory care were valid (1).

“We weren’t surprised,” said Mallika Mendu, MD, medical director for quality and safety at Brigham and Women’s Hospital in Boston and assistant professor at Harvard Medical School. The “we” she refers to are the members of the ASN Quality Committee. As quality and safety experts, she said, they regularly address questions about the value of quality measures, including those raised by the ACP paper, which she praised for providing the committee a framework to address their concerns.

and kidney replacement planning. The committee found this measure to be highly valid and underscored its importance, calling it “all-encompassing toward improving quality of initiation of dialysis care.” The authors considered the measure especially relevant in light of the Advancing American Kidney Health (AAKH) initiative announced by the U.S. Department of Health and Human Services (HHS) in 2019.

AAKH is intended to spur greater use of home dialysis and transplantation. Mendu said educating patients about home dialysis and evaluating whether their living situations can support it is a lot more work for clinicians than referring patients to a dialysis center. Nevertheless, “It’s the right thing to do,” she said, and universal adoption of a well-crafted measurement such as Optimal ESKD Starts has the potential to “fundamentally shift practice.”

In an editorial in the same issue of *JASN*, Paul M. Palevsky, MD, FASN, laid out the many challenges inherent in measuring quality (3). “Quality is subjective,” he said, but quality measurement needs a firmer grounding. The University of Pittsburgh professor of nephrology and chief of the renal section at the VA Pittsburgh Healthcare System has contributed to several quality measurement initiatives—

in developing a MIPS Value Pathway for nephrology.”

MIPS Value Pathways are CMS’s answer to clinician complaints that the MIPS program is overly complex and burdensome. CMS hopes this new framework will better identify measures that are relevant to clinicians’ scope of practice, meaningful to patient care, and in alignment across performance categories in each specialty (4). The agency has also convened a technical expert panel (TEP), which includes ASN members, to consider the development of a measure to track clinicians’ success in slowing the progression of kidney disease and delaying kidney failure.

Capturing and improving the patient experience

Another key finding of the ASN Quality Committee study was a paucity of measures for the patient experience of care. The committee found only two and rated both as having medium validity. Both Mendu and Palevsky would like to see more measures that reflect what matters to people with kidney disease: avoiding hospitalization, minimizing their symptoms, being healthy enough to work and function in their daily lives, and ultimately, the length of their survival (3).

They also want to see more measures that touch the lives of kidney care patients before their disease becomes severe. “Most measures focus on the small percentage of patients who are on dialysis,” Palevsky said. “They are the most expensive group of patients with kidney disease and the ones at greatest risk of complications, but there are millions of others with early stage kidney disease, and we really don’t have many useful measures on the quality of care they are receiving.”

Mendu agreed. “If our goal is to decrease the number of our patients who are on dialysis, we have to make sure that we have measures that are helping slow that progression to dialysis.”

Both are eager to see the nephrology community rally behind current efforts to develop better quality measures and take the lead in writing and validating measures to make sure they are truly meaningful. This won’t be easy. Having had a hand in developing some of the current measures, Palevsky is humbled by the challenge of developing measures that can capture genuinely high-quality care. “We need to do better, but we are humans,” he reflected. “We try things and we figure out what works and what doesn’t work, and then we move forward again. It’s an iterative process, and of course, medicine changes, and the right thing to do in 2020 may not be the right thing to do in 2025.”

Mendu also acknowledged that quality measurement is challenging, but when done correctly, she believes it is an effective tool for driving practice improvement. She said she hopes nephrologists, policymakers, and patients will all become invested in creating better measures, so the nephrology community will have objective ways to recognize and reward quality in the future. ■

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With the administration currently working out the details of its kidney care initiatives, Mendu believes the time is right for nephrologists to encourage the development of more well-designed measures and the retirement of those with limited validity.

Existing kidney care measures

In 2019, the ASN Quality Committee members began the task of investigating the measures being used to evaluate nephrologists’ performance. They compiled a comprehensive list of 60 quality measures related to kidney disease from multiple established sources, cataloged them according to the aspect of kidney care measured, and used the criteria defined by the ACP to evaluate each measure’s validity. What did they learn?

Only 29—fewer than half—of the 60 measures studied were highly valid in the committee’s view, and they found other problems as well. Eighteen of the measures were determined to be not attributable to nephrologists. Some were poorly defined, particularly when it came to exclusion criteria and risk adjustment. Others were out of step with the latest evidence or guidelines, and far too many measures—28 in all—focused on dialysis. In contrast, only 2 focused on slowing the progression of kidney disease, the ultimate purpose of kidney care (2).

These findings, which appeared in the December 2019 issue of the *Journal of the American Society of Nephrology* (*JASN*), lay a much-needed foundation for improving quality measurement in nephrology, and ultimately, for improving care. “We hope our study will give backing to what a lot of nephrologists are probably feeling, which is, why do I need, for example, another measure on vascular access success, which I don’t have a lot of control over?” said Mendu, the study’s lead author. She would like to see the focus shift to measures where nephrologists do have control and where gains can drive improvement in clinical outcomes.

One such measure is the National Quality Forum’s Optimal ESKD Starts, which is the only measure among the 60 reviewed that is associated with advanced kidney disease

as past chair of the Renal Physicians Association Quality, Safety and Accountability Committee, and as a co-chair of the American Medical Association-convened Physician Consortium for Performance Improvement renal measures work group.

“We have performance measures, which are typically based on clinical practice guidelines, but many of those guidelines are not based on rigorous evidence,” he said. What’s more, quality measures often focus on what’s easy to measure rather than what’s most important, Palevsky added, and in healthcare, the involvement of multiple conditions and multiple providers in a patient’s health can make it difficult to attribute improvement to the intervention of one particular physician.

An opportune time to advocate for change

With the administration currently working out the details of its kidney care initiatives, Mendu believes the time is right for nephrologists to encourage the development of more well-designed measures and the retirement of those with limited validity. “If the administration is focused on improving care, but we have the wrong measures,” she said, “then it doesn’t matter how much federal funding there is or how many innovative care models we have.”

David White, ASN regulatory and quality officer, agrees. He said last year the Centers for Medicare & Medicaid Services (CMS) eliminated four nephrology measures from its Merit-based Incentive Payment System (MIPS), which ties participating clinicians’ reimbursement to their ability to provide high-quality, cost-efficient care. In order to receive incentive payments, clinicians must score well on eligible MIPS measures. “We are working with CMS to highlight more useful metrics,” White said, “and to assist the agency

Standardized Interfaces across Health IT Products, Restrictions on “Information Blocking” are Provisions in HHS Plan

By Terrence Jay (T.J.) O'Neill

How many of you have been here?

It's 11 p.m. The 68-year-old lady just brought in by EMS is unresponsive on the gurney. Her BP is—well, it's not good—and while you're judiciously giving her IV fluids you're wondering when it's going to be pressor time. Many initial labs are still cooking, but the creatinine is 4.8 mg%. Her family is on the way in, but her daughter isn't sure just what meds she is on, and anyway she thinks the PCP changed a couple of them at her mother's visit last week. She just isn't sure which ones. The voicemail at the PCP's closed office gave you the name and number of the covering MD, but she hasn't responded yet. There's a patient portal, but the lady on the gurney has the password.

