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FDA, EU Regulators Expand Indications for Semaglutide to Include Kidney Benefits for Patients With Diabetes

By Bridget M. Kuehn

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Recent decisions from regulators in the United States and the European Union (EU) have expanded the indications for the glucagon-like peptide-1 receptor (GLP-1) agonist semaglutide to include kidney protection for patients with type 2 diabetes.

In late January 2025, the US Food and Drug Administration (FDA) approved semaglutide as a therapy that can reduce the risk of worsening kidney diseases and kidney failure and death due to cardiovascular disease in patients with type 2 diabetes and chronic kidney disease (CKD), according to a press release from the drug's maker Novo Nordisk USA (1). FDA had not released a public statement or updated the product's label at press time. In mid-December 2024, the European Medicines Agency, FDA's counterpart in the EU, similarly updated the drug's label to include reducing the risk of events related to kidney diseases (2).

"This is very exciting news for [people] with kidney disease[s]," said Matthew Sparks, MD, FASN, associate professor and director of the Nephrology Fellowship Program at Duke University School of Medicine, Durham, NC. He explained that many patients' insurers have balked at covering semaglutide for patients without obesity, but the new indication for CKD and type 2 diabetes may increase coverage. "This is a big step to now approve it just in the context of diabetes and [CKD] alone, [which] could open the door for a lot of patients that need this."

The regulators based their decisions on the results of the FLOW trial (Effect of Semaglutide Versus Placebo on the Progression of Renal Impairment in Subjects With Type 2 Diabetes and Chronic Kidney Disease), which demonstrated that semaglutide substantially reduced the risk of kidney events and cardiovascular death in patients with type 2 diabetes (3). FLOW trial coauthor Kathleen Tuttle, MD, FASN, executive director for research for Providence Inland Northwest Health and professor of medicine in the Division of Nephrology and the Kidney Research Institute at the University of Washington in Spokane, called the approval the next step in the "revolution in CKD therapies." Tuttle

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New ASN Kidney Health Guidance Focuses on Outpatient Dialysis for Patients With AKI

By Bridget M. Kuehn

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A small but growing number of patients with acute kidney injury (AKI) are receiving outpatient dialysis in a system that was not designed with their needs in mind. In fact, the number of patients with AKI receiving outpatient dialysis nearly doubled in recent years from about 6500 to almost 12,000 (1).

To help nephrologists and other clinicians better care for this population, ASN's Kidney Health Guidance (KHG) Oversight Committee convened a workgroup comprised of AKI experts in adult and pediatric nephrology, social work, pharmacy, and advanced practice nursing to review the literature and develop consensus guidance for clinicians. The document is ASN's second KHG (2); the first, published in September 2024, focused on care for obesity (3). Anitha Vijayan, MD, FASN, Senior Medical Director of Kidney Services and professor of medicine at Intermountain Health in Salt Lake City, UT—a co-corresponding author of the guidance—explained that patients requiring outpatient dialysis for AKI make up a small proportion of the more than half a million patients receiving dialysis in the United States.

"These patients are extremely vulnerable, and the care they are receiving in outpatient dialysis settings is sometimes not optimal in promoting recovery of kidney function," she said. "Patients with AKI often receive the same

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INDICATION

XPHOZAH (tenapanor) 30 mg BID is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

XPHOZAH is contraindicated in:

- Pediatric patients under 6 years of age
- Patients with known or suspected mechanical gastrointestinal obstruction

WARNINGS AND PRECAUTIONS

Diarrhea

Patients may experience severe diarrhea. Treatment with XPHOZAH should be discontinued in patients who develop severe diarrhea.

MOST COMMON ADVERSE REACTIONS

Diarrhea, which occurred in 43-53% of patients, was the only adverse reaction reported in at least 5% of XPHOZAH-treated patients with CKD on dialysis across trials. The majority of diarrhea events in XPHOZAH-treated patients were reported to be mild-to-moderate in severity and resolved over time, or with dose reduction. Diarrhea was typically reported soon after initiation but could occur at any time during treatment with XPHOZAH. Severe diarrhea was reported in 5% of XPHOZAH-treated patients in these trials.

Please see Brief Summary of full Prescribing Information on the following page.

Reference: XPHOZAH® (tenapanor) full Prescribing Information. Waltham, MA: Ardelyx, Inc.; 2023.

ardelyx®

XPHOZAH (tenapanor) tablets, for oral use
Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

XPHOZAH is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

4 CONTRAINDICATIONS

XPHOZAH is contraindicated in patients under 6 years of age because of the risk of diarrhea and serious dehydration *[see Warnings and Precautions (5.1), Use in Specific Populations (8.5)]*.

XPHOZAH is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

5 WARNINGS AND PRECAUTIONS

5.1 Diarrhea

Diarrhea was the most common adverse reaction in XPHOZAH-treated patients with CKD on dialysis *[see Dosage and Administration (2) in the full Prescribing Information, Contraindications (4) and Adverse Reactions (6.1)]*. In clinical trials, diarrhea was reported in up to 53% of patients, reported as severe in 5%, and associated with dehydration and hyponatremia in less than 1% of patients. Treatment with XPHOZAH should be discontinued in patients who develop severe diarrhea.

6 ADVERSE REACTIONS

6.1 Clinical Trial 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 practice.

The safety data described below reflect data from 754 adults with CKD on dialysis taking XPHOZAH in clinical trials as monotherapy and in combination with phosphate binders. Among the 754 patients, 258 patients were exposed to tenapanor for at least 26 weeks and 75 were exposed to tenapanor for at least one year. *[see Clinical Studies (14) in the full Prescribing Information]*.

Most Common Adverse Reaction

Diarrhea, which occurred in 43-53% of patients, was the only adverse reaction reported in at least 5% of XPHOZAH-treated patients with CKD on dialysis across trials. The majority of diarrhea events in the XPHOZAH-treated patients were reported to be mild-to-moderate in severity and resolved over time, or with dose reduction. Diarrhea was typically reported soon after initiation but could occur at any time during treatment with XPHOZAH. Severe diarrhea was reported in 5% of XPHOZAH-treated patients in these trials *[see Warnings and Precautions (5.1)]*.

7 DRUG INTERACTIONS

7.1 OATP2B1 Substrates

Tenapanor is an inhibitor of intestinal uptake transporter, OATP2B1 *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Drugs which are substrates of OATP2B1 may have reduced exposures when concomitantly taken with XPHOZAH. Monitor for signs related to loss of efficacy and adjust the dose of concomitantly administered drug as needed.

Enalapril is a substrate of OATP2B1. When enalapril was coadministered with XPHOZAH (30 mg twice daily for five days), the peak exposure (Cmax) of enalapril and its active metabolite, enalaprilat, decreased by approximately 70% and total systemic exposures (AUC) decreased by 50 to 65% compared to when enalapril was administered alone *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. However, the decrease in enalaprilat's exposure with XPHOZAH may be offset by the inherently higher exposures observed in patients with CKD on dialysis due to its reduced renal clearance. Therefore, a lower starting dose of enalapril, which is otherwise recommended in patients with CKD on dialysis is not required when enalapril is coadministered with XPHOZAH.

7.2 Sodium Polystyrene Sulfonate

Separate administration XPHOZAH and sodium polystyrene sulfonate (SPS) by at least 3 hours. SPS binds to many commonly prescribed oral medicines.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Tenapanor is essentially non-absorbed systemically, with plasma concentrations below the limit of quantification (less than 0.5 ng/mL) following oral administration *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Therefore, maternal use is not expected to result in fetal exposure to the drug.

The available data on XPHOZAH exposure from a small number of pregnant women have not identified any drug associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcomes. In reproduction studies with tenapanor in pregnant rats and rabbits, no adverse fetal effects were observed in rats at 0.2 times the maximum recommended human dose and in rabbits at doses up to 15 times the maximum recommended human dose (based on body surface area) *[see Nonclinical Toxicology (13.1) in the full Prescribing Information]*.

The estimated background risk of major birth defects and miscarriage for women with CKD on dialysis with hyperphosphatemia is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the United States general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Animal Data

In an embryofetal development study in rats, tenapanor was administered orally to pregnant rats during the period of organogenesis at dose levels of 1, 10 and 30 mg/kg/day. Tenapanor doses of 10 and 30 mg/kg/day were not tolerated by the pregnant rats and was associated with mortality and moribundity with body weight loss. The 10 and 30 mg/kg dose group animals were sacrificed early, and the fetuses were not examined for intrauterine parameters and fetal morphology. No adverse fetal effects were observed in rats at 1 mg/kg/day (approximately 0.2 times the maximum recommended human dose) and in rabbits at doses up to 45 mg/kg/day (approximately 15 times the maximum recommended human dose, based on body surface area). In a pre- and post-natal developmental study in mice, tenapanor at doses up to 200 mg/kg/day (approximately 16.5 times the maximum recommended human dose, based on body surface area) had no effect on pre- and post-natal development.

8.2 Lactation

Risk Summary

There are no data available on the presence of tenapanor in either human or animal milk, its effects on milk production or its effects on the breastfed infant. Tenapanor is essentially non-absorbed systemically, with plasma concentrations below the limit of quantification (less than 0.5 ng/mL) following oral administration *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. The minimal systemic absorption of tenapanor will not result in a clinically relevant exposure to breastfed infants. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XPHOZAH and any potential adverse effects on the breastfed infant from XPHOZAH or from the underlying maternal condition.

8.4 Pediatric Use

Risk Summary

XPHOZAH is contraindicated in patients less than 6 years of age. In nonclinical studies, deaths occurred in young juvenile rats (less than 1-week old rats; approximate human age-equivalent of less than 2 years of age) and in older juvenile rats (approximate human age-equivalent of 2 years of age) following oral administration of tenapanor, as described below in Juvenile Animal Toxicity Data.

The safety and effectiveness of XPHOZAH in pediatric patients have not been established.

Juvenile Animal Toxicity Data

In a 21-day oral dose range finding toxicity study in juvenile rats, tenapanor was administered to neonatal rats (post-natal day (PND) 5) at doses of 5 and 10 mg/kg/day. Tenapanor was not tolerated in male and female pups and the study was terminated on PND 16 due to mortalities and decreased body weight (24% to 29% reduction in females at the respective dose groups and 33% reduction in males in the 10 mg/kg/day group, compared to control).

In a second dose range finding study, tenapanor doses of 0.1, 0.5, 2.5, or 5 mg/kg/day were administered to neonatal rats from PND 5 through PND 24. Treatment-related mortalities were observed at 0.5, 2.5, and 5 mg/kg/day doses. These premature deaths were observed as early as PND 8, with majority of deaths occurring between PND 15 and 25. In the 5 mg/kg/day group, mean body weights were 47% lower for males on PND 23 and 35% lower for females on PND 22 when compared to the controls. Slightly lower mean tibial lengths (5% to 11%) were noted in males and females in the 0.5, 2.5, and 5 mg/kg/day dose groups on PND 25 and correlated with the decrements in body weight noted in these groups. Lower spleen, thymus, and/or ovarian weights were noted at the 0.5, 2.5, and 5 mg/kg/day doses. Tenapanor-related gastrointestinal distension and microscopic bone findings of increased osteoclasts, eroded bone, and/or decreased bone in sternum and/or femorotibial joint were noted in males and females in the 0.5, 2.5, and 5 mg/kg/day dose groups.

In juvenile rats administered tenapanor at 0.03, 0.1, or 0.3 mg/kg/day on PND 5 through PND 61, treatment-related mortalities were observed at 0.3 mg/kg/day. Lower mean body weight gains were noted in the 0.3 mg/kg/day group males and females compared to the control group primarily during PND 12–24 but continuing sporadically during the remainder of the dosing period; corresponding lower mean food consumption was noted in this group during PND 21–33. As a result, mean body weights were up to 15.8% and 16.8% lower in males and females, respectively, compared to the control group; the greatest difference was on PND 24 for males and PND 21 for females. Mean body weight in the 0.3 mg/kg/day group males was only 3.9% lower than the control group on PND 61. There were no tenapanor-related effects on mean body weights, body weight gains, or food consumption in the 0.03 and 0.1 mg/kg/day group males and females. A dosage level of 0.1 mg/kg/day was considered to be the no-observed-adverse-effect level (NOAEL) for juvenile toxicity of tenapanor *[see Contraindications (4), Warnings and Precautions (5.1)]*.

In a 21-day oral dose range finding study in older (weaned) juvenile rats administered tenapanor at 0.1, 1, or 5 mg/kg/day on PND 21 through PND 41 (approximate human age-equivalent of 2 to 12 years of age), treatment-related mortalities or moribundities were observed during the first two days of the study in the 1 mg/kg/day males and the 5 mg/kg/day males and females. Watery feces, decreased food consumption, and lower mean body weight were also observed in the 1 and 5 mg/kg/day groups.

In weaned juvenile rats administered tenapanor at 0.1, 0.3, and 0.7 (males) or 1 (females) mg/kg/day on PND 21 through PND 80, no mortalities were observed. Significant decreases in mean body weights were observed in the 0.3 and 0.7 mg/kg/day males throughout the dosing period (up to 20.3% lower than control) and in the 1 mg/kg/day females between PND 23 to 35 (up to 16.7% lower than control), with food consumption notably decreased on PND 21 to 29. There were also reductions in tibia length between PND 76 and 80 in the 0.3 and 0.7 mg/kg/day males, and between PND 36 and 64 in the 0.7 mg/kg/day males, which were not observed during the 14-day recovery period. The NOAEL was considered to be 0.1 mg/kg/day for juvenile toxicity of tenapanor.