And she's not telling.

She was in a different ER three weeks ago, but the daughter said her PCP was still waiting for information about that visit last week.

You just received the 40-page, near-illegible fax from a hospital the patient was admitted to a month ago. After discharge she was briefly in a skilled nursing facility but their computer system won't talk to yours, so they'll send a fax, “when we can—we're pretty short-staffed.”

I think we've all been there at least once.

Despite a requirement for hospitals and medical practices to have EHRs for over a decade (and getting payments of \$35 billion for doing so) the result is a Babel of non-communicating systems, each with its database not talking to the others. Worse, some organizations have treated the data as proprietary and have deliberately blocked access.

So there you are, poring over illegible paper, juggling a couple of phones and trying to guess which information from the family is reliable—if any—hoping you'll “do no harm,” with your patient in dire straits.

Well, that may be about to change.

On March 9, 2020, the Department of Health and Human Services released a 473-page Final Rule on Interoperability and Patient Access “intended to move the health care ecosystem in the direction of interoperability . . . to improve access to, and the quality of, information that Americans need to make informed health care decisions, including data about health care prices and outcomes, while minimizing reporting burdens on affected plans, health care providers, or payers.” For those interested in the details go to <https://www.cms.gov/files/document/cms-9115-f.pdf>). The fact that it took several weeks to process the comments suggests the discussion was unusually robust.

The Final Rule requires creation of standardized interfaces across health IT products and systems. (see <http://bit.ly/3cRnuSI>) These are referred to as “APIs,” a specific set of technical instructions that allow one piece of software to interact with another piece. Even though there was a functionality criterion as far back as 2015, progress toward universal standards has been slow, in part because CMS estimated that there would be a one-time implementation cost of \$789,356 per organization or state, and ongoing maintenance costs of \$158,359. Needless to say, this caused concerns.

There is also the problem of unambiguously identifying patients. In the hacker era, SSAN won't do. Different healthcare systems use different identifiers for the same patient. This spurred efforts to develop a unique patient identifier (UPI). That effort was abandoned in 2000 because like the SSAN, the UPI was felt to be a potential security back door. Back doors are bad in the context of over 270 data breaches involving over 4.3 million individuals' re-



cords between 2017 and 2018. Although the UPI is dead, the Office of the National Coordinator for Health Information launched the Patient Matching Algorithm Challenge to develop approaches using multiple demographic factors in 2017.

CMS is also apparently out of patience with “information blocking” legally defined as “the practice of withholding data or intentionally taking action to limit or restrict the compatibility or interoperability of health IT.” There were complaints that some providers use existing loopholes to limit or prevent data exchange in an effort to retain patients by preventing them from moving freely within the healthcare market. The new Final Rule makes this an offense and offers a channel to report it.

Also, effective January 1, 2022, Medicare Advantage organizations, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan issuers on the Federally-Facilitated Exchanges must support the electronic exchange of, at a minimum, data included in the “United States Core Data for Interoperability” (USCDI; see <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>), via a payer-to-payer data exchange. That amounts to a requirement that payers must send to any other payer the defined information if the date of service is on or after January 1, 2016, at the direction of a current or former enrollee. And, in case patients and their caregivers don't know how to work this new system, the Rule also contains a requirement for all entities operating on a Federally-facilitated insurance Exchange to provide simple, non-technical and easy-to-understand educational resources in an easily accessible location on its public website and via other appropriate ways for current and former enrollees about how to obtain and transfer their medical information.

Identifying dual Medicare/Medicaid patients has also been difficult due to lack of data sharing. Under the Final Rule, all States must participate in daily exchange of buy-in data called the “MMA data” to CMS by April 1, 2022. This includes both sending data to CMS and receiving responses from CMS. States transmit system-generated data

files, at least monthly, to CMS to identify all dual-eligible individuals, including full-benefit and partial-benefit dually eligible beneficiaries (that is, those who get Medicaid help with Medicare premiums, and often for cost-sharing).

These efforts should allow patients to easily access their own records and data via smartphone and other platform apps, while making it easier for CMS to see who they are responsible for.

Skilled nursing facilities have lagged in adopting EHR technology. As of 2016, only three out of 10 skilled nursing facilities electronically exchanged key clinical information. Only 7% had the ability to electronically send, receive, find, and integrate patient health information. Partly this disconnect was because long-term care facilities, nursing homes, and home health agencies weren't eligible for the incentive program under HITECH, despite being required to submit standardized patient assessment data to CMS. The Final Rule changes the Conditions of Participation to require Medicare- and Medicaid-participating hospitals, psychiatric hospitals, skilled nursing facilities, and Critical Access Hospitals (CAHs) to send “Electronic Notifications,” to post-acute care services providers and suppliers, and to whoever is identified by the patient as primarily responsible for his or her care. This is also the case upon the patient's registration in an emergency department or admission to inpatient services, and also either immediately prior to, or at the time of, the patient's discharge or transfer. Hospitals and CAHs must also demonstrate that they have made a reasonable effort to ensure that their systems send notification to all applicable post-acute care services.

This is a lot to digest. It will be expensive—which probably explains the protracted time it has taken for negotiating the comments to the Proposed Rule. But, it's progress. Barring protests, watch for these changes to take effect between the first of January 2021 and 2022. ■

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MY TRANSPLANT JOURNEY

How to Prepare Mentally to Pursue a Living Donor

By Jennifer Jones



The Executive Order on Advancing American Kidney Health calls for an increased focus on transplantation, including provisions to increase the availability of organs for transplant and support for living donors through compensation for costs such as lost wages and child and elder care expenses. For the next few months, the Kidney News series “My Transplant Journey” will feature perspectives on the patient experience with transplantation.

The nephrologist’s voice sounded far away as he told me about my diagnosis. *Membranoproliferative glomerulonephritis, type 1 idiopathic*. My immune system had caused damage to my kidneys, and no one could tell me why.

I asked him if I could still serve in the Marine Corps.

“Oh, of course not,” he said matter-of-factly.

He was right. After serving almost 12 years as a combat camera videographer, I was medically retired. I lost more than a military career. I was in my 20s, single, and living alone away from my family. I felt like I no longer had an identity—and no control over my body.

One minute I’m deployed to Afghanistan, and the next I’m a kidney disease patient. Instead of deployments, I traveled to dialysis three times a week. I couldn’t see spending the rest of my life like that.

After a period of accepting my situation and becoming compliant with my treatment, I completed the process to be eligible for a transplant. My transplant coordinator encouraged me to pursue a living donor instead of waiting on the list for a cadaver donor. I agreed, but I expressed concern about what that would entail.

There are plenty of resources for how to find a living donor, but we do not talk about how to prepare mentally

for such a task. The first thought that comes to many is this: “How can I have the nerve to ask someone for a kidney?”

To fully commit, you must release any negative limiting beliefs that may cause you to give up . . . or, worse, to not try at all. It may seem overwhelming to focus on finding a living donor and enduring life with kidney failure. Here are the steps I went through to become mentally prepared to pursue and successfully find a living donor.

Limiting beliefs about pursuing a living donor

I had a lot of thoughts and emotions about seeking a living donor. Three of the most common ones were these:

“I am in denial.”

It took me a while to accept what I was going through. I thought I had lost my life. For a while, I didn’t care about improving my quality of life with a transplant from either a living or a cadaver donor. I only knew the bare minimum of my diagnosis just to function. I even considered whether going through it all was worth it.

Accepting the differences in life brought about by kidney disease requires input from your healthcare team and

support system, and from educating yourself as much as possible. Once I asked for help and learned more about my illness and how dialysis affected my body, I did everything needed to become a compliant patient and a candidate for kidney transplantation.

“I’m a private person.”

I grew up in an environment where you’re taught to keep your business to yourself to prevent others from talking about you. There are many misconceptions and stigmas about kidney disease, especially when for some it can be an invisible illness. I had to release my concern that individuals would judge and criticize me and instead focus on educating people. It was (and still is) difficult to share my journey, but doing so led me to my living donor.

“I don’t deserve a kidney.”

Although my disease was an anomaly, I wondered why anyone would consider giving me a kidney. I have encountered others who felt they were not worthy of a transplant because of guilt, low perception of themselves, or not wanting to become a burden to anyone during the healing process (and potential risk that goes along with transplantation). Knowing your “why” for wanting a

transplant and why you deserve one will give you what you need to stay motivated in your pursuit of a living donor.

Steps toward mental preparedness

Step 1: Prioritize your physical and mental health

Above all, you must remain transplant eligible. Without that, having a living donor is meaningless. You may not have thought about it, but you are the one who is most responsible for your health. It is your responsibility to use your healthcare team as a resource; educate yourself about your diagnosis, kidney disease, and transplantation; and comply with your treatment.

Don't be afraid to ask questions. Share your thoughts and feelings with your healthcare team, a psychiatrist, friends, and/or family. You can't go through any of this alone.

Learn how to ask for help. I know it may feel painful to ask for help when you know you need it. To even consider asking someone to donate a kidney may seem impossible. Remember that there are people who want to help you just as you desire to help others. Seek help when you need it.

Step 2: Become comfortable sharing your story

Whether you pursue a living donor online, with signs, flyers, or by word of mouth, be ready to share your story. Remember that you choose how much you feel comfortable sharing. I recommend just speaking from the heart. Here are some story topics:

- What is your diagnosis and how was it discovered?
- What is your life like on dialysis?
- How will your life be improved with a transplant?
- What are the facts about kidney disease and living donation?

You do not have to ask someone to be your living donor.

Instead, just spread awareness of your situation. You will draw individuals to your story who will feel compelled to share and hopefully desire to get tested as a potential candidate. The more you share your story, the easier it will get.

Step 3: Know why you want a kidney transplant

A transplant is not a cure; it's a treatment so you will not need dialysis to function. Transplantation is not just about the act of pursuing a living donor; it's also about preparing yourself mentally and physically for a life-changing surgical procedure that may improve your quality of life.

When you know why you want to pursue a living donor and receive a kidney, then what you must do to get one will be more significant to you because you will have created a purpose. This purpose is a part of your story. It will connect you with those who will want to support you and help you on this journey. Share it with your healthcare team, your friends, and your family.

The outcome

My purpose went beyond avoiding the prolonged physical effects of dialysis. I wanted to one day live an exciting life like I did when I served in the Marines—not bound to being on a dialysis machine. I wanted a second chance at life to learn from the mistakes I'd made in the past and truly show gratitude for everything I have by serving others.

I used social media to share my story, and on April 2, 2015, I received a kidney transplant from an amazing woman who didn't know me but saw my story and felt compelled to give me that second chance at life. When I woke up from the surgery, all I could do was cry tears of joy.

That day was worth the emotional roller coaster. It was worth being disciplined as I followed my diet and complied with my treatment. It was worth putting myself out there for people to judge or criticize me. Regardless of the new list of challenges having a kidney transplant placed on me, it was the best decision I made for myself during this entire experience.

In the United States there are 102,962 registrations on the donor list and only 12,740 donor kidneys recovered as of August 31, 2019 (1). If you decide that you want a kidney transplant, you owe it to yourself to do your best to care for yourself mentally and physically. It is possible to find a living donor instead of waiting for years on the list. Of all the many things you lose control



over because of kidney disease, the act of pursuing a donor is all yours. ■

Jennifer Jones is a resilience consultant, public speaker, and Kidney Disease Advocate. After receiving a medical retirement from the US Marine Corps, her current mission is helping others maintain and develop a resilient lifestyle through personal development, well-being, and self-actualization. While serving as an ambassador for the American Association of Kidney Patients, Jennifer is active in communicating with legislators on Capitol Hill on behalf of fellow kidney patients and living donors and promoting awareness about finding a living donor. Her website is <http://www.genresilient.com> and she may be reached at jen@genresilient.com

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AKI!Now: From Recognition to Recovery

By Jorge Cerdá and Bonnie L. Freshly

Acute kidney injury (AKI) affects people of all ages, races, genders, ethnicities, and socioeconomic status across the world. For those persons, the stakes are high: in the most severe forms of AKI, the associated morbidity and mortality are higher than those of other common critical conditions, such as acute respiratory distress syndrome and septic shock.

Most commonly, AKI is first encountered by a variety of non-nephrology healthcare providers, including primary care physicians, pediatricians, intensive care unit and emergency department providers, surgeons, nurses, advanced care providers, pharmacists, trainees, hospital

administrators, and quality control experts.

Despite the ubiquity of AKI and its grave consequences, effective means to treat established AKI and to promote kidney recovery, other than supportive treatment, are as yet largely unavailable. Therefore, while those treatments are being developed, the main goals of management focus on early recognition and avoidance of progression to the most severe stages of AKI. Unfortunately, limited awareness of the condition and inadequate understanding of early management impair efforts to achieve those goals, often resulting in very severe patient outcomes. Therefore, raising awareness and educating healthcare providers, patients, and their families on AKI recognition, diagnosis, and management are of uppermost importance.

AKI!Now: the background

To fulfill these needs, the American Society of Nephrology (ASN), supported by funding from an unrestricted educational grant from Baxter Healthcare Corporation, has launched a new initiative, AKI!Now: Promoting Excellence in the Prevention and Treatment of Acute Kidney Injury, to promote excellence in the prevention and treatment of AKI by building a foundational program that transforms the delivery of AKI care, reduces morbidity and mortality, and improves long-term outcomes.