8.5 Geriatric Use

Of 1010 adult patients with CKD on dialysis randomized and treated in two randomized, double-blind, placebo-controlled randomized withdrawal clinical trials for XPHOZAH (TEN-02-201 and TEN-02-301) as well as a third randomized, double-blind, placebo-controlled trial (TEN-02-202) for XPHOZAH in combination with phosphate binders, 282 (28%) were 65 years of age and older. Clinical studies of XPHOZAH did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently than younger patients.

10 OVERDOSAGE

No data are available regarding overdosage of XPHOZAH in patients. Based on nonclinical data, overdose of XPHOZAH may result in gastrointestinal adverse effects such as diarrhea, as a result of exaggerated pharmacology with a risk for dehydration if diarrhea is severe or prolonged *[see Warnings and Precautions (5.1)]*.

17 PATIENT COUNSELING INFORMATION

Advise Patients:

Diarrhea

Instruct patients to contact their healthcare provider if they experience severe diarrhea *[see Warnings and Precautions (5.1)]*.

- Instruct patients not to use stool softeners or laxatives with XPHOZAH.

Administration and Handling Instructions

Instruct Patients:

- To take XPHOZAH just prior to the first and last meals of the day *[see Dosage and Administration (2.2) in the full Prescribing Information]*.
- Patients should be counseled not to take XPHOZAH right before a hemodialysis session, and to take XPHOZAH right before the next meal, as some patients may experience diarrhea after taking XPHOZAH.
- If a dose is missed, take the dose just before the next meal. Do not take 2 doses at the same time *[see Dosage and Administration (2.2) in the full Prescribing Information]*.
- To keep XPHOZAH in a dry place. Protect from moisture. Keep in the original bottle. Do not remove desiccant from the bottle. Keep bottles tightly closed *[see How Supplied/Storage and Handling (16) in the full Prescribing Information]*.

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said, "We truly have therapies—this one in particular—that save kidneys, hearts, and lives."

Going with FLOW

FDA previously approved semaglutide to improve glycemic control in patients with type 2 diabetes in 2017 and added the reduction of major cardiovascular events as an additional indication in 2020. It was approved as a weight-loss treatment in 2021. Along the way, trials for the drug suggested kidney benefits. The FLOW trial added to that evidence.

The FLOW trial enrolled 3533 patients with type 2 diabetes and CKD at 387 sites in 28 countries. Investigators randomized patients to receive a 1-mg weekly dose of semaglutide or placebo. Patients were also receiving standard-of-care therapies. After a median of 3.4 years of patient follow-up, the trial ended early based on an interim analysis that met its prespecified goals. "The bar was set very high to stop this trial early," Tuttle said. "It took an overwhelming benefit to get to the point that the Data and Safety Monitoring Board said, 'You should stop now.'"

The final analysis showed a 24% reduction in the trial's primary outcome: A composite of kidney failure, a sustained 50% or greater reduction in estimated glomerular filtration rate, or death from kidney or cardiovascular causes. The number needed to treat was 20. The semaglutide group also met the trial's secondary endpoints, including a slower estimated glomerular filtration rate decline, a reduced risk of cardiovascular events, and a reduced risk of all causes of death.

"We felt the evidence was strong enough to say [that] people can get better," Tuttle said. "That changes the entire conversation on the outlook for the patient. Not only can we say [that] your kidneys are much less likely to fail, [but] you're also much more likely to stay alive and not have cardiovascular events."

"Game-changer drug"

The FLOW results, along with a growing number of meta-analyses, suggest that GLP-1 agonists are part of what Tuttle calls the "four pillars" of care for people living with CKD and type 2 diabetes: Sodium-glucose cotransporter-2 (SGLT2) inhibitors, GLP-1 agonists, mineral corticoid receptor antagonists, and renin-angiotensin-aldosterone system (RAAS) inhibitors.

The lead author of the FLOW trial, Vlado Perkovic, MBBS, PhD, provost at the University of New South Wales, Sydney, Australia, said that historically, nephrologists have been aware of the potential glycemic or heart-protective effects of GLP-1 agonists, but they may have felt those medications were the domain of endocrinologists or cardiologists. However, the FLOW trial shows that these medications can be an essential tool for nephrologists. "We do not have too many life-prolonging therapies available for our patients, and this is now one," he said. Combining semaglutide with other available medications may help multiply the benefits, he added.

"There's a growing body of data suggesting that the benefits are additive, and that's important because it means that rather than getting the one-quarter reduction in renal outcomes that we got in FLOW, if you use it with an SGLT2 inhibitor and an MRA [mineral corticoid receptor antagonist] on top of [an] RAAS inhibitor, we're talking about a two-thirds reduction in the risk of kidney failure," Perkovic said. "It's a dramatic development that changes the game, not just for the nephrology community but for health care and public health more broadly."

Sparks agreed. He noted the importance of having a fourth drug that helps reduce the risk of kidney failure, lowers blood pressure, promotes weight loss, and reduces blood sugar. He urged his colleagues to make prescribing the GLP-1 agonist class of drugs part of their practice and not deferring to primary care physicians or endocrinologists. "This is a game-changer drug," he said. "We as a nephrology community need to own this and think about how we integrate this into our clinical practice."

Tuttle also noted that patients are eager to take GLP-1 agonists because of collateral benefits, including weight loss, improved glycemic control, reduced cardiovascular risk, and reduced risk of death. The drug's effects may also allow them to reduce medication burden by allowing them to lower the doses of some medicines or discontinue others, Sparks said. It also creates an alternative option for patients who are unable to tolerate certain drug classes. "Some patients just cannot take RAAS inhibitors, or some patients cannot take SGLT2 inhibitors," Sparks said. "[The semaglutide approval] allows us to have options, which is also really important."

Sparks said nephrologists need to gain experience in prescribing the drug, managing side effects, and helping patients access it. "We are going to look back 5 years from now and say, 'How did we ever not have GLP-1 agonists in our armamentarium?'" he speculated.

Access challenges

The FDA approval and the EU label extension will likely expand the use of semaglutide globally, provided that barriers such as the drug's high cost and supply issues can be overcome, Perkovic said. He explained that the injectable drug is expensive, and the high demand has led to supply problems.

In the United States, the drug can cost $1000 to $1400 out-of-pocket without insurance depending on the indication and dose (4). Many patients with and without chronic diseases are willing to pay out-of-pocket for the drug's dramatic weight-loss effects. Sparks noted that this has reduced pharmaceutical companies' interest in lowering prices.

Tuttle explained that the price tag, along with the high demand for common conditions—obesity, sleep apnea, diabetes, and cardiovascular disease—has created concerns for payors about the cost of the medications. She argued, however, that the long-term payoff of preventing kidney failure is potentially huge, especially for the public. "Medicare has an investment in this because [it bears] the burden of the end-stage renal disease program," she said. "But private insurers often are not so interested in long-term outcomes because people change insurance so often. That's an issue to be addressed at the policy level."

Policy changes to lower the cost of semaglutide for Medicare are already underway. In mid-January when former President Biden was in office, the US Department of Health and Human Services' Centers for Medicare & Medicaid Services announced plans to negotiate prices for semaglutide and 14 other drugs covered by Medicare Part D (5). The negotiated prices would go into effect in 2027. The negotiations are required as part of the Inflation Reduction Act, and with an announcement on January 29th**,** after President Trump's inauguration, it was affirmed that the plans would move forward with community input (6).

Newer oral versions of this class of drugs are in development that may lower the costs and increase the availability of the medication, Perkovic said. Tuttle noted that the eventual emergence of generic versions may also help. In the meantime, Sparks said that he and his colleagues try to find coupons to help patients with the costs and work to make the case to insurers about the benefits, even for patients without obesity.

"Even if insurance companies approve it, it still can have a high copay associated with it," Sparks said. "It's made it challenging for the ones that really need it to get it. [The FDA approval] hopefully will allow us to break down some of those barriers for patients [who] do not have obesity to get them to be able to take this drug." Tuttle said that another potential concern is that limited access to only those who have the means to afford the drug's high cost could widen health disparities. "We have to stand up for giving the best care to everybody," she said.

"It's a dramatic development that changes the game, not just for the nephrology community but for health care and public health more broadly."

Sparks added that additional research is needed on whether GLP-1 agonists will benefit people living with kidney diseases without diabetes and [GLP-1 agonists'] impacts across different types of kidney diseases. In the meantime, he celebrated having medications that can help nephrologists alter the course of their patient's kidney disease.

"We need to tell people that nephrology is in business, and our business is stopping people from [needing] dialysis," he said. ■

References

1. Novo Nordisk USA. FDA approves Ozempic® (semaglutide) as the only GLP-1 RA to reduce the risk of worsening kidney disease and cardiovascular death in adults with type 2 diabetes and chronic kidney disease. January 28, 2025. Accessed February 6, 2025. https://www.novonordisk-us.com/media/news-archive/news-details.html?id=915253
2. Reuters. Europe allows Novo to include reduction of kidney disease in Ozempic label. December 12, 2024. https://www.reuters.com/business/healthcare-pharmaceuticals/european-drug-regulator-allows-novo-include-reduction-kidney-disease-ozempic-2024-12-12/
3. Perkovic V, et al.; FLOW Trial Committees and Investigators. Effects of semaglutide on chronic kidney disease in patients with type 2 diabetes. *N Engl J Med* 2024; 391:109–121. doi: 10.1056/NEJMoa2403347
4. Drugs.com; Anderson LA, medical reviewer. How much does semaglutide cost? January 29, 2025. Accessed February 6, 2025. https://www.drugs.com/medical-answers/how-semaglutide-cost-3576795/
5. Centers for Medicare & Medicaid Services. HHS announces 15 additional drugs selected for Medicare drug price negotiations in continued effort to lower prescription drug costs for seniors. CMS.gov. January 17, 2025. https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower
6. Centers for Medicare & Medicaid Services. CMS statement on lowering the cost of prescription drugs. CMS.gov. January 29, 2025. https://www.cms.gov/newsroom/press-releases/cms-statement-lowering-cost-prescription-drugs

New ASN Kidney Health Guidance Focuses on Outpatient Dialysis for Patients With AKI

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protocolized treatment typical of care for [people with kidney failure]."

Preventing "dialytrauma"

AKI is a common condition affecting approximately one in four patients who are hospitalized. In the most severe cases, dialysis therapy is potentially lifesaving, but nearly one-third of survivors continue to require dialysis after discharge (4). However, unlike people with kidney failure, these patients may recover kidney function with appropriate supportive care. "In patients with acute kidney injury, the most important outcome is recovering kidney function," said KHG's co-corresponding author Michael Heung, MD, MS, FASN, professor and Associate Chief of Nephrology at the University of Michigan in Ann Arbor.

Yet, dialysis itself poses a risk of further kidney injury—also known as dialytrauma—which can dash a patient's chance of recovery. "Dialysis is a lifesaving therapy but also has risks involved as with any other therapy," Heung said. "We want to identify recovery as soon as possible to limit the risk of dialytrauma."

Limiting dialytrauma is critical to giving patients with AKI their best chance at recovery, he said. Yet, the system for providing outpatient dialysis care is designed for people with kidney failure on long-term dialysis or waiting for transplant and may not be optimized to care for patients with AKI, he noted. He explained that many patients with AKI on dialysis have recently been discharged after a traumatic hospitalization; they may be very sick and not remember much about their hospitalization and may not have had kidney health patient education.

"They need to have a bit more individualized care as opposed to patients on maintenance dialysis who tend to receive more protocolized care," he said. That individualized care should start with a warm handoff between the clinicians caring for the patient in the hospital and those in the outpatient facility, emphasized Vijayan.

Ideally, she said that there should be a face-to-face meeting between the clinicians with the patient present, but if that is not possible, there should be a telephone call or other person-to-person communication. That conversation should highlight the cause of the injury, the patient's prognosis for recovery of kidney function, their overall prognosis, and parameters to monitor their kidney function for signs of recovery, she said.

Once patients are on outpatient dialysis, clinicians should also actively monitor blood and urine laboratory studies to measure kidney function and evaluate recovery of kidney function. For patients with good prospects for recovery, that period of observation should occur for at least 90 days unless there are signs of recovery sooner. "If there is a high likelihood of recovery, then we're doing everything possible to ensure that happens," Vijayan said. "If there's a low likelihood of [kidney] recovery, we're still doing everything possible to get that patient off dialysis, but we also know that there's a chance this patient will need maintenance dialysis long-term or a transplant."

Vijayan recommended urine output assessment at each dialysis visit and an analysis of laboratory measurement trends at least weekly. She also emphasized the importance of active medication management and discontinuing or dose-adjusting potentially nephrotoxic medications.

The overall goal of the guideline is to help clinicians better care for this patient subpopulation focused on kidney function recovery.

For patients with frailty, pre-existing kidney diseases, or comorbidities that make recovery less likely, clinicians may want to consider beginning to discuss the next steps for their care as early as at 30 days, Heung said. Vijayan emphasized the need for patient education about possible long-term treatment modalities, including home dialysis, transplant, and vascular access options. Patient engagement in these discussions and decision-making is key, she said.