A six-member steering committee, including Jorge Cerdá, MD, MS, FASN (chair); Anupam Agarwal, MD, FASN; Stuart Goldstein, MD, FASN; Mark Okusa, MD, FASN; Kathleen Liu, MD, FASN; and Anitha Vijayan, MD, FASN, leads the AKI!Now Initiative.

Addressing AKI: an international undertaking

Acknowledging the global impact of AKI, the AKI!Now initiative began its work with a review of existing international efforts to have an impact on the recognition and recovery of AKI. They include the following:

- Think Kidneys: “The NHS campaign to improve the care of people at risk of, or with, acute kidney injury” (website: <https://www.thinkkidneys.nhs.uk/aki/>)
- Oby25: This initiative by the International Society of Nephrology (ISN) “aims to eliminate preventable deaths from Acute Kidney Injury (AKI) worldwide by 2025” (website: <https://www.theisn.org/all-articles/616-0by25>)

Each of these campaigns shares with AKI!Now an interest in having an impact on the early recognition and treatment of AKI through discovering best practices and raising awareness through education. All three campaigns agree on the core importance that these education initiatives reach not only healthcare providers but also patients, government entities, and the general public.

The AKI!Now initiative has redoubled interaction with those and other resources across the world. It further maintains tight relationships with other national and international societies, such as the National Kidney Foundation (NKF), to ensure cross-pollination and resource sharing.

Convening international expertise

To further investigate shared goals and resources, during

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AKI!Now

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2019 Kidney Week in Washington, DC, the AKI!Now steering committee convened an expert roundtable and a focus group of students, residents, practitioners, and colleagues interested in AKI who focused their discussion on targeting best AKI practices and treatment pathways.

Specifically, the 26 expert participants in the roundtable discussed these topics:

- AKI landscape
- The value of the development of a clinical compendium of AKI publications and educational material
- The need for educational products focused on treatment pathways and best practices

The 50 attendees at the focus group included nephrologists, patients, nurse practitioners, and fellows working in AKI. Discussion points included the following:

- How comfortable are you with critical care nephrology?
- Educational pathways: what tools should be developed to help practitioners recognize AKI and to facilitate the application of established treatment practices?
- How can we promote patients' recovery and follow-up?

Recognizing the key role and unique needs of patients in kidney management and recovery, both events included a testimonial from Marla Levy, who described her experience and shared her opinions and recommendations as a person who encountered severe AKI.

Landscape analysis

After the in-person dialogues, the steering committee assessed the data and insights gathered, and compiled an AKI landscape analysis. This analysis identified four core themes:

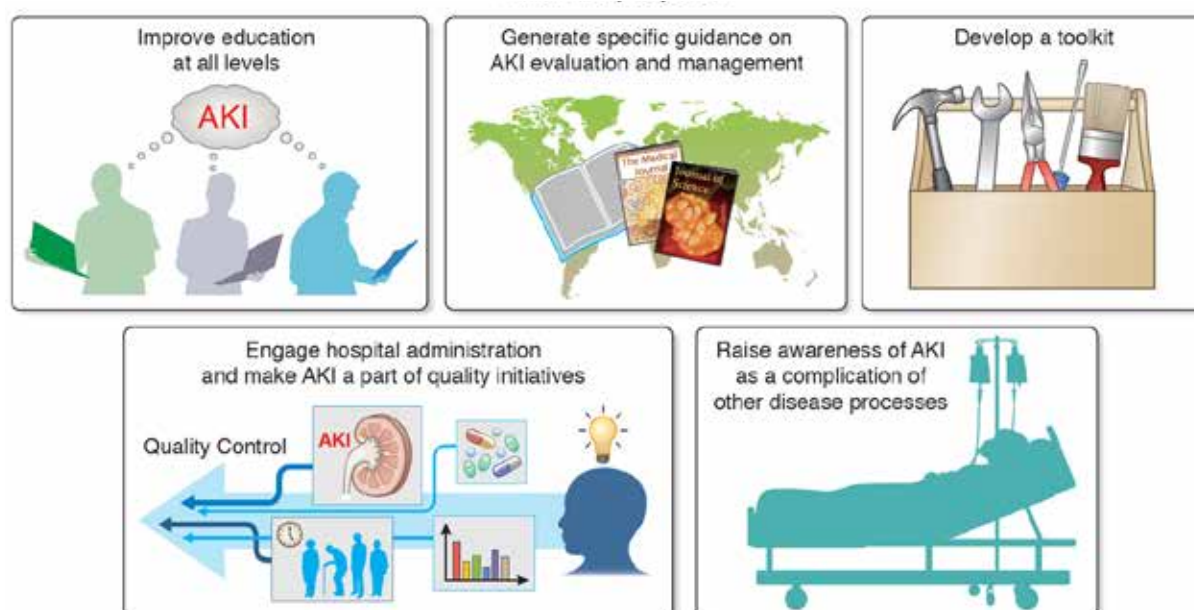
Opportunities for partnership

- Nephrologists have a key role, but they must work together across all stages of care, and across multiple areas of practice, to ensure appropriate recognition and management. As described previously, the scope of healthcare professionals who may encounter AKI in practice is vast. Nephrologists must partner with these non-nephrology practitioners to ensure appropriate AKI recognition and to promote recovery.
- Nephrology must recognize that the providers to partner with will vary by their geographic and economic context:
 - In high-income countries, AKI may be encountered by intensivists, emergency department physicians, hospitalists, and other medicine and surgery providers, nurses, dietitians, and nephrologists when necessary.
 - In low-income and middle-income countries, AKI may be encountered by primary care physicians where they are available, but more commonly, nurses or primary health care providers in rural dispensaries will conduct management, with support from regional centers; nephrologists will rarely or never be available.
- The nephrologists' role should be proactive rather than reactive, and evidence demonstrates the benefit of nephrologists' intervention.
- There is a great opportunity to partner with training program directors to enhance AKI education and training for fellows, residents, and medical students.

Communication

- Opportunities exist to improve communication across care pathways and between primary care practitioners and nephrology providers.
- Such opportunities include the use of electronic alerts and early referrals by means of electronic medical re-

Figure 1. Proposals advanced by AKI!Now



Reprinted with permission from the United States Renal Data System.

cords, education, and interaction with pharmacists on medication interactions and risk of kidney injury, and the importance of communication to streamline kidney care after discharge.

- Communication throughout the AKI process with patient and family is key to patient recovery and mitigation of long-term physical and emotional injury.

Messaging

- There is a consensus that raising AKI awareness is needed across all medical specialties and among the general public at large.
- Different modes of education are needed for different environments, cultures, and languages.
- Recently developed educational initiatives in the UK, and resources adapted to various low-income and rural environments in the 0by25 initiative, are models to learn from and to modify and adapt. For example, the UK Think Kidneys program includes resources such as a video, "Why We Need to Think Kidneys," and a case study addressing "Reducing UTIs and Improving Care."
- A national campaign, through either national systems such as the Veterans Administration or Epic Systems, or large medical practices such as Kaiser, or well-known spokespersons, should be considered.
- Efforts to raise awareness must focus on the general population, and large efforts must be made to widely disseminate the importance of AKI and its short-term and long-term consequences. Broad initiatives must disseminate that message by using vehicles such as World Kidney Day, public campaigns, electronic media communications, and—crucially—disseminating the voices of patients and their families as they relate their encounters with AKI.