For Doylan Jackson of Ann Arbor, MI, who developed AKI after a series of heart attacks, his main focus as a patient is "just being able to live a normal life besides the treatments." He said his clinicians have helped enable that by doing a good job educating him and helping him shift from 3 days of dialysis each week down to 2 days. He has been satisfied with their willingness to work with him to improve his quality of life. "If there is something I do not like, I can see if we can adjust it to fit my needs, my daily needs physically and mentally," he said.

Policy and research needs

KHG also highlights areas in which federal- or center-level policy changes or additional research are needed to optimize care for patients requiring outpatient dialysis for AKI.

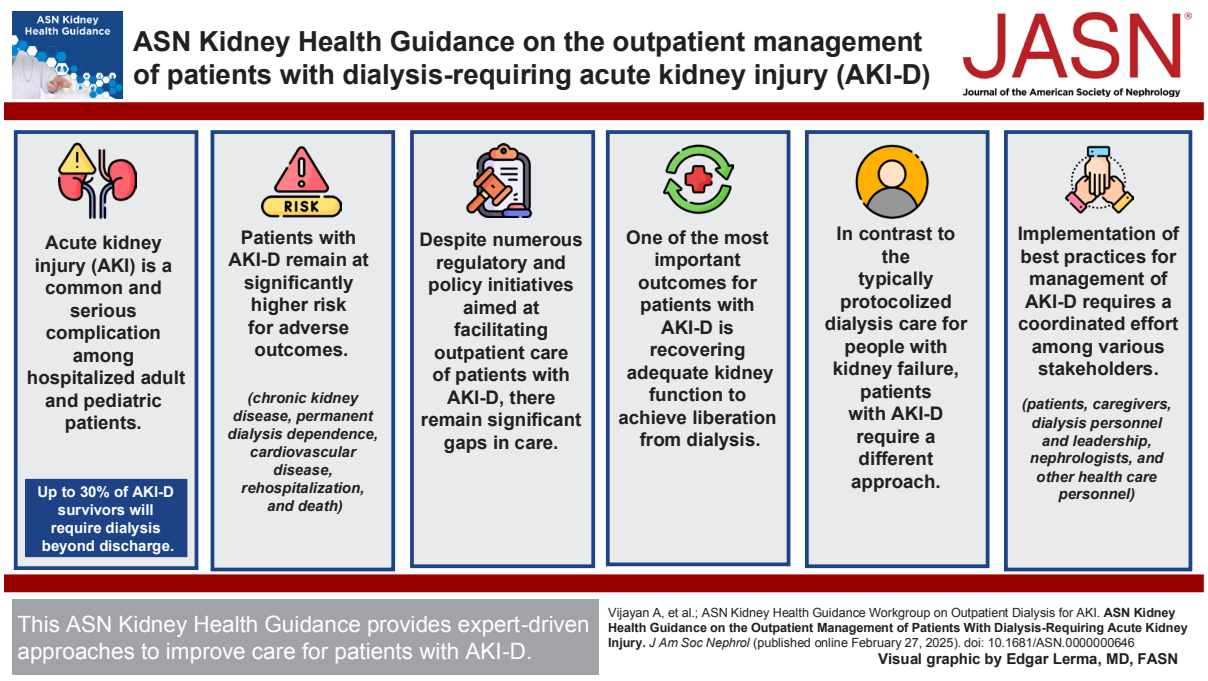
There are substantial differences in the way patients with AKI are cared for in inpatient and outpatient dialysis settings. During hospitalization, the nurse-to-patient ratio may be 1:1 or 1:2, facilitating more personalized care. In outpatient dialysis, a single nurse may be responsible for 8 to 12 patients. "We do not think that a patient with AKI will be getting sufficient attention or monitoring in that [outpatient setting with a high patient-to-nurse ratio]," Vijayan said.

Hemodialysis technicians, dietitians, nursing staff, and educators at outpatient dialysis centers are trained to provide care for people with kidney failure, Vijayan noted. They may need specific training on the care and needs of people with AKI. Many patients discharged with AKI need mental and physical rehabilitation. They are also not eligible for the same disability benefits that are available for people with permanent kidney failure.

"Social workers and nursing staff need to be aware that these patients have just gone through a traumatic hospitalization and are dealing with the consequences, including [rehabilitation] and multiple other physician appointments," she said. "Patients may have been employed before their hospitalization and are now facing uncertainty about their job and when or if they can go back."

According to the guidance, additional research on best practices is also needed. Vijayan said that there is a need for studies on the best way to assess kidney function recovery. She noted that currently, some people assess only creatinine values, whereas others assess both urine output and creatinine clearances. Evidence is also needed to help nephrologists decide what level of kidney function recovery is sufficient to end dialysis and how to take people off dialysis. Some centers currently stop with careful monitoring, whereas others may gradually step down dialysis. The overall goal of the guideline is to help clinicians better care for this patient subpopulation focused on kidney function recovery. For example, clinicians may be less aggressive with fluid management or blood pressure control in these patients.

"It is important that clinicians at dialysis centers are aware which patients are patients with AKI, why they are different, and how we may care for them a little differently to promote recovery," Heung said. ■



This ASN Kidney Health Guidance provides expert-driven approaches to improve care for patients with AKI-D.

Vijayan A, et al.; ASN Kidney Health Guidance Workgroup on Outpatient Dialysis for AKI. **ASN Kidney Health Guidance on the Outpatient Management of Patients With Dialysis-Requiring Acute Kidney Injury.** *J Am Soc Nephrol* (published online February 27, 2025). doi: 10.1681/ASN.0000000646

Visual graphic by Edgar Lerma, MD, FASN

References

1. *2024 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States*. US Renal Data System, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2024. https://usrds-adr.niddk.nih.gov/2024
2. Vijayan A, et al.; ASN Kidney Health Guidance Workgroup on Outpatient Dialysis for AKI. ASN Kidney Health Guidance on the outpatient management of patients with dialysis-requiring acute kidney injury. *J Am Soc Nephrol* (published online February 27, 2025). doi: 10.1681/ASN.0000000646
3. Ikizler TA, et al.; ASN Kidney Health Guidance Workgroup on Obesity and Kidney Diseases. ASN Kidney Health Guidance on the management of obesity in persons living with kidney diseases. *J Am Soc Nephrol* 2024; 35:1574–1588. doi: 10.1681/ASN.0000000512
4. Esposito P, et al. Recognition patterns of acute kidney injury in hospitalized patients. *Clin Kidney J* 2024; 17:sfae231. doi: 10.1093/ckj/sfae231

Rituximab in Podocytopathies: A Promise Realized?

By Ayesha M. Malik, Alejandro Garcia-Rivera, and Harish Seethapathy

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The management of podocytopathies, such as minimal change disease (MCD) and primary focal segmental glomerulosclerosis (FSGS), poses significant challenges in adults. For many patients, what begins as a promising response to glucocorticoids often devolves into a frustrating cycle of relapses, steroid dependence, or resistance. Initial steroid responsiveness (~80%–95% in MCD; 50%–60% in FSGS) is crucial, as resistance carries a higher risk of kidney failure (1, 2). However, even among patients with steroid-responsive MCD and FSGS, remission rates are less than 45% (3). B Cell depletion with rituximab has demonstrated efficacy in inducing remission, as evidenced in small studies, offering an alternative to repeated steroid courses.

The RITERM study is a pivotal international, multicenter effort that illuminates the long-term outcomes of rituximab in adults with difficult-to-treat MCD and FSGS (4). Among 183 adult patients treated at 30 nephrology centers worldwide, 82% achieved complete or partial remission within 6 months, and 55% of responders remained relapse-free for 3 years. Maintenance rituximab therapy emerged as the strongest predictor of relapse-free survival in initial responders (61% versus 36%), enabling many patients to taper off other immunosuppressants entirely. However, consistent with prior case series, ~50% of steroid-resistant patients did not respond (5).

For patients grappling with relentless relapses, the reduction in annual relapse rates—from 1.00 to 0.17 relapses per year—and the subsequent steroid independence can be transformative. Beyond achieving remission, rituximab also stabilized kidney function in responders. Unfortunately, nonresponders experienced a significant decline in kidney function (11 mL/min/1.73 m^2 reduction in estimated glomerular filtration rate over 3 years [interquartile range, 6–33 mL/min/1.73 m^2]), underscoring the need to identify likely responders (6). Importantly, distinctions between MCD and FSGS were observed: While patients with MCD had higher initial remission rates (95% versus 59% in FSGS), the efficacy of maintenance rituximab therapy was consistent across both conditions for initial responders, similar to prior studies (7).

The RITERM study raises several key questions (4). First, how can we better identify potential responders among patients with steroid-resistant diseases? Recent findings revealed anti-nephrin antibody positivity in 69% of patients with MCD and 90% of patients with idiopathic nephrotic syndrome not receiving immunosuppression. Anti-nephrin levels also closely correlated with disease activity and rituximab response in three patients. Could anti-nephrin positivity help pinpoint patients with antibody-mediated podocytopathies likely to benefit from B cell depletion (8, 9)? Although anti-nephrin antibodies are found in only 9% of patients with FSGS, the RITERM study reported a 59% response rate among patients with FSGS, suggesting additional mechanisms at play. Second, what is the optimal maintenance dosing strategy for rituximab? Fixed-dose maintenance therapy carries risks, including recurrent respiratory infections and bronchiectasis (10). Would a strategy based on B cell return lower these risks? Notably, the RITERM study found no difference in relapse rates between fixed-dose and tailored approaches, emphasizing the need for ongoing trials.

Ultimately, the RITERM study underscores the vital role of B cell depletion in managing frequently relapsing and steroid-dependent podocytopathies (4). It offers hope for improved remission rates, reduced reliance on traditional immunosuppressants, and better kidney protection. Future research must refine our understanding of the interplay between anti-nephrin antibodies and disease response, improve identification of responders, and optimize therapy for steroid-resistant disease. ■

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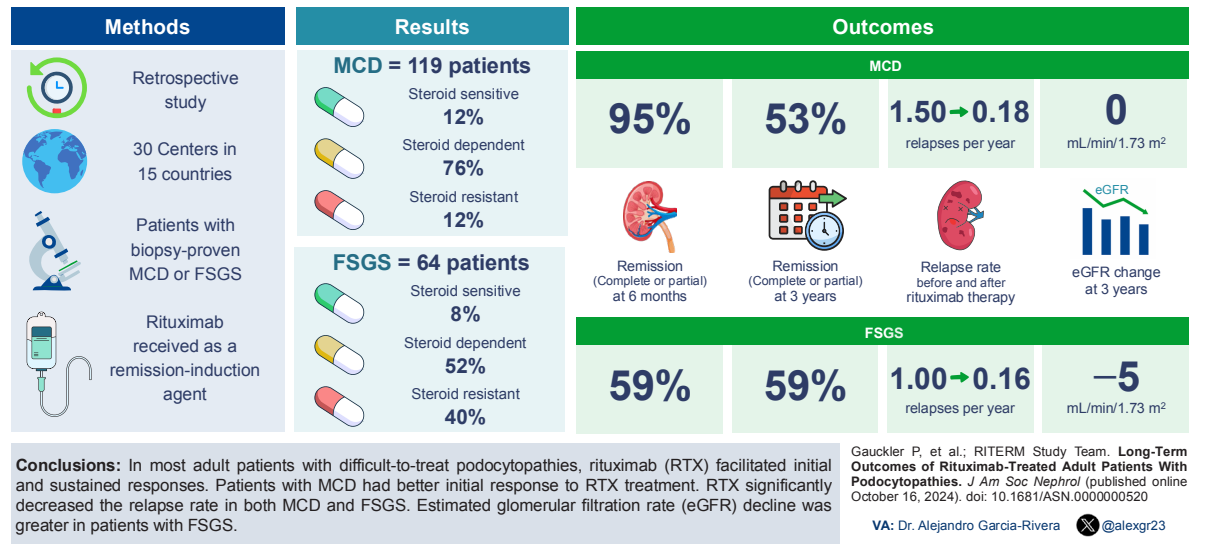
References

1. Waldman M, et al. Adult minimal-change disease: Clinical characteristics, treatment, and outcomes. *Clin J Am Soc Nephrol* 2007; 2:445–453. doi: 10.2215/CJN.03531006
2. Korbet SM. Treatment of primary FSGS in adults. *J Am Soc Nephrol* 2012; 23:1769–1776. doi: 10.1681/ASN.2012040389
3. Yamamoto R, et al.; Japan Nephrotic Syndrome Cohort Study investigators. Time to remission of proteinuria and incidence of relapse in patients with steroid-sensitive minimal change disease and focal segmental glomerulosclerosis: The Japan Nephrotic Syndrome Cohort Study. *J Nephrol* 2022; 35:1135–1144. doi: 10.1007/s40620-022-01279-z
4. Gauckler P, et al.; RITERM Study Team. Long-term outcomes of rituximab-treated adult patients with podocytopathies. *J Am Soc Nephrol* (published online October 16, 2024). doi: 10.1681/ASN.0000000520
5. Hansrivijit P, et al. Rituximab therapy for focal segmental glomerulosclerosis and minimal change disease in adults: A systematic review and meta-analysis. *BMC Nephrol* 2020; 21:134. doi: 10.1186/s12882-020-01797-7
6. Wang X, et al. Rituximab for non-responsive idiopathic membranous nephropathy in a Chinese cohort. *Nephrol Dial Transplant* 2018; 33:1558–1563. doi: 10.1093/ndt/gfx295
7. Cortazar FB, et al. Continuous B-cell depletion in frequently relapsing, steroid-dependent, and steroid-resistant nephrotic syndrome. *Clin Kidney J* 2019; 12:224–231. https://academic.oup.com/ckj/article/12/2/224/5058003
8. Watts AJB, et al. Discovery of autoantibodies targeting nephrin in minimal change disease supports a novel autoimmune etiology. *J Am Soc Nephrol* 2022; 33:238–252. doi: 10.1681/ASN.2021060794
9. Hengel FE, et al.; International Society of Glomerular Disease. Autoantibodies targeting nephrin in podocytopathies. *N Engl J Med* 2024; 391:422–433. doi: 10.1056/NEJMoa2314471
10. Gkrania-Klotsas E, Kumararatne DS. Serious infectious complications after rituximab therapy in patients with autoimmunity: Is this the final word? *Clin Infect Dis* 2021; 72:738–742. doi: 10.1093/cid/ciaa131



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ASN Executive Vice President's Update

Evaluating the Current Landscape of US Health Care

By Tod Ibrahim

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To shape the future of nephrology as a specialty—and ensure high-quality care for the more than 37 million Americans living with kidney diseases—ASN and the rest of the kidney community must navigate the complex landscape of health care in the United States. In evaluating the current environment, ASN and the community should remember the observation (often credited to Sir Winston Churchill), "A pessimist sees difficulty in every opportunity; an optimist sees the opportunity in every difficulty" (1).