Patient involvement

- Patients' stories about their experiences with AKI are powerful and extremely effective educational tools.
- In addition to these stories, systematic education to instruct patients and their families on recognizing AKI and the need for post-discharge follow-up with primary care physicians and specialists (including medication reconciliation) represent key areas of opportunity.

Putting the analysis into action

The Landscape Analysis highlights commonalities and common concerns in the recognition and treatment of AKI across the globe. It further suggests steps that can be taken in partnership to improve the care of patients with AKI. Broadly, the AKI!Now initiative will take the following steps (Figure 1):

Teach healthcare providers how to recognize AKI

Develop and/or identify and collect all available educational instruments on RECOGNITION resources, such as these:

- The UK Think Kidneys campaign, and all other printed or media educational instruments currently in use that can be used in education campaigns
- Educational materials already available from ASN and the NKF
- Educational materials developed and adapted for the community and rural regions in the 0by25 ISN initiative

Describe what to do with recognized AKI

Identify and collect all available educational instruments on MANAGEMENT from resources such as these:

- UK Think Kidneys educational materials
- ASN educational materials
- ISN's 0by25 procedures to manage early AKI in the community under regional hospital supervision and support

Work to better define the best pathways to kidney recovery after AKI

Also, collaborate with experts in defining the best interventions to promote function regain and to decrease relapse.

Encourage collection of data and creation of a continuous education repository of evidence

The AKI!Now initiative seeks to identify, catalog, and describe available data.

Use a public forum to discuss cases and raise awareness

The ASN AKI community and open forums are a resource to communicate initiatives and to promote AKI recognition and care.

Reach a wide medical audience

Identify means to implement educational campaigns to colleagues who are primarily, and in many cases the only, providers of kidney care. Raise awareness of AKI as an important complication of other disease processes.

Engage hospital administrations, and make AKI a quality metric

Establish administrative and quality initiatives to leverage the hospital systems, to achieve early recognition and management.

Educate the public

Stress the importance of recognition, impact on health, and cost of AKI, and leverage public support and education to improve AKI care.

To meet these goals, multiple action steps are in place.

First, the AKI!Now steering committee has assembled a workgroup, culled from the roundtable and focus group participants, to review existing AKI educational resources and revise them for new audiences. An initial set of these resources will be released in conjunction with the first AKI!Now webinar, “AKI Recognition and Management in High-Risk Populations: The Webinar You Can’t Afford to Miss,” scheduled for April 21, 2020, at 12:00 p.m. EDT. This webinar, the first of a two-part series for the year 2020, will address the identification and management of AKI in high-risk populations, and review resources.

Second, the AKI!Now steering committee has authored a series of three articles, which will be published in *CJASN*, including the following:

- A white paper: “Recognition of Acute Kidney Injury in High-Risk Patient Populations” (accepted for publication, 2020)
- “Recovery After Critical Illness and Acute Kidney Injury” (soon to be submitted)
- “Patient Perspective on AKI and Recovery,” which gives a voice to the patient perspective (soon to be submitted)

Third, the AKI!Now steering committee is developing a compendium of all AKI-related content available on ASN’s primary communication channels, including *CJASN*, *JASN*, *Kidney News*, *Kidney News Online*, *Kidney*

360, NephSAP, and Kidney Week abstracts. This online searchable index will allow users to access and save relevant content. ASN members will have the capability to view and search full articles. This compendium is projected to be released in July 2020.

To achieve meaningful change in AKI recognition and recovery, partnership across the medical continuum is crucial. The AKI!Now steering committee invites you to be part of this change: participate in the upcoming webinar, use the new resources, use the compendium, and share your questions, ideas, and best practices with the AKI community. ■

Jorge Cerdá, MD, MS, FASN, is chair of the AKI!Now initiative. Bonnie L. Freshly, MEd, CMP, is project coordinator with Nephrologists Transforming Dialysis Safety.

Anna’s Story: When Home Hemodialysis Improves Peoples’ Lives and Saves Medicare Money

By David McFadden

Anna has been providing home hemodialysis for 6 years to her husband, who has chronic kidney disease stage 4.

Initially, when the couple were given options for the available forms of dialysis treatment—in-center dialysis, peritoneal dialysis, and home hemodialysis—Anna was extremely reluctant to do home dialysis because she had no medical background. They ultimately decided on home hemodialysis, however, because of her husband’s work schedule.

Over the past 6 years, Anna has been a champion for home hemodialysis. Changes to Medicare reimbursement for telemedicine visits have enabled her

husband to receive virtual nephrology visits at home, which keeps him from missing time from work. He can have up to eight virtual visits a year at home.

Anna’s mother recently started dialysis because of heart failure. In response, Anna immediately took on the challenge of providing home hemodialysis for her, as well as for her husband; all live together in the same home. Virtual visits enable her mother, who is 89, to avoid facing the harsh winters of Chicago to get to a dialysis center.

Anna has saved the Centers for Medicare & Medicaid Services a tremendous amount of money by providing home hemodialysis to her mother and her husband

compared with the cost of in-center dialysis. These savings to Medicare result from decreased hospitalization, decreased use of medications such as erythropoietin and blood pressure medication, and better fluid management, leading to fewer hospitalizations and readmissions.

She has also saved her family time and money and improved their quality of life by reducing travel time to and from the dialysis unit, wear and tear on their car, and strain on their health resulting from travel and inclement weather.

Anna’s story illustrates how Advancing American Kidney Health is having an impact on patients’ lives. ■

Using Telemedicine to Improve Lives

Medicare began paying for eight telemedicine visits a year instead of 12 face-to-face visits as of January 2019. This allows patients to avoid missing work and reduces exposure to inclement weather, as in Anna’s family’s case. In addition, telemedicine visits save the family and the nephrologist travel expense.

This year I plan to use population health management with my kidney failure patients, both at home and in center, to decrease hospitalizations. For example, I will send push notifications to my kidney failure patients through their cell phones each weekend to encourage them to avoid excess fluid and potassium-enriched foods. This alone will decrease admission rates. In addition, I plan to push notifications to my chronic kidney disease patients to help slow the progression of kidney disease. For example, I will send monthly push notifications through my patients’ cell phones to avoid salt and nonsteroidal anti-inflammatory drugs and to exercise regularly. These are just some of the many ways in which telemedicine can be used to combat kidney disease.

David McFadden, MD, is an independent nephrologist in Morris, Joliet, and New Lenox, Illinois. He is affiliated with Affiliated Dialysis, in which he has a joint venture in a home hemodialysis program and in an in-center dialysis facility. He is also affiliated with Myowndoctor, a telemedicine company.