With both opportunities and difficulties, seven dynamics are shaping US health care.

1 Increasing consolidation, corporatization, and employed physicians

With a near-duopoly in dialysis companies, as well as multiple near-duopolies in manufacturers of dialysis devices and products, the kidney community understands increasing consolidation in health care. Beyond the dialysis industry, every sector in health care is consolidating. For example, five insurers control approximately 70% of the Medicare Advantage market (2).

While the definition continues to evolve, corporatization in health care usually refers to "the consolidation of health care entities into ownership by a central corporate force that guides or supersedes local autonomy," shifting "the behavior of hospitals and health systems to focus on profit rather than patient care" (3). Earlier this year, a bipartisan report from the Senate highlighted that private equity (PE) and other private funds "spent more than $1 trillion on all manner of health care acquisitions" during the past decade, including "an all-time high of 515 deals valued at $151 billion" in 2021 (4). The report described "negative consequences for general and acute care hospitals during the first three years of PE ownership as compared to non-PE-owned hospitals, including lower quality of care, increased transfers to other hospitals, decreased staffing, and higher prices."

In 2024, the Physicians Advocacy Institute and Avalere Health reported that 77.6% of physicians in every setting are employed, and 58.5% of physician practices are owned by hospitals, health systems, and other corporate entities (5). According to the report, "In 2012, only 25.8% of physicians were employed by hospitals or health systems." (Unfortunately, specific data on employed nephrologists are not available.)

2 Shifting locations for the delivery of care and evolving care-delivery models

During the past 50 years, care delivery has evolved to include the emergency room (the American Board of Emergency Medicine started in 1976, and the emergency medicine specialty joined the National Resident Matching Program in 1983), while inpatient physicians became known as hospitalists in 1996 (and the National Association of Inpatient Physicians rebranded as the Society of Hospital Medicine in 2003). The COVID-19 pandemic accelerated the adoption of telehealth as well.

From 2014 to 2023, the number of urgent care centers in the United States doubled from 7220 to 14,382 (6). "Urgent care centers treated almost 206 million non-emergent cases" in 2022 compared with emergency departments, which included 131 million visits. Generational differences have also been observed, with "Gen Z and Millennials," at 56% and 45%, respectively, having visited urgent care centers "more than three times in the past 12 months, compared to only [26%] and [22%] of Boomers and Silent Gen."

During this time, care-delivery models have evolved toward value-based care (VBC). When this concept was first articulated in 2006, the health economist Uwe E. Reinhardt, PhD, called it "a utopian vision of a health system that might occur to anyone possessed of a modicum of common sense but not too familiar with the real world of health care" (7). Since its establishment by the Affordable Care Act in 2010, the Centers for Medicare & Medicaid Services Innovation Center has initiated 90 payment models to advance VBC across medicine—including three focused on kidney care (and a fourth to promote kidney transplant set to start on July 1, 2025)—resulting in at least 10 kidney VBC companies (8).

3 Growing shortages in the physician and health professional workforce

The Association of American Medical Colleges estimates that "the United States will face a physician shortage of up to 86,000 physicians by 2036" (9), and the Health Resources and Services Administration projects "a shortage of 63,720 FTE RNs [full-time equivalent registered nurses] in 2030" (10).

These shortages include:

- **Blurring lines across medical specialties (and among health professionals).** Concerns are increasing about the scope of practice, the dilution of expertise within specific specialties, and the lack of boundaries (and governing policies such as requirements for certification, recertification, and licensure) among different health professions.
- **Expanding state efforts to bypass profession-sanctioned standards.** A growing number of states (and the American Board of Internal Medicine) have proposed or enacted legislation to allow alternate licensure pathways for graduates of international medical schools who have completed training and practiced outside the United States.
- **Raising questions about how the increase in investor-owned, for-profit hospitals affects graduate medical education.** For example, when Paladin Healthcare Capital closed Hahnemann University Hospital in Philadelphia, PA, in 2019, approximately 600 residents and fellows were forced to scramble to find an accredited graduate medical education program to continue their training (11).
- **Increasing interest in unionization.** While only 8% of the current physician workforce belonged to a union in 2022, "nine medical residency programs at hospitals...formed unions" in 2024, increasing the possibility that these trainees will expect unionization when they enter practice (12).

4 Worsening health disparities, inequities, and other injustices

The National Institutes of Health's National Institute on Minority Health and Health Disparities released a recent study finding that "racial and ethnic health disparities cost the US economy $451 billion" in 2018, "a 41% increase from the previous estimate of $320 billion in 2014" (13). The study also concluded that "the total burden of education-related health disparities for persons with less than a college degree in 2018 reached $978 billion, about two times greater than the annual growth rate of the US economy in 2018."

Focusing only on socioeconomic inequities highlights clear trends: The poor are getting poorer, the rich are getting richer, the college educated live longer, and women still fare worse financially than men. The percentage of Americans who live in middle-class households decreased to 51% in 2023 from 61% in 1971 (14). Almost 70% of the country's wealth in 2021 was held by the top 10% of Americans, up from 61% in 1989 (15). Americans with college degrees currently live about 9 years longer than those without higher education (16). In 2021, 31% of women lived in lower-income households compared with 26% of men (17).

The World Economic Forum in 2020 used 10 pillars—such as health, education, and wages—to rank 82 countries on social mobility (the downward or upward movement of people from one economic level to another) (18). The United States ranked 27th, and health inequalities contributed greatly to this low score. The report noted that "the gap in life expectancy between the richest 1% and poorest 1% of individuals is nearly 15 years for men and 10 years for women" in the United States.

5 Overcoming unreliable sources of health information (especially on social media)

Since 1889, US physicians have governed themselves, determining their skills, knowledge, abilities, competence, and professionalism. This self-governance has resulted in the current system to accredit undergraduate and graduate medical education, certify and recertify physicians, and license physicians at a state level.

The COVID-19 pandemic, however, challenged physician autonomy through state laws to prohibit boards of medicine from disciplining physicians, federal laws to allow patients "access to unapproved medications with virtually no oversight by the Food and Drug Administration," and greater acceptance of longstanding "medical freedom" arguments (19). Today, "the antiexpertise perspective has moved into the mainstream," and "members of the public are coming to believe that facts don't exist—that all facts are political and therefore a matter of opinion."

Nearly every aspect of modern society fuels medical misinformation and disinformation—especially more social media, less traditional journalism, more populism in politics, and less trust in institutions—and this epidemic extends beyond the United States. In raising concerns, the World Health Organization observes, "The key difference between

disinformation and misinformation is not the content of the falsehood but the knowledge and intention of the sender" (20). Misinformation misleads; disinformation deceives.

6 Adapting to augmented and artificial intelligence (AI)

Following the release of ChatGPT in November 2022:

- More than 350 AI experts released a "Statement on AI Risk": "Mitigating the risk of extinction from AI should be a global priority alongside other societal-scale risks such as pandemics and nuclear war" (21).
- The National Academy of Medicine launched "a 3-year project convening health, tech, research, and bioethics leaders in producing a code of conduct for the development and use of Artificial Intelligence in health, medical care, and health research" (22).
- The Biden administration issued an Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence that included provisions to "help ensure the safe, responsible deployment and use of AI in the [health care], public-health, and human-services sectors" (23). (In January 2025, President Trump signed an Executive Order abolishing this policy.)

In the first year after the release of ChatGPT, "the number of press releases on generative AI in [health care]" increased by 45% (24). Fueled by a combination of PE and investments by companies like Amazon, Google, and Microsoft, health technology (including AI) is "the fastest growing segment of the [health care] sector." Despite financial opportunity, investors are wary of the implications of AI to improve health delivery due to a complex regulatory environment (which varies by country) and dependence on sensitive data (which must remain secure).

Public and health professionals share many of these concerns, particularly differentiating hype from reality and safeguarding information. While excited about the possibility of AI improving health outcomes, lowering health care costs, and enhancing population health, public and health professionals worry that AI will worsen disparities, inequities, and other injustices throughout the world, including in the United States; exacerbate human-caused error and bias in health care; and increase medical misinformation and disinformation.

7 Escalating concerns about sustainability and the impact of climate change on health care

As was widely reported, 2024 was the hottest year since scientists started recording global temperatures in the 1880s, and the past decade has been "the warmest 10 years since record-keeping began" (25). In at least three ways, this reality has implications for health care in general and nephrology in particular: 1) worse health especially for laborers, 2) amplified natural disasters, and 3) fears about medical supplies (including power and water) and waste.

For example, *Time* declared in 2023, "Chronic kidney disease is poised to become the black lung of climate change" because chronic kidney disease of nontraditional origin "tends to manifest among outdoor laborers who work grueling hours in high heat conditions" (26). The changing climate also increases the likelihood of natural disasters, such as causing crush injuries from earthquakes; taking dialysis facilities offline from flooding and power outages caused by hurricanes; and creating other emergencies for people, regardless of whether their kidneys are healthy or not.

The use of power and water in dialysis is well documented (27–29). What is less well-known is that The Joint Commission, which "accredits and certifies more than 22,000 health care organizations and programs in the United States," recently initiated a Sustainable Healthcare Certification to provide "a framework to help organizations expand or continue their decarbonization efforts and to receive public recognition of their commitment and achievements in contributing to environmental sustainability" (30).

Midway through the third decade of the 21st century, these seven dynamics are driving unprecedented change in US health care. To ensure high-quality patient care across the spectrum of kidney health, ASN and the rest of the kidney community must work together with government, policymakers, and anyone else committed to advancing opportunities and overcoming difficulties. ■

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References

1. Langworth RM. Churchill on the optimist and the pessimist. Richard M. Langworth webpage. June 20, 2017. Accessed January 2025. https://richardlangworth.com/optimist-pessimists
2. Murphy N. Trends and consequences in health insurer consolidation. Center for American Progress (CAP) Action Fund. December 4, 2024. https://www.americanprogress.org/article/trends-and-consequences-in-health-insurer-consolidation
3. Fox M. Surgeons are prioritizing patients amid the corporatization of healthcare. American College of Surgeons. March 6, 2024. https://www.facs.org/for-medical-professionals/news-publications/news-and-articles/bulletin/2024/march-2024-volume-109-issue-3/surgeons-are-prioritizing-patients-amid-the-corporatization-of-healthcare
4. Whitehouse S, Grassley CE.; 118th Congress; Senate Budget Committee. Profits over patients: The harmful effects of private equity on the U.S. healthcare system. Senate Budget Committee bipartisan staff report. January 2025. https://www.budget.senate.gov/imo/media/doc/profits_over_patients_the_harmful_effects_of_private_equity_on_the_ushealthcaresystem1.pdf
5. Physicians Advocacy Institute. Updated report: Hospital and corporate acquisition of physician practices and physician employment: 2019-2023. Avalere Health. April 2024. https://www.physiciansadvocacyinstitute.org/PAI-Research/PAI-Avalere-Study-on-Physician-Employment-Practice-Ownership-Trends-2019-2023
6. Urgent Care Association. Urgent care industry white paper: The essential nature of urgent care in the healthcare ecosystem post-COVID-19. August 2023. https://urgentcareassociation.org/wp-content/uploads/2023-Urgent-Care-Industry-White-Paper.pdf
7. Reinhardt UE. Health reform: Porter and Teisberg's utopian vision. *Health Affairs*. October 10, 2006. https://www.healthaffairs.org/content/forefront/health-reform-porter-and-teisberg-s-utopian-vision
8. CMS.gov. Innovation models. Centers for Medicare & Medicaid Services. https://www.cms.gov/priorities/innovation/models
9. Association of American Medical Colleges. New AAMC report shows continuing projected physician shortage. March 21, 2024. https://www.aamc.org/news/press-releases/new-aamc-report-shows-continuing-projected-physician-shortage
10. National Center for Health Workforce Analysis. Nurse workforce projections, 2020-2035. Health Resources and Services Administration Health Workforce. November 2022. https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/Nursing-Workforce-Projections-Factsheet.pdf
11. Murphy B. Address private equity's growing impact on residency training. American Medical Association. November 16, 2022. Accessed January 30, 2025. https://www.ama-assn.org/education/gme-funding/address-private-equity-s-growing-impact-residency-training
12. Hochwald L. Why more doctors are joining unions. *MDedge*. Family Practice News Digital Network. September 10, 2024. https://www.mdedge.com/familypracticenews/article/270714/business-medicine/why-more-doctors-are-joining-unions
13. National Institute on Minority Health and Health Disparities, National Institutes of Health. NIH-funded study highlights financial toll of health disparities in the United States. May 16, 2023. https://www.nih.gov/news-events/news-releases/nih-funded-study-highlights-financial-toll-health-disparities-united-states
14. Kochhar R. The state of the American middle class: Who is in it and key trends from 1970 to 2023. Pew Research Center. May 31, 2024. https://www.pewresearch.org/race-and-ethnicity/2024/05/31/the-state-of-the-american-middle-class/
15. Siripurapu A. The U.S. inequality debate. Council on Foreign Relations. April 20, 2022. https://www.cfr.org/backgrounder/us-inequality-debate
16. Rubin A. Life expectancy gap in America widens depending on college education. *Axios*. October 16, 2023. https://www.axios.com/2023/10/16/life-expectancyeducated-adults-mortality-rate
17. Kochhar R, Sechopoulos S. How the American middle class has changed in the past five decades. Pew Research Center. April 20, 2022. https://www.pewresearch.org/short-reads/2022/04/20/how-the-american-middle-class-haschanged-in-the-past-five-decades/
18. World Economic Forum. The global social mobility report 2020: Equality, opportunity, and a new economic imperative. January 2020. https://www3.weforum.org/docs/Global_Social_Mobility_Report.pdf
19. Baron RJ, Coleman CH. Protecting the legitimacy of medical expertise. *New Engl J Med* 2023; 388:676–678. doi: 10.1056/NEJMp2214120
20. World Health Organization. Disinformation and public health. February 6, 2024. https://www.who.int/news-room/questions-and-answers/item/disinformationand-public-health
21. Hinton G.; Center for AI Safety. Statement on AI risk. May 2023. https://www.safe.ai/work/statement-on-ai-risk
22. National Academy of Medicine. NAM Leadership Consortium collaborates with leading health tech, research, and bioethics organizations to develop health care AI code of conduct. June 20, 2023. https://nam.edu/nam-leadership-consortium-collaborateswith-leading-health-tech-research-and-bioethics-organizations-to-develop-health-careai-code-of-conduct/
23. Biden JR Jr. Executive Order on the safe, secure, and trustworthy development and use of artificial intelligence. The White House. October 30, 2023. https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence
24. Neveling N. How AI is reframing PE healthcare investing. Private Equity International. July 1, 2024. https://www.privateequityinternational.com/how-ai-isreframing-pe-healthcare-investing
25. Sommer L. 2023 Was extremely hot. Then came 2024. All Things Considered. National Public Radio. WAMU 88.5, American University Radio. December 24, 2024. https://www.npr.org/2024/12/24/nx-s1-5230783/2024-hottest-year-record-heat-climate-change-el-nino
26. Baker A. Chronic kidney disease is poised to become the black lung of climate change. *Time*. August 9, 2023. https://time.com/6303020/chronic-kidney-disease-climate-change/
27. Barraclough KA, et al. Updating the data: The resource consumption of modern-day hemodialysis systems. *Kidney Int Rep* 2024; 9:1521–1524. doi: 10.1016/j.ekir.2024.02.010
28. Hmida MB, et al. Water implications in dialysis therapy, threats and opportunities to reduce water consumption: A call for the planet. *Kidney Int* 2023; 104:46–52. doi: 10.1016/j.kint.2023.04.008
29. U.S. Centers for Disease Control and Prevention. Water use in dialysis. Accessed January 31, 2025. https://www.cdc.gov/dialysis-safety/hcp/recommendationsresources/water-use-in-dialysis.html
30. The Joint Commission. Sustainable Healthcare Certification. Accessed January 31, 2025. https://www.jointcommission.org/what-we-offer/certification/certifications-by-setting/hospital-certifications/sustainable-healthcare-certification/

A New Era in CKD Management: Hybrid Telemedicine and In-Person Care Models

By Fawaz Al Ammary and Anju Yadav

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Telemedicine represents a transformative opportunity to overcome geographic and logistical barriers to health care access, particularly for people with chronic diseases like chronic kidney disease (CKD) (1). Scherzer et al. conducted a single-center observational study and explored the potential of a hybrid telenephrology model within the Veterans Affairs (VA) health system (2). Findings demonstrate that remote care can provide outcomes comparable to traditional in-person visits. By focusing on a medically complex and often underserved population, the study underscores the ability of telemedicine (real-time video visits) to expand access, optimize resources, and deliver patient-centered care. Scherzer et al. (2) report that patients who are managed with telenephrology—defined as more than 50% of visits conducted virtually—experienced similar rates of estimated glomerular filtration rate decline as those managed predominantly in-person, reflecting the potential for timely and proactive interventions for people living with CKD through virtual care (3, 4).

That said, a notable limitation of the study by Scherzer et al. (2) is the inherent selection bias, as patients assigned to telenephrology may have been healthier or faced fewer comorbidities than their in-person counterparts. These baseline differences could partially explain the reduced health care utilization (emergency department visits and hospital admissions) observed in the telenephrology group. Without randomization, it is difficult to disentangle the effects of care modality from underlying patient characteristics. Whereas the hybrid model offers flexibility by tailoring care to patients' needs, variability in visit-modality selection and prescribing practices raises concerns about consistency in care. Standardized workflows and clinical decision support systems are essential to maintain continuity of care quality across modalities.

Patient and clinician values and quality of care performance measures are critical for expanding telemedicine services and evaluating the long-term success of hybrid models in CKD as well as with kidney transplantation (5–7). Future research should explore these aspects alongside clinical outcomes to optimize telemedicine models. Identifying patient subgroups most likely to benefit from remote care based on disease severity, comorbidities, or social determinants of health will also be essential.

Furthermore, the generalizability of the study's findings requires careful consideration. The VA, with its national network and ability to provide care across state lines, is uniquely positioned to overcome regulatory and logistical barriers that often hinder telemedicine expansion. In contrast, non-VA health care systems remain constrained by state licensure requirements and inconsistent reimbursement policies, which hinder the widespread adoption and expansion of telemedicine services (8). For policymakers, this underscores the urgent need to harmonize licensure regulations and expand telemedicine access to ensure equity in health care delivery.

In brief, Scherzer and colleagues (2) provide promising findings that telenephrology can match in-person care for CKD management while offering flexibility and improving access. However, the findings reflect the advantages of the VA's unique system, emphasizing the need for broader policy reforms to expand telemedicine services without geographic restrictions to enhance health care access for all patients. As the health care landscape evolves, telemedicine holds significant promise, but realizing its full potential requires rigorous research, standardized protocols, and supportive policies that prioritize equity and quality. ■

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CKD management in the age of telenephrology: Hybrid telemedicine and in-person care models

KidneyNews

Methods

- Observational study
  Linear regression models
- Veterans Affairs (VA)
- 1098 Patients
- 4230 Visits analyzed
- >50% Virtual visits (televisits)
- ≤50% In-person visits

Results

	Televisit cohort	In-person visit cohort
eGFR change slope per year	0.81 mL/min/1.73 m²	−0.23 mL/min/1.73 m²
	p = 0.41	
Proteinuria change per year	−0.9 mg/g	6.1 mg/g
	p = 0.12	

Limitations

- Observational single-center study
- Inherent selection bias
- Lack of generalizability out of the VA setting

Barriers to the generalization of this study:

The VA has no state licensing regulatory and logistical barriers contrary to other health systems.
Non-VA systems have inconsistent reimbursement.
The study lacks standardized workflows.
Limited information is available on patient and physician satisfaction with telemedicine.

Future directions:

Identify patient subgroups likely to benefit from telemedicine based on comorbidities and social determinants of health.
Advocate policymakers to remove geographic barriers to expanding telemedicine services.
Encourage randomized clinical trials to study and develop standardized workflows and clinical decision support systems.

Conclusions: Data from this observational study within a VA health care system suggest that patients who are medically complex with multimorbidities with CKD can expect a similar rate of estimated glomerular filtration rate (eGFR) decline when care is delivered using a hybrid system that includes a majority of telenephrology when compared with those managed in face-to-face visits.

Scherzer ZA, et al. **CKD Management in the Age of Telenephrology: An Observational Analysis of a Hybrid Telenephrology System Within a Veteran's Affairs Medical Center**. *Kidney360* 2025; 6:69–75. doi: 10.34067/KID.0000000641

Visual abstract by Anju Yadav, MD, FASN

References

1. Koraishy FM, Rohatgi R. Telenephrology: An emerging platform for delivering renal health care. *Am J Kidney Dis* 2020; 76:417–426. doi: 10.1053/j.ajkd.2020.02.442
2. Scherzer ZA, et al. CKD management in the age of telenephrology: An observational analysis of a hybrid telenephrology system within a Veteran's Affairs medical center. *Kidney360* 2025; 6:69–75 doi: 10.34067/KID.0000000641
3. Tan J, et al. Telenephrology: Providing healthcare to remotely located patients with chronic kidney disease. *Am J Nephrol* 2018; 47:200–207. doi: 10.1159/000488004
4. Ishani A, et al.; Center for Innovative Kidney Care. Telehealth by an interprofessional team in patients with CKD: A randomized controlled trial. *Am J Kidney Dis* 2016; 68:41–49. doi: 10.1053/j.ajkd.2016.01.018
5. Mendu ML, et al. Measuring quality in kidney care: An evaluation of existing quality metrics and approach to facilitating improvements in care delivery. *J Am Soc Nephrol* 2020; 31:602–614. doi: 10.1681/ASN.2019090869
6. Al Ammary F, et al. The scope of telemedicine in kidney transplantation: Access and outreach services. *Adv Chronic Kidney Dis* 2021; 28:542–547. doi: 10.1053/j.ackd.2021.10.003
7. Qaseem A, et al.; Performance Measurement Committee of the American College of Physicians. Performance measures for physicians providing clinical care using telemedicine: A position paper from the American College of Physicians. *Ann Intern Med* 2023; 176:694–698. doi: 10.7326/M23-0140
8. Al Ammary F, et al. Health care policy and regulatory challenges for adoption of telemedicine in kidney transplantation. *Am J Kidney Dis* 2021; 77:773–776. doi: 10.1053/j.ajkd.2020.09.013

Will Obi Replace BeLi? The Ultimate Lupus Nephritis-Class Missile Frigate

By Purva Sharma, Gashu Ayehu, and Kenar D. Jhaveri

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Trials in lupus nephritis (LN) have seen a surge in the last decade. To treat a disease for which we only had mycophenolate mofetil (MMF), cyclophosphamide, and steroids, we now have several additional agents to add to the armamentarium. In the past few years, belimumab ("BeLi") and voclosporin have been added to the mix (1) as a US Food and Drug Administration-approved treatment for LN. Belimumab works by targeting B cells through a monoclonal antibody mechanism, whereas voclosporin acts as a calcineurin inhibitor (CNI) to stabilize kidney podocytes, offering new treatment options for patients with active LN when used alongside standard therapies. However, there is still uncertainty regarding long-term outcomes and the best approach to using these drugs in combination (2, 3).

Recent American College of Rheumatology guidelines (4) provide conditional recommendations for a triple immunosuppressive regimen in patients with active class III and IV LN, which includes glucocorticoid and one of three immunosuppressive combination regimens: MMF plus belimumab, MMF plus CNI therapy, or low-dose cyclophosphamide plus belimumab. For class V LN, the conditional recommendation for treatment with a specific "triple therapy" is the most desirable therapy that includes glucocorticoid, MMF, and CNI therapy. Belimumab and voclosporin have also made their way to the updated 2024 Kidney Disease: Improving Global Outcomes (KDIGO) guidelines for LN (5). For class III and class IV LN, with or without a membranous component, the new KDIGO guidelines recommend glucocorticoids in combination with MMF, low-dose intravenous cyclophosphamide, belimumab plus either MMF or low-dose cyclophosphamide, or MMF with a CNI including voclosporin (5). Recommendations for class V LN with nephrotic-range proteinuria include glucocorticoids in combination with MMF, cyclophosphamide, CNI, rituximab, or azathioprine (5).

The LUNAR trial (A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Rituximab in Subjects With ISN/RPS Class III or IV Lupus Nephritis) was a randomized controlled trial that showed that although rituximab led to more responders and greater reductions in double-stranded DNA and C3/C4 levels, it did not improve clinical outcomes at 1 year of treatment. But now, here comes obinutuzumab ("Obi") (6). Obinutuzumab is a humanized type II anti-CD20 monoclonal antibody that binds to the CD20 antigen, a proven target for $CD20^+$ B cells.

REGENCY, a phase 3, double-blind, placebo-controlled trial randomized adults with biopsy-proven active proliferative LN 1:1 to placebo or one of two intravenous obinutuzumab dosing schedules (1000 mg on day 1 and weeks 2, 24, 26, and 52, with or without a dose at week 50) in addition to standard therapy (7). The primary endpoint was complete renal response (CRR), defined as a urine protein-to-creatinine ratio (UPCR) < 0.5 mg/mg, an estimated glomerular filtration rate (eGFR) of 85% or more of baseline, no intercurrent events (rescue therapy, treatment failure, death, or early study withdrawal) at week 76, and assessment in the intention-to-treat population. Key secondary endpoints included CRR at week 76 with successful prednisone taper to 7.5 mg/day or lower between weeks 64 and 76, a UPCR < 0.8 mg/mg at week 76 with no intercurrent events, change in eGFR from baseline to week 76, and kidney-related events or death through week 76. Incidence and severity of adverse events through week 76 were compiled.