Transplantation for Undocumented Immigrants: Time to Change the Way the Story Ends

By Areeba Jawed



I am worried your brother might not be allowed to give you a kidney, Jose,” I said to my patient of 5 years while shifting my feet, nervous that my actions would give away the guilt that was suffocating me.

I had taken care of Jose throughout his journey with kidney disease, and he was now approaching the need for dialysis or transplantation.

Jose was accompanied by his Spanish-speaking brother, who looked bewildered as he read our faces. Fumbling with the contents of his wallet, he pointed to the heart on his driver’s license.

Unsure how to respond to this stark awareness of our healthcare system’s double standard regarding organ donation, I sought refuge in my computer screen while the brothers conversed in Spanish. At a loss for words, I looked up apologetically as Jose said, “Gracias, Doctora.”

Background

Approximately 10.5 million unauthorized immigrants lived in the United States in 2017 (1), and an estimated 6500 of them had kidney failure (2). The diagnosis of kidney failure grants nearly universal health insurance coverage for provision of dialysis to citizens in the United States; however, undocumented immigrants’ lack of eligibility for state-funded insurance programs has resulted in divergent practice patterns across the states with regard to the availability of scheduled dialysis and organ transplantation (3).

Current legislation

The policy of the Organ Procurement and Transplantation Network (OPTN) clearly states that “deceased donor organ allocation to candidates for transplantation shall not differ on the basis of the candidate’s residency or citizenship status in the United States.”

There appears to be no legislation barring undocumented immigrants from receiving organs, but the lack of federally funded health insurance achieves that end, resulting in automatic and indirect exclusion. The Omnibus Budget Reconciliation Act passed by Congress in 1986 prohibits the use of federal Medicaid funding for payment of care provided to undocumented immigrants except for what qualifies as emergency medical care under the Emergency Medical

Treatment and Active Labor Act (EMTALA).

In 1996, further legislation denied all state and local public benefits to undocumented immigrants and left the states to pass their own laws to determine the eligibility criteria under which public benefits would be available to undocumented immigrants. Additional legislation was passed to augment federal Medicaid funding to states with the greatest number of undocumented immigrants. Undocumented immigrants with catastrophic illnesses such as kidney failure, cancer, or traumatic brain injuries are also excluded from the Patient Protection and Affordable Care Act.

Under EMTALA, all states must offer at least emergent-only dialysis to all patients; however, kidney transplantation is not considered to be part of this program and is not offered to undocumented immigrants (4). Illinois was one of the first states to offer organ transplantation to undocumented immigrants under state-funded Medicaid, followed by California.

By contrast, once undocumented immigrants do enter the healthcare system, the mandates by the Joint Commission and Medicare ensure they are asked regarding their wishes about organ donation without any consideration of their citizenship status (5).

Transplantation outcomes

Most undocumented immigrants who reach kidney failure are younger, are more likely to be employed, have better functional status, and have fewer comorbidities despite longer wait times for transplantation compared with citizens receiving dialysis (4, 6). Hence, it would be reasonable to expect them to do well as transplant recipients.

A study by Shen et al. (6) compared transplantation outcomes in undocumented immigrants with those in citizens and found that nonresident aliens had a >45% lower unadjusted risk for all-cause transplant loss, death-censored transplant loss, and death compared with US citizens. In the pediatric population, a similar study from California found undocumented children to have similar graft survival 1 and 5 years after transplantation, and their mean estimated GFR at 1 year was higher than that in recipients who were citizens. In addition, the risk of allograft failure was lower in undocumented recipients than in citizens 5 years after transplantation, after adjustment for patient age, donor age, donor type, and HLA mismatch (7).

Transplantation outcomes have also been explored in other solid organ transplantation settings; for example, in one study the liver and graft survival among unauthorized immigrants was comparable to that in citizens/residents (8).

Inherent limitations of all these studies include that the classification of non-US citizens and non-US residents is based on self-reporting and thus they are at risk for misclassification; furthermore, owing to the tenuous path to organ transplantation, there may be a selection bias to include recipients with better financial and social support, which would explain the optimal transplantation outcomes. Nonetheless, undocumented residents appear to protect their transplanted organs just as well as citizens, resulting in better outcomes.

Patient perspectives

Even though a greater percentage of Hispanics have kidney failure, disproportionately fewer Hispanics than whites receive a living donor kidney transplant (9). In addition to system-level barriers mentioned previously, studies have explored the knowledge and attitudes of undocumented immigrants toward organ donation.

Baru et al. interviewed 59 undocumented immigrants from Chicago in a qualitative study and concluded adequate knowledge among 65% of participants (10). The study participants showed a willingness to donate despite being suspicious of the healthcare system and in the face of the knowledge that they had few chances of receiving organs themselves.

In a study of the illness experience of undocumented immigrants receiving dialysis, many participants wanted to undergo transplantation and had family members interested in donating a kidney; yet, they lacked access because of insurance-related reasons. They were aware of the double standard concerning organ donation and their ability to donate after death despite their ineligibility to receive organs (11). Other studies among Hispanic populations have also identified lack of knowledge, financial barriers, and logistic barriers to organ donation (12, 13).

Ethical analysis

Right to healthcare

Those who oppose undocumented immigrants’ right to healthcare do so on the basis of the immigrants’ illegal status in the country and have concerns regarding their financial contributions to society (14, 15). Furthermore, others believe that by offering free healthcare to undocumented immigrants we may be extending an invitation for abuse of limited healthcare resources, resulting in an unfair burden on society (15).

Proponents argue that access to healthcare is a basic human right that should be granted to all. Several studies have shown transplantation to be cheaper than emergent dialysis, making it the more financially feasible option for society (16). It is imperative to mention that undocumented immigrants do contribute financially in the form of nearly \$12 billion in taxes, with \$2.4 billion directed toward Medicare, contributing substantially more than what they withdraw in comparison with citizens. They also generate a surplus in the magnitude of billions in Social Security programs, which they are unlikely to claim (17).

Beyond the scope of this article, but prudent to mention here, is that the right to healthcare in the United States even for citizens is under debate because it would mean nearly universal healthcare coverage. That is not the case, despite

the obligation many physicians feel to provide such care.

A healthcare system that readily accepts organs for donation from a subset of the population without addressing their inability to receive organs seems grossly unjust. No comprehensive data on the citizenship status of organ donors is available from procurement organizations, although studies show that undocumented immigrants are more likely to donate than they are to receive (18).

According to OPTN data, illegal immigrants contributed as much as 2.5% of all donations between 1988 and 2007 but received only 0.63% of the organs. One would expect that with this knowledge, fewer individuals would donate; however, studies have shown high donation rates despite the awareness of this double standard (10).

Rationing of limited resources

Opponents argue that organs are a limited resource and should be rationed to legal residents who are most likely to benefit from them and demonstrate the highest need. Studies have reported that undocumented immigrants are more likely to have living donors, the majority being healthy family members (6); hence, they are less likely to affect the organ pool. Furthermore, they contribute as living and deceased donors; however, their ability for living donation is limited.