Among 271 participants, 46.4% in the obinutuzumab group achieved CRR compared with 33.1% in the placebo group (p = 0.02). Secondary endpoints, including a lower prednisone dose and reduced proteinuria, were also met more frequently with obinutuzumab. More patients in the obinutuzumab group achieved CRR at week 76 with successful prednisone taper (42.7% versus 30.9%; adjusted difference, 11.9 percentage points; 95% confidence interval [CI], 0.6%–23.2%; p = 0.04) and a proteinuric response (UPCR < 0.8 mg/mg) with no intercurrent events at week 76 (55.5% versus 41.9%; adjusted difference, 13.7 percentage points; 95% CI, 2.0%–25.4%; p = 0.02). Numerical changes in eGFR from baseline to week 76 favored obinutuzumab compared with placebo, and fewer patients in the obinutuzumab group experienced the composite outcome of death or kidney-related events through week 76. Prespecified subgroup analyses demonstrated numerically greater CRR rates with obinutuzumab in patients with potentially more active disease at enrollment, such as those with class IV LN, concomitant class V disease, and baseline UPCR = 3 mg/mg or greater serologic activity. No new safety signals were observed based on the established safety profile of obinutuzumab in oncology indications. More COVID-19 events were observed in the obinutuzumab group, which primarily occurred during the acute phase of the COVID-19 pandemic. There were three deaths in the obinutuzumab group and one in the placebo group, which were mainly complications of COVID-19. Overall, obinutuzumab significantly improved kidney outcomes in patients with LN compared with standard therapy alone.

What is fascinating is that the data were mostly in patients with proliferative LN and not in many patients with class V LN, but we know from nonlupus membranous nephropathy data that obinutuzumab also works well in those cases. We may have arrived at a more potent B cell therapy for LN that may become standard of care for our patients with proliferative LN and perhaps even with class V LN.

Some questions remain:

- Will obinutuzumab become first in line in addition to MMF and steroids? Or can we replace steroids with CNI and make this truly steroid-sparing?
- Will obinutuzumab work in class V LN?
- Will chimeric antigen receptor T cells with CD19 even be necessary if we have such a robust response from obinutuzumab?
- Will obinutuzumab replace belimumab in treatment of LN?
- If obinutuzumab works, can rituximab? (Maybe we need a better study to demonstrate that.) ■

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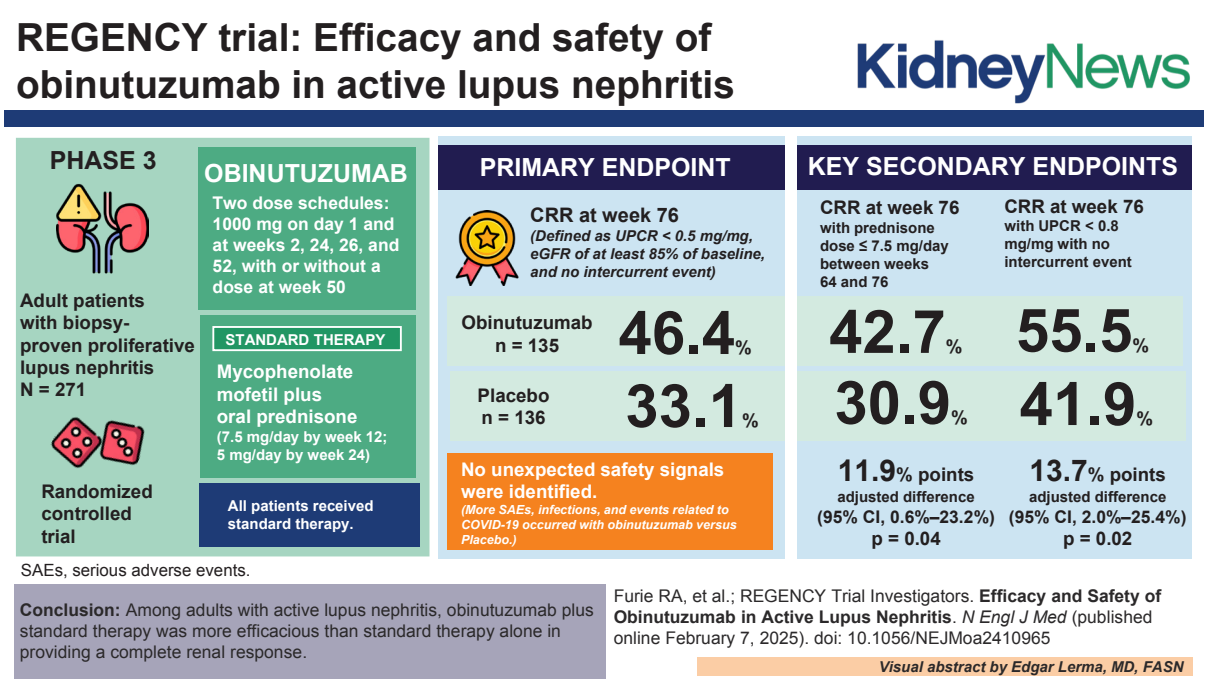
The authors report no conflicts of interest.

References

1. Porta SV, et al. Controversies in systemic lupus erythematosus 2021: Changing the paradigm in the management of lupus nephritis. *J Clin Rheumatol* 2022; 28:229–233. doi: 10.1097/RHU.0000000000001859
2. Furie R, et al. Two-year, randomized, controlled trial of belimumab in lupus nephritis. *N Engl J Med* 2020; 383:1117–1128. doi: 10.1056/NEJMoa2001180
3. Rovin BH, et al. Efficacy and safety of voclosporin versus placebo for lupus nephritis (AURORA 1): A double-blind, randomised, multicentre, placebo-controlled, phase 3 trial. *Lancet* 2021; 397:2070–2080. doi: 10.1016/S0140-6736(21)00578-X [Erratum: *Lancet* 2021; 397:2048. doi: 10.1016/S0140-6736(21)01160-0].
4. American College of Rheumatology. New ACR guideline summary provides guidance to screen, treat, and manage lupus nephritis. November 18, 2024. https://rheumatology.org/press-releases/new-acr-guideline-summary-provides-guidance-to-screen-treat-and-manage-lupus-nephritis
5. Rovin BH, et al. Executive summary of the the KDIGO 2024 Clinical Practice Guideline for the Management of Lupus Nephritis. *Kidney Int* 2024; 105:31–34. doi: 10.1016/j.kint.2023.09.001
6. Rovin BH, et al.; LUNAR Investigator Group. Efficacy and safety of rituximab in patients with active proliferative lupus nephritis: The lupus nephritis assessment with rituximab study. *Arthritis Rheum* 2012; 64:1215–1226. doi: 10.1002/art.34359
7. Furie RA, et al.; REGENCY Trial Investigators. Efficacy and safety of obinutuzumab in active lupus nephritis. *N Engl J Med* (published online February 7, 2025). doi: 10.1056/NEJMoa2410965



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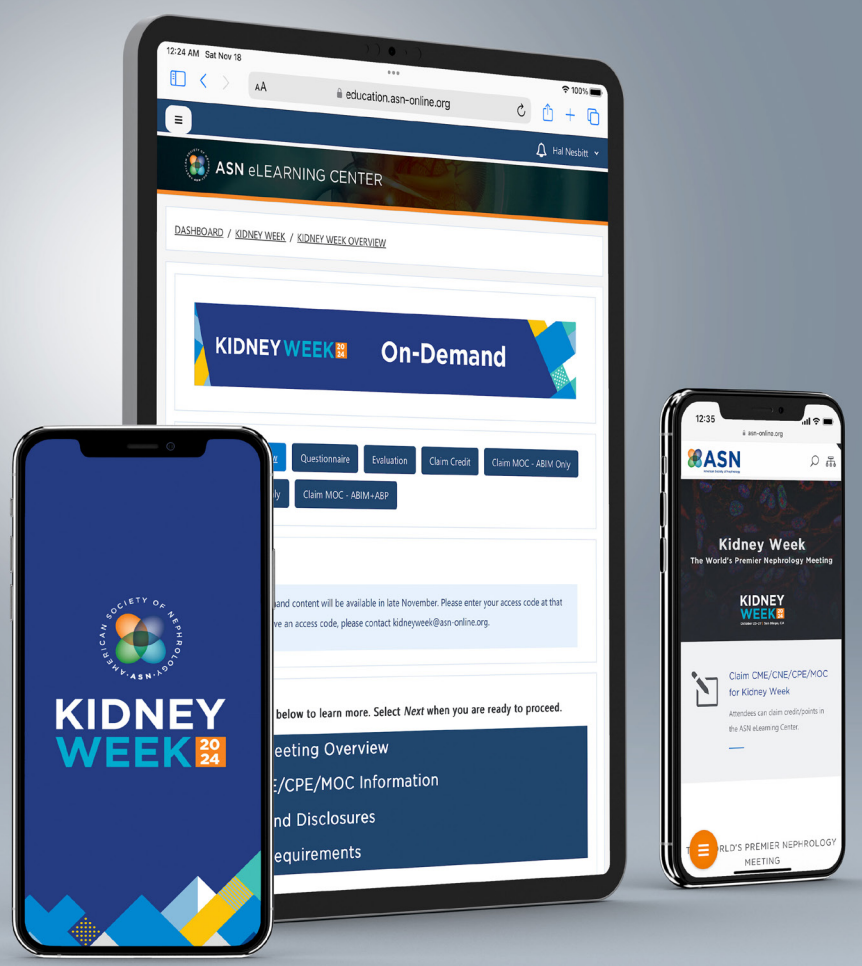

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BEYOND THE EXAM ROOM

Fitting Independent Practice Into a Multidisciplinary Care Model

By Katherine Kwon and Tim Fitzpatrick

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Nephrologists remain in private practice in greater numbers than many of their physician peers. Historically, this is due to their partnership with dialysis units, which gives them a diversified income stream apart from their hospital and clinic service lines. Nephrology has become a laboratory of sorts for alternative payment models, because costs of the end stage renal disease entitlement program are so high—exceeding $50 billion annually—and Medicare has been the primary payor of those costs. This has made nephrologists become experts in health care payment policy and in navigating the challenges of shifting payor demands. The business sense and nimbleness of private practice nephrology are assets to the specialty and to the medical system as a whole; if we cannot make something work, it is unlikely to succeed at scale.

New challenges for private practice nephrologists come as the practice of medicine expands out from the examination room and into the realm of care coordination and population health. At the same time, efforts to define and pay for the value of medical care continue to evolve. With advanced cardiovascular-kidney-metabolic syndrome affecting 15% of US adults (1), many of whom require input from multiple, overlapping specialists, it is clear that nephrology care cannot thrive in a vacuum. To meet this challenge, we need better tools—easy lines of communication with our peers, robust data analytics, and interdisciplinary team members to address the whole patient.

This special section highlights different approaches that, in the best tradition of independent practice, our innovative colleagues have developed. One article explores a practice's experience—both the benefits and challenges—of participating in the Comprehensive Kidney Care Contracting payment model. Another practice has built its own interdisciplinary clinic, while keeping nephrologists in charge of the care of their patients with kidney diseases. Because payment policies drive what is possible, we also examine the intended and unintended consequences of site-neutral payments and explore policy ideas that would reduce the barriers faced during private practice nephrology's transition to interdisciplinary care.

Medicare compensation to physicians, adjusted for inflation, has declined 29% since 2001 (2). This stark fact represents an existential threat to private practice doctors of all specialties, who still have to make their payroll and overhead from their earnings. Meanwhile, graduating residents are not choosing nephrology; only 66% of fellowship positions were filled in the Match in 2024 (3). To successfully rebuild the nephrology physician workforce, there needs to be diverse practice offerings and business models so that we can attract and retain as many interested fellows as possible. Over 37 million Americans are living with kidney diseases including 14% of US adults, and most are unaware of their condition and have not seen a nephrologist (4). Ensuring the viability of private practice nephrology remains an important part of attracting the next generation to the field. Now more than ever, nephrologists are called upon to practice at the top of their licenses—and beyond the four walls of the clinic. ■

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The section coeditors report no conflicts of interest.

References

1. Aggarwal R, et al. Prevalence of cardiovascular-kidney-metabolic syndrome stages in US adults, 2011-2020. *JAMA* 2024; 331:1858–1860. doi: 10.1001/jama.2024.6892
2. American Medical Association. Medicare basics. The Medicare economic index. 2024. https://www.ama-assn.org/system/files/medicare-basics-medicare-economic-index.pdf
3. Pivert KA.; American Society of Nephrology. First look: AY 2024 Match. ASN Data. November 29, 2023. https://data.asn-online.org/posts/ay_2024_match/
4. U.S. Centers for Disease Control and Prevention. Chronic kidney disease in the United States, 2023. May 15, 2024. https://www.cdc.gov/kidney-disease/php/data-research/index.html

Weaving the Threads of Care for Cardiac, Kidney, and Metabolic Diseases

By Brian Rifkin and Elba Medina

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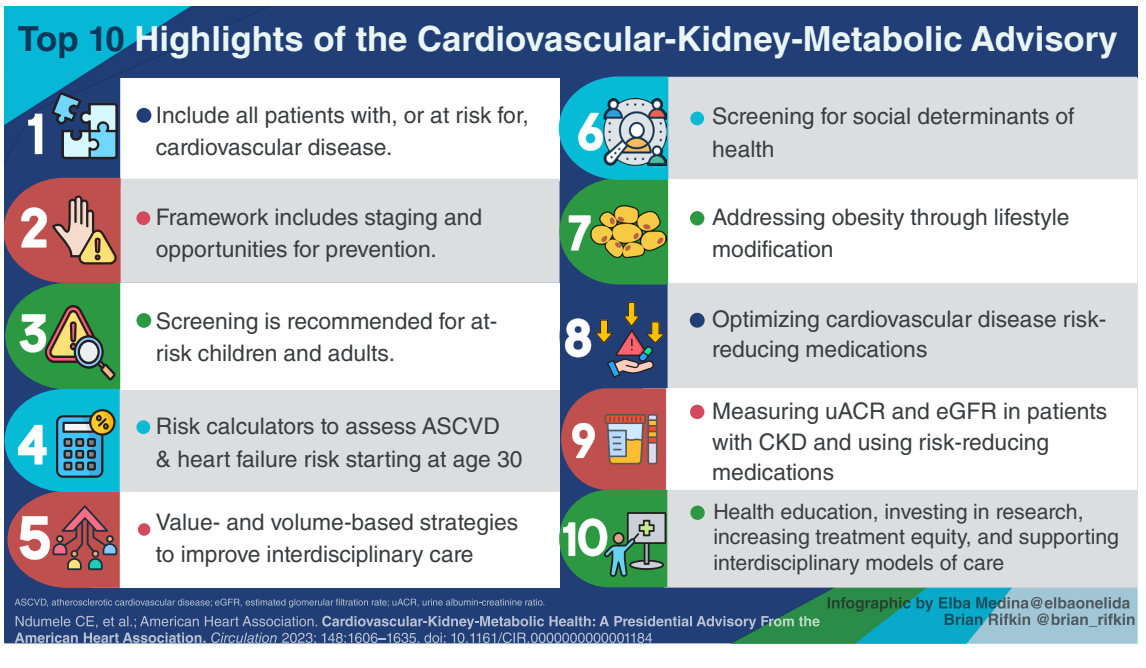
In 2023, the American Heart Association (AHA) proposed a broader, multidirectional concept of cardiovascular disease (CVD) modification called the Cardiovascular-Kidney-Metabolic (CKM) Health Initiative and Cardiometabolic Alliance. CKM syndrome is defined as the interaction among CVD, chronic kidney disease (CKD), diabetes, and obesity (1). The clinical presentation of CKM syndrome is often heterogeneous; yet early recognition and treatment can change the trajectory of poor outcomes, including premature death. The primary focus of the CKM health initiative is prevention, achieved by scrutinizing the individual fibers of diseases in CKM disorders. The AHA-proposed staging system represents a qualitative approach to assessing the risk of component disease progression (2). Unfortunately, patients with varied comorbid conditions within the CKM basket often receive disjointed care. In private practice, in which physicians may not be part of large multispecialty groups, integrated care across diverse electronic medical records, geography, and socioeconomic communities can be challenging.

AHA's CKM Advisory Committee came up with 10 key points to address the scope of this project (Figure). The details of this plan include staging, screening, suggestions for treatments, and interdisciplinary care implementation to reduce CVD risk. Diabetes, CKD, and obesity are also addressed individually, as they are intimately woven into the pathophysiology of CVD morbidity and mortality. Perhaps most importantly, the advisory paradigm attempts to address barriers to exceptional care by examining lifestyle modification, equity of therapeutics, and environmental factors including social determinants of health (3). The CKM Advisory Committee seems to understand that it is one thing to conduct a randomized control trial on sodium-glucose cotransporter-2 inhibitors, showing benefits across a broad population of patients; however, it is a completely different scenario to implement those treatments to, for example, a resource-limited single mother of three living in the rural Mississippi Delta. By attempting to address barriers and find patients at earlier stages of component diseases, the CKM paradigm of disease recognition and treatment might have a chance at meaningful health improvement in marginalized communities.

As private practice clinicians, how can we best use this framework to improve the care of our patients with the most challenges? Screening and recognition are paramount, but this program is bigger than any individual or nephrology group. There needs to be a renewed interest in creating systems to address the web of complexity of CKM syndrome with members of the community, government, and health care systems (4). Community leaders and social workers need to help identify obstacles and solutions for outreach and education. Local and federal governments need to invest in health equity and financial support for increased access to medications, transportation, and availability of unprocessed foods. Lifestyle modifications aimed at improving nutrition, increasing activity levels, and decreasing obesity need life coaches and motivated peer counselors to encourage healthy habits. Health care proxies and advocates, with physician support, need to create easier access to regular screening of patients who are high risk for CKM syndrome. Finally, physicians need education on how to best integrate all of these interventions. Which people or groups choose to lead this extensive initiative will ultimately determine its success. CVD remains the number one killer worldwide, and CKM diseases deserve greater attention and resources if we are ever going to weave together a healthier world. ■

Figure. CKM advisory paradigm of disease recognition and treatment



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The authors report no conflicts of interest.

References

1. Ndumele CE, et al.; American Heart Association. Cardiovascular-kidney-metabolic health: A presidential advisory from the American Heart Association. *Circulation* 2023; 148:1606–1635. doi:10.1161/CIR.0000000000001184 [Erratum: *Circulation* 2024; 149:e1023. doi: 10.1161/CIR.0000000000001241].
2. Massy ZA, Drueke TB. Combination of cardiovascular, kidney, and metabolic diseases in a syndrome named cardiovascular-kidney-metabolic, with new risk prediction equations. *Kidney Int Rep* 2024; 9:2608–2618. doi: 10.1016/j.ekir.2024.05.033
3. Belay KE, et al. Social determinants of health for cardiovascular-kidney-metabolic syndrome among patients with diabetes. *J Endocr Soc* 2024; 9:bvae208. doi: 10.1210/jendso/bvae208
4. Cases A, et al. Cardiovascular-kidney-metabolic syndrome definition and its role in the prevention, risk staging, and treatment. An opportunity for the nephrology. *Nefrologia (Engl Ed)* 2024; 44:771–783. doi: 10.1016/j.nefroe.2024.11.011

From Volume to Value: Nephrology's Tough Transition

By Vidooshi Maru

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Our nephrology practice has been involved in Medicare value-based care (VBC) models since 2017. We were drawn to the alignment of higher quality care with shared savings incentives. Despite our successes, we find the programs difficult to navigate due to year over year changes in quality metrics, delayed data reporting, surprises in the shared savings waterfall (i.e., the retrospective trend adjustment and normalization factor), as well as overall program complexity.

VBC is resource intensive. Although only 33% of our patients are aligned with our current model, we have hired kidney care coordinators and expanded our educational and outreach programming to address the needs, depending on risk factors, of 100% of our patients. The revenue we earn back from participating in the Kidney Contracting Entity (KCE) in the form of quality incentives, the Advanced Alternative Payment Model (or AAPM) bonus, and shared savings helps subsidize the cost of this care for our patients who are not KCE-aligned. Medicare's continued cuts to fee-for-service make paying for these direct resources cost prohibitive.

Indirect costs are also substantial. We work closely with our dialysis staff to minimize unnecessary trips to the emergency department. We created robust transitional care workflows to minimize readmissions. We learned risk adjustment to further close gaps in care in an otherwise fragmented health system. We educated our referral base on the need for earlier referrals. We shared optimal start data on cost savings and survival advantage with our surgical teams and hospital administration and after extensive collaboration, have expedited pathways for placement of urgent peritoneal dialysis catheters and arteriovenous accesses, both inpatient and outpatient. This nonreimbursed administrative burden comes at the expense of direct patient care and time spent on actual practice management.

Changing the culture of a practice from fee-for-service to VBC, and straddling both models concurrently, is difficult. The program structure is defined, but implementation and execution fall on independent nephrologists. Some of us have fully engaged in the above work, while others wait on the sidelines. Most have partnered with private equity to absorb downside risk, provide analytics, and navigate regulatory compliance, although the perceived need for this partnership is a barrier to entering the VBC space for many. How do we support nephrologist independence? How do we get small or solo and academic nephrologists on board with VBC? How will our indirect costs be accounted for? What will happen to our kidney care coordinators once KCE subsidization ends? Who will do the meaningful work required of VBC when only 73% of adult nephrology fellowship positions were filled in the 2025 Match (1)? Will nephrologists be at the table to discuss the specifics of implementation when the Center for Medicare and Medicaid Innovation (CMMI) makes changes to KCE metrics and considers a successor model?

Our participation in future VBC models depends on improvements that would make these models reliable, executable, and sustainable for independent practices. Direct engagement of CMMI with practicing nephrologists may help address any remaining obstacles that we face in fully transforming to a VBC model. As the KCE sunsets, we hope for stabilization and look forward to maturation of the model. ■

Vidooshi Maru, MD, is a nephrologist with Nephrology Associates of Michigan, Ypsilanti.

The author reports no conflicts of interest.

Reference

1. Pivert KA.; American Society of Nephrology. First Look: AY 2025 Match. ASN Data. December 4, 2024. https://data.asn-online.org/posts/ay_2025_match/

Value-based care (VBC) in nephrology: Challenges and future considerations

The shifting landscape of VBC

- **What is VBC?** VBC is a shift from fee-for-service to a model that rewards quality and cost-effective patient care.
- **Goals:** Improve patient outcomes, enhance care coordination, and control health care costs.
- **How it works:** Payor and physician share savings if quality care is delivered at lower cost.

Challenges to VBC execution

Resource intensive: VBC requires significant upfront investment.

Limited patient penetration: Only a fraction of the patient population is enrolled in a specific VBC program.

High administrative burden: Efforts in coordinating care, tracking metrics, and compliance are not directly reimbursable.

Ongoing concerns for future VBC plans

Perceived need for industry partnerships: Many nephrologists feel that they need private equity support.

Time-limited programs: There is uncertainty around the Kidney Contracting Entity (KCE) model sunset and future policy changes.

Nephrology workforce shortage: Only 73% of nephrology fellowship positions were filled in 2025.

Takeaways

- Direct engagement with nephrologists is crucial to refine and sustain VBC models.
- There is a need for financial sustainability beyond the KCE subsidy.
- Retention and training of nephrologists must be prioritized for long-term success.
- Uncertainty in government policies hinders long-term planning, especially when benchmarks are adjusted retroactively.

Visual graphic by Jia H. Ng, MD, MSCE

PRINE Health: Multispecialty Care for Chronic Kidney Disease

By Simon Prince and Meagan Marrero

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PRINE is a unique, independent multispecialty group (PRINE Health Medical Group [PHMG]) and wrap-around practitioner network (PRINE Health Independent Practice Association [IPA]) focused on chronic kidney disease (CKD), created by nephrologists for nephrologists. PRINE is supported by a physician-owned managerial service organization (PRINE Health MSO), offering value-oriented population health and traditional practice management services.

Founded in 2019, PRINE began as a merger of six nephrology groups under a single tax identification in Long Island, New York. The vision for PRINE is a multidisciplinary ecosystem focused on addressing the needs of people living with advanced CKD. The name PRINE stands for PRImary NEphrology. Since its inception, PRINE has expanded from nephrology to include primary care and other complementary specialties. Its mission is to achieve the "quadruple aim" for people living with CKD—improving the quality of kidney care, reducing costs, and enhancing both the patient and clinician experience. PRINE currently includes 75 practitioners in PHMG and 200 in the PRINE Health IPA Network (which includes PHMG along with other independent nephrology and complementary practices to expand reach while contracting together with managed care payors).

Promoting independence and autonomy for nephrologists is a core value for PRINE. By occupying a strategic position between small, independent practices and large health systems, nephrologists and other physicians remain independent of hospital or large, nonphysician-owned corporate employment while giving them a meaningful voice in governance. PRINE physicians are empowered to offer an integrated, multidisciplinary approach to managing all stages of CKD. All partners in the practice share in revenue streams generated from value-based contracts, care management services, vascular laboratories, infusion centers, a mobile sonography business, an in-house blood laboratory, research activities, and other business ventures (Figure 1).

PRINE's homegrown care program, PRINE Care, includes nurses, health coaches, and dietitians trained in kidney care. It provides kidney disease education and tailored management through the PRINE Comprehensive Kidney Care (PCKC) program, focusing on CKD progression and transitioning to the best choice for managing kidney failure. This approach supports PRINE's value-based goals of improving care quality and patient engagement, with specific aims of delaying CKD progression to kidney failure and increasing home dialysis and kidney transplantation (Figure 2). Nephrologists (including transplant nephrologists) work closely with non-nephrologists and care managers to create a comprehensive care team working to achieve successful outcomes.

We feel that designing practice like ours can position value-based kidney care initiatives to allow for more optimized patient care. ■

Simon Prince, DO, MSc, MBA, FASN, is president and CEO, and Meagan Marrero, MBA, is the Director of Business Development at PRINE Health, Long Island, NY.

The authors report no conflicts of interest beyond their affiliations.