Undocumented immigrants who receive transplants have transplantation outcomes comparable with those of citizens and are more likely to be employed, consistent with judicious use of organs, resulting in maximum benefit to recipients.

Conclusion

Making transplantation available to undocumented immigrants with kidney failure is the ethical, humane, just, and economically feasible path to take. The United Network for Organ Sharing needs to develop a transparent policy reflective of public opinion when it comes to transplantation in undocumented immigrants. Efforts should be made to highlight their economic contributions to society, their minimal use of healthcare resources, and their continued contribution to the organ pool, which exclusively benefits citizens. We must at least advocate for living donation in this disadvantaged population, allowing them to continue to be productive members of society without tapping the organ pool. ■

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Findings

Faster Resolution of UACR After Bariatric Surgery in Diabetic Teens

Among patients with type 2 diabetes undergoing bariatric surgery, adolescents have earlier resolution of elevated urinary albumin to creatinine ratio (UACR), compared to adults, reports a study in *Kidney International*.

The researchers analyzed 161 adolescents with severe obesity who underwent Roux-en-Y gastric bypass surgery. For comparison, they looked at a group of 396 adults undergoing gastric bypass—all with a reported history of obesity at age 18 or younger. Before gastric bypass, type 2 diabetes was present in 14% of the adolescents and 31% of the adults. For patients with preoperative type 2 diabetes, the adolescents and adults were similar in terms of preoperative weight, body mass index (BMI), and glycated hemoglobin. Among those without preoperative diabetes, the adolescents had higher weight, BMI, and insulin levels.

Renal outcomes 5 years after bariatric surgery were compared between age groups, focusing on spot UACR measurement and estimated glomerular filtration rate measured by serum creatinine and cystatin C. Analyses were stratified by the presence of preoperative type 2 diabetes.

Before surgery, the prevalence of elevated UACR was 22.5% in adolescents with type 2 diabetes, compared to 9.0% in diabetic adults. Follow-up data showed earlier improvement in elevated UACR in teens with preoperative diabetes compared to adults. In adolescents, adjusted prevalence of elevated UACR decreased from baseline to 1 year, remaining stable thereafter. In adults, adjusted prevalence of elevated UACR was stable from baseline to year 4, with a significant decline in year 5.

In contrast, there was no difference in UACR in response to gastric bypass between adolescents or adults without preoperative diabetes. Teens with preoperative type 2 diabetes had a higher prevalence of hyperfiltration (prevalence ratio 2.36), which persisted across the 5-year study period.

The study is the first to compare kidney outcomes after bariatric surgery in adolescents versus adults. “Adolescents with pre-operative type 2 diabetes experienced a more precipitous resolution of elevated UACR following gastric bypass compared to their adult counterparts,” the researchers write.

The age-related difference in UACR response after bariatric surgery adds to previous evidence that adolescents have “greater plasticity for comorbidity reversal.” Further studies with extended follow-up are needed to clarify the risks and benefits of bariatric surgery for severely obese adolescents, with and without type 2 diabetes [Bjornstad P, et al. Five year kidney outcomes of bariatric surgery differ in severely obese adolescents and adults with and without type 2 diabetes. *Kidney Int* 2020; DOI: <https://doi.org/10.1016/j.kint.2020.01.016>]. ■

For Older Adults with Kidney Failure, Dialysis Linked to More Hospital Days

In older adults with kidney failure, the decision to undergo maintenance dialysis is associated with increased hospital and ICU days and decreased use of inpatient palliative care, reports a study in *JAMA Network Open*.

Using Alberta health data, the researchers identified 968 older adults (65 or older) with kidney failure: 489 men and 479 women, median age 78.5 years. All had at least two consecutive outpatient estimated glomerular filtration rate (eGFR) meas-

urements of less than 10 mL/min/1.73 m² over at least 90 days—a level at which patients and physicians discuss and decide whether to pursue maintenance dialysis. Time-varying exposure to maintenance dialysis was analyzed for association with cumulative hospital days, with adjustment for covariates. A wide range of secondary outcomes were analyzed as well.

Maintenance dialysis was performed in 57.5% of patients. Those not receiving dialysis were more likely to be female, older

(median age 83.6 years), to have higher comorbidity, and to reside in a long-term care facility.

Patients receiving maintenance dialysis spent more days in the hospital, incidence rate ratio (IRR) 2.47: the typical patient treated with dialysis had an additional 22 hospital days per year. There was no increase in the rate of hospital admissions, but patients in the maintenance dialysis group had a higher rate of ICU admissions: 98.37 versus 54.51 per 1000 hospitaliza-



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tions, IRR 1.80.

Maintenance dialysis was also associated with a lower rate of inpatient palliative care: 3.92 versus 8.60 per 1000 hospital days, IRR 0.45. Of 627 patients who died during follow-up, those treated with dialysis were more likely to die in the hospital: 66.0% versus 48.4%, relative risk 2.93.

For older adults with kidney failure, time spent in the hospital is an important patient-oriented outcome that may affect the decision to initiate dialysis. There are few data on comparative outcomes for patients choosing dialysis or nondialysis care in this situation.

The new study shows increased inten-

sity of care, including a substantial increase in hospital days, for older adults with kidney failure who receive maintenance dialysis. Dialysis is also associated with a lower rate of inpatient palliative care and an increased likelihood of dying in the hospital. The authors note that the findings in their Canadian cohort—including the 40% rate of treatment without dialysis—may not be generalizable to the United States and elsewhere [Tam-Tham H, et al. Association of initiation of dialysis with hospital length of stay and intensity of care in older adults with kidney failure. *JAMA Network Open* 2020; 3:e200222]. ■

In Advanced CKD, Prehydration Before Contrast Doesn't Reduce AKI

For patients with CKD stage 3, the standard practice of prehydration before contrast administration does not reduce the risk of AKI, reports a randomized trial in *JAMA Internal Medicine*.

The “Kompas” trial included 523 patients with stage 3 CKD undergoing nonemergency contrast-enhanced computed tomography (CECT) at six hospitals in the Netherlands. The patients were 336 men and 187 women, median age 74 years. They were assigned to undergo prehydration or no prehydration before contrast administration. Prehydration consisted of 1-hour infusion of 250 mL of 1.4% sodium bicarbonate.

The two groups were compared for their mean relative increase in serum creatinine 2 to 5 days after CECT, compared to baseline; the noninferiority margin was less than a 10% increase. Secondary outcomes included AKI developing 2 to 5 days after contrast administration, mean relative increase in creatinine at 7 to 14 days, incidence of acute heart failure or renal failure requiring dialysis, and health-care costs.

Mean relative increase in serum creatinine at 2 to 5 days was 3.5% with prehydration and 3.0% with no prehydration: a nonsignificant difference. Postcontrast AKI developed in 1.5% of patients in the prehydration group (4 cases) and 2.7% in the no-prehydration group (7 cases); relative risk 1.7. No patient developed acute heart failure or kidney failure requiring dialysis.

There was no difference in the effects of prehydration versus no prehydration in specified patient subgroups. The cost of prehydration (mean €119) was avoided in the comparison group; other costs were not significantly different.

For more than a decade, prehydration protocols have been widely used with the goal of preventing postcontrast AKI in patients with CKD stage 3. This is despite the lack of evidence on the effectiveness of this intervention, as well as the potential for adverse effects such as volume overload.

The Kompas randomized trial finds no difference in the relative increase in serum creatinine for stage 3 CKD patients receiving prehydration versus no prehydration before CECT. Other outcomes are also similar between groups, including health-care costs. “[O]ur study provides sufficient evidence that preventive hydration can be withheld in this population,” the researchers conclude [Timal RT, et al. Effect of no prehydration vs sodium bicarbonate prehydration prior to contrast-enhanced computed tomography in the prevention of postcontrast acute kidney injury in adults with chronic kidney disease: the Kompas randomized clinical trial. *JAMA Intern Med* 2020; DOI: 10.1001/jamainternmed.2019]. ■

It's time for kidney talk

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Hidden signs

- Patients often go undiagnosed**, as the clinical presentation of AS is highly variable and family history may be unavailable^{3,9-11}
- Persistent, microscopic hematuria is the cardinal sign of AS** and should prompt immediate diagnostic investigation—particularly when combined with any family history of chronic kidney disease^{8,11,12}

Early action

- Expert guidelines published in the *Journal of the American Society of Nephrology* now **recommend genetic testing as the gold standard for diagnosing Alport syndrome**⁸
- Early AS detection via genetic diagnosis, and its ability to guide a patient's treatment decisions, demonstrates the **powerful impact of precision medicine in nephrology**¹²⁻¹⁴

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Fellows Corner

Dialysis Care of Undocumented Immigrants: Can We Do Better?

By Dorreen Danesh, Sarah Stern, and Eddy J. De Jesus



Dorreen Danesh



Sarah Stern



Eddy J. De Jesus

What does it take for a man to refuse life-saving dialysis? Despite thorough counseling, our team stood still as our patient continued to refuse hemodialysis for his kidney failure. Admitted because of his severely elevated potassium levels, he understood his imminent risk for sudden cardiac arrest. Yet, as the buildup of toxins in his bloodstream worsened his lethargic and nauseated state, he remained adamant that his family lacked the means to continue with the emergency dialysis he needed to survive.

For our patients of undocumented status, the tragic lack of access to scheduled dialysis is all too common.

An estimated 6500 undocumented immigrants with kidney failure live in the United States (1). Whereas all American citizens who either qualify for Social Security or are dependents of persons who qualify are guaranteed coverage for dialysis by the End-Stage Renal Disease Amendment to the Social Security Act (2, 3), this coverage does not extend to patients of undocumented status. Thus, these patients' care varies vastly between states. Twelve states provide Medicaid or emergency care coverage for scheduled dialysis (4). Yet, in the majority of states in this country, patients qualify for intermittent emergency dialysis only in the presence of life-threatening laboratory abnormalities or symptoms under the 1986 Emergency Medicaid Treatment and Active Labor Act (EMTALA) (5). After treatment, patients are instructed to return to the emergency department when their symptoms inevitably worsen.

Studies have consistently demonstrated the consequences of emergency-only dialysis, including life-threatening physical symptoms and psychosocial stressors for patients, in addition to harms experienced by clinicians and the public at large. Undocumented patients receiving emergency dialysis have a 14-fold higher odds ratio of death (6) and a lower quality of life in comparison with undocumented patients receiving scheduled dialysis (7). In some cases, symptoms from uremic toxins have been so distressing that patients have reported intentionally consuming high levels of potassium with the goal of satisfying the criteria for emergency dialysis (8).

Despite the injustice placed on patients and their families when we resort to emergency-only dialysis, studies have also highlighted the significant toll placed on our healthcare system, especially safety-net hospitals. Compared with their counterparts receiving scheduled care, patients of undocumented status receiving emergency-

only dialysis were found, on average, to require more days of inpatient care (162 days vs. 10 days), more emergency department visits (26.3 vs. 1.4), more blood transfusions (24.9 vs. 2.2) and greater yearly costs (\$284,655 vs. \$76,906) (9, 10).

A study in Texas noted cost savings of \$4316 per patient per month after the transition from emergency-only dialysis to scheduled dialysis (11). The cost savings from reductions in healthcare expenditures were noted to exceed the cost increases from vascular access and scheduled dialysis (11, 12). In addition to increased patient morbidity and poor quality of life, there is the well-documented burden of emergency dialysis on the use of healthcare. This is particularly of concern for hospitals such as Grady Memorial Hospital, Atlanta's major safety-net hospital, which reported that its 88 dialysis patients accounted for one-tenth of Grady's total losses despite representing only a small fraction of the greater than 800,000 patient visits it completed that year (13).

In addition to advocating for the universal implementation of scheduled dialysis, a crucial part of the solution lies in improving access to screening and preventive care. This can be approached on the continuum of disease prevention, from primary prevention in addressing common risk factors such as diabetes and high blood pressure, to slowing the progression of chronic kidney disease.

Kidney disease often has no symptoms, but simple urine or blood tests can detect early disease and alert clinicians to manage risk factors aggressively. Notably, risk factors such as diabetes and high blood pressure can be managed in impressively cost-effective ways. Affordable generic medications can be made available at \$4 and \$10 at major retail corporations, such as Walmart and Target, and thus be made accessible to low-income populations (14, 15). Given that many undocumented immigrants have difficulty navigating the healthcare system in the United States and often rely on federally qualified health centers, population-specific implementation of public health initiatives and outreach can be beneficial for both patients and communities.

Scheduled dialysis is the standard of care for all patients with kidney failure and should be accessible to all people with kidney failure. It has been shown to reduce mortality, healthcare use, and costs when compared with emergency-only dialysis (1, 2, 4–7, 9–11). The universal practice of scheduled dialysis, in place of emergency-only dialysis, avoids the psychosocial distress that plagues both patients and the clinicians who care for them.

As professionals who all take an oath to uphold the highest standard of care and humanism, we cannot let the citizenship status of our patients define the lifesaving care we provide. As individual physicians, we face the front line and witness the impact of harmful policy on our patients' lives. Our profession has the power to have an impact on policies and, most important, advocate on behalf of the patients and communities we serve. Together we can do better, and we must. ■

Dorreen Danesh and Sarah Stern are members of the University of Florida College of Medicine class of 2020. Eddy J. De Jesus, MD, is chief nephrology fellow (PGY-5) in the division of nephrology, hypertension, and renal transplantation, department of medicine, University of Florida.

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- Administration
- Clinic Manager/Coordinator
- Social Work
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Specialty Area

- General Nephrology
- Transplantation
- Dialysis
- Laboratory
- Other

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- Hospital <100 beds
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- Other

Please Circle Degree:

- MD MD/PhD DO
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- BS Other



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