Figure 1. Current PRINE internal offerings

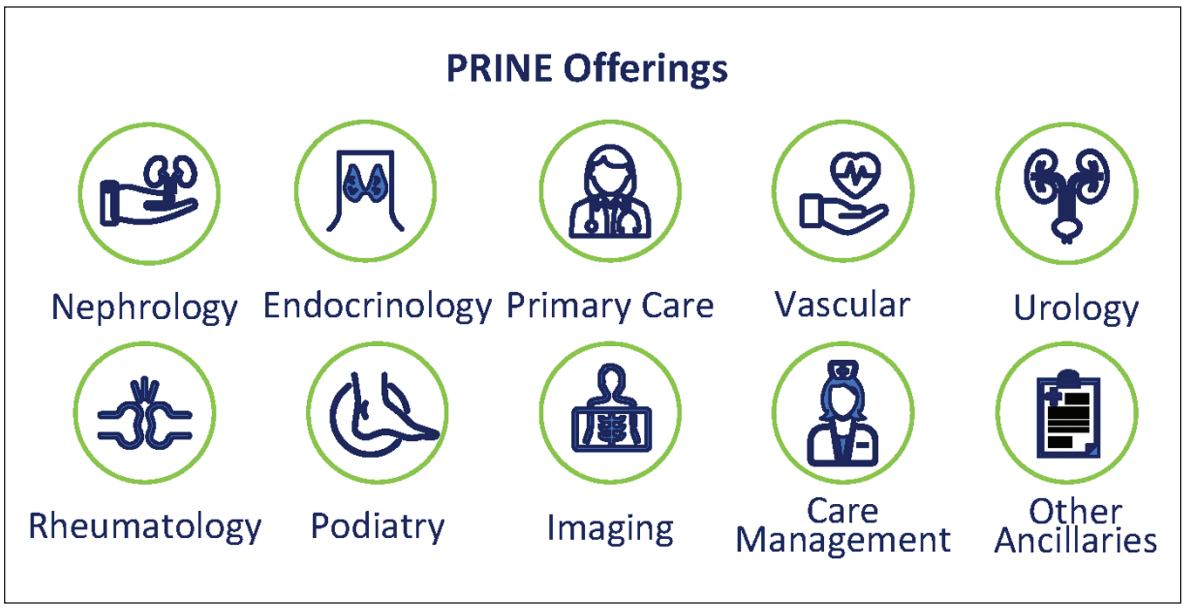
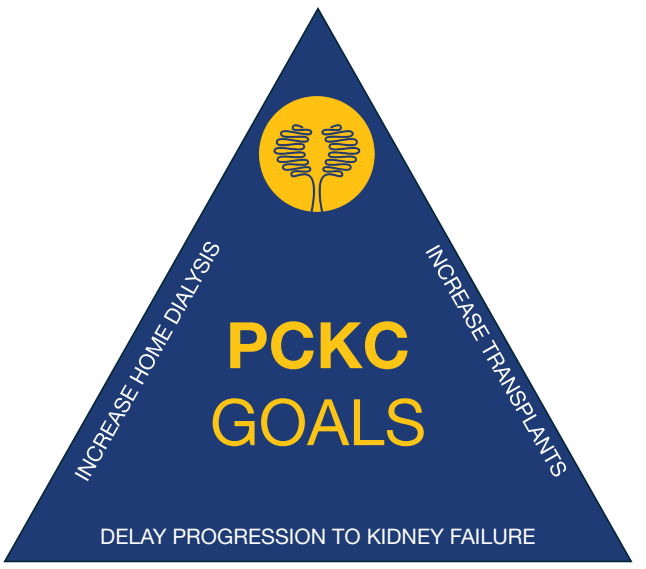


Figure 2. PRINE Comprehensive Kidney Care program goals



Impact of Site Neutrality on Private Nephrology Practice

By Keith A. Bellovich

https://doi.org/10.62716/kn.000182025

Health system-owned outpatient facilities receive an additional fee from Medicare for each patient encounter, on top of the physician fee. As health care costs continue to rise, elimination of this fee, termed "site neutrality," has been suggested as a way to reduce spending. At its core, the site-neutral payment policy aims to standardize payments to facilities for health care services, ensuring that they remain equivalent regardless of where the service is delivered. While this may sound beneficial initially, it poses significant longer-term implications, especially for private nephrology practices in which economic dynamics distinctly differ from large health systems.

Understanding the economics

Hospitals and private practices operate under contrasting financial paradigms. Hospitals generally incur higher operational costs due to their "24-7" service mandate, regulatory compliance, and broader range of patient care, which translate into higher pricing structures. Conversely, private practices and ambulatory surgical centers often operate with lower overheads, allowing more cost-efficient service delivery. This dichotomy leads to differing interests; while hospitals resist site-neutral payments due to potential revenue losses, private practices view this shift as a chance to remain competitive.

Currently, Medicare's payment system exemplifies this disparity with higher reimbursements allocated to hospital outpatient departments compared with ambulatory surgical centers or office-based procedures, often up to 50% more, according to the Ambulatory Surgery Center Association. The Lower Costs, More Transparency Act (HR 5378), introduced in December 2023, suggests a move toward unified payment structures, projecting potential Medicare savings of $3.7 billion over a decade.

Potential impact on nephrology practices

The introduction of site neutrality could bring about several changes for private nephrology practices. On one hand, it can level the playing field, enhancing competition with larger health systems. However, on the flip side, reduced hospital revenues could lead to cutbacks, potentially affecting service quality and patient access, particularly in rural areas. This presents both opportunities and challenges for private nephrology practices, which must adapt to potentially increased patient volumes alongside the constraints of limited reimbursements.

Partnerships and policy perspectives

In recent years, partnerships between health systems and private practices have been growing, providing an advantageous model for sharing costs and improving care delivery efficiency. Nationally, there has been a noticeable increase in these alliances, with site-neutral policies possibly serving as a catalyst. However, the policy remains controversial. The American Medical Association supports fair payment adjustments to protect high-quality care standards across all settings, whereas the American Hospital Association opposes the likely reduction in payments that site-neutral policies entail.

Politically, site neutrality garners bipartisan backing as part of a broader agenda aimed at cutting health care costs and enhancing transparency. Organizations like the Medicare Payment Advisory Commission advocate for payments reflecting the resources needed in the most efficient setting, underscoring the rationale behind this shift.

Future speculations

Although policymakers push toward site neutrality, the path is fraught with uncertainties. Rural access issues, conflicts of interest in health care ownership, and the potential implications of new administrations or congressional agendas remain potent considerations. Practitioners, however, may discover new lifestyle benefits, such as reduced stress from urgent, late-day procedures in these evolving practice environments.

As site-neutral payment policies continue to develop, nephrology practices must prepare for proactive negotiations with payors, joint venture partners, and the local health care community to ensure fair revenue sharing and system sustainability. Addressing these evolving dynamics will be crucial to maintaining the balance between cost efficiency and high-quality patient care in the future landscape of health care. ■

Keith A. Bellovich, DO, FASN, is the chief medical officer and chief of the Division of Nephrology at Henry Ford St. John Hospital, Detroit, MI.

Dr. Bellovich currently serves as president of the Renal Physicians Association.

Advocacy Issues in Private Practice Nephrology

By Leslie Wong and David White

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There are numerous policy levers to support private practices—some are national in nature (the federal government) and others are state-based. For the purpose of this discussion, this article primarily focuses on federal efforts. Additionally, payment and alignment of incentives continue to be important factors in the robust growth of value-based care (VBC) arrangements, including physician and practice participation in accountable care organizations. With the significant increase in VBC arrangements, this piece outlines three suggestions for how private practices can thrive in a VBC environment.

1 Create very specific and practice-restricted (stimulus) subsidies to enable adoption of technology that can handle CMS data and administer incremental evolution of quality programs.

Such an approach provides more effective support for practices as opposed to just increasing reimbursement for participating in VBC programs—a limited approach that generally restricts payments to modernize software and hardware. Nephrologists may be unwilling to invest in infrastructure without sufficient assurance that the reward from quality programs is worth it. Instead, practices could pay to use a participating Centers for Medicare & Medicaid Services (CMS)-sponsored initiative using hybrid information technology and a business system integration platform for data analytics, financial reporting, and bidirectional exchanges of secure program information with clear guidelines about use.

Increasing reimbursement up front without adequate controls and financial support has the unintended consequences of leading nephrologists to pay to adopt the solutions of third-party vendors or to join their aggregated group(s).

The platform(s) would need the federal government's involvement to integrate with major electronic health records systems (e.g., Epic, Cerner, Allscripts, NextGen, Athena, and eClinicalWorks) for a seamless approach.

2 Design and share quality metrics and clinical and financial methodologies with more transparency, lead notice, clarity, and user-friendliness in VBC models.

Many early participants of the Kidney Care Choices model expressed frustration with infrequent communications and lack of information transparency. Many participants expressed interest in the Center for Medicare and Medicaid Innovation (CMMI) increasing transparency in communications over upcoming modifications or changes and the time lag in performance data.

Participants have cited CMS webinars as an inadequate tool for disseminating information, especially because the information is not in a querying format and is not generally released contemporaneously. The CMS help desk also frequently references queries back to the originating question without clarifying or asking for feedback from the person asking the question.

The 4i website (https://4innovation.cms.gov/) is used by entities in certain CMMI models and is open to active model participants only, thereby serving as a gatekeeper to updated technical specifications and educational materials related to the models. On the CMMI website, these materials are often outdated and not specific enough for those seeking to study and understand the workings of the model, including quality benchmarks and methodology. It may be more workable to restrict Kidney Contracting Entities data access but, for the sake of transparency, give registered 4i users the ability to look at all program educational and operational manuals.

Pervasive across health care, parsimony in metrics and within program design is in great need as well. As systems grow more complicated, and challenges such as an overabundance in metrics continue, it is more difficult for private practices to cope and compete with much larger institutions and systems. It is critical for CMMI to include more practicing nephrologists in conceiving and designing the programs.

3 Lower the barriers to accessing data for nephrologists and their practices.

In the End-Stage Renal Disease Treatment Choices (ETC) Model, the process of accessing data for nephrologists was generally not well understood. Many nephrologists who had enrolled in ETC never even knew they were in the program. Those aware that they were in an ETC geography often had no understanding of the actual process of monitoring and assessing data. Most nephrologists rely on office managers or other administrators to manage these functions and require additional steps to enroll and delegate access. CMS data files are notoriously unwieldy and are formatted using unfamiliar terminology. Office managers and nephrologists who are not able to navigate these requirements or to understand what the data mean to them are unlikely to be engaged participants.

From a financial perspective, the claims and data lag periods make it almost impossible for practitioners to get any kind of quality data feedback on their actions in enough real time to motivate and convince them to change their behavior. CMMI should consider rewarding practices for participating by giving them tax breaks that can be additive (and retroactive) based on actual dollars saved versus baseline, instead of continuing to move goalposts on quality and performance every year.

Big barriers

These are some of the levers that could be used to help private nephrology practices in the current environment. However, the Stark Law and language in the Affordable Care Act, further strengthening its tenants, have opened the door to increased private equity investment in health care. This had led to business decisions that outrank decision-making based on the physician's recommendations in consultation with patients and their caregivers. Nephrologists face considerable pressure to affiliate with privately held entities, not because they want to cede autonomy over care for their patients but to overcome the considerable practice entry barriers into VBC so they are not left behind. It may be too late to correct what is an inherent obstacle; however, we highly recommend that physicians and their care teammates continue to raise this issue with policymakers and in relevant venues. ■

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The authors report no conflicts of interest.

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4-Q723

ASN's Health Policy Scholar Advocates in First Year for Increasing Transplants, Sustainable Dialysis, and Clinician Support

By Karen Blum

https://doi.org/10.62716/kn.000242025

Suzanne Watnick, MD, FASN

A nephrologist with a long history of political advocacy, Suzanne Watnick, MD, FASN, in 2024 became ASN's inaugural Health Policy Scholar in Residence. Watnick, professor of medicine at the University of Washington and a physician with the Seattle Veterans Affairs Medical Center, has served in many additional capacities at ASN, including spearheading its virtual Dialysis Core Curriculum and serving on the ASN Quality and Policy Committees.

In a recent interview, Watnick spoke with *Kidney News* about key legislative efforts that are important to the kidney community and what nephrologists can do to help.

Q: What were some of your highlights from your first year as a health policy scholar?

A: We've accomplished a lot in the last year with several initiatives. I worked at the ground level on the latest prize for KidneyX, a public-private partnership between ASN and the Department of Health and Human Services (HHS). I worked very closely with HHS to stand up this prize to improve dialysis care and launch the competition to make a difference for the community. I also helped find technical advisors to make recommendations, get judging panels, and award the prizes. We did all of this in less than 1 year. This just shows that bringing the community together to help improve the care for people with kidney diseases really can make a difference.

We also had unexpected events [that] I was able to help address. With the closure of Baxter's manufacturing plant as a result of Hurricane Helene and flooding that impacted half of all PD [peritoneal dialysis] fluids in the country, I helped lead the community to create guidance over the course of 1 week to address PD fluid shortages. We published [the guidance] and worked very closely with ISPD [International Society for Peritoneal Dialysis] and CMOs [chief medical officers] of leading dialysis organizations as well as our Home Dialysis Task Force and other kidney community leaders to address this from an emergency preparedness perspective.

We're moving forward on a number of initiatives in the transplant space. I worked closely with the [ASN] policy team and [strategic policy advisor] Rachel Meyer. Given the OPTN [Organ Procurement and Transplantation Network] Modernization Initiative at HRSA [Health Resources and Services Administration] and multiple pieces of legislation that have come up, we've accomplished so much from bills that we helped not only support but actually helped draft with our legislators.

Q: Can you give us an example?

A: Sure...the Expanding Support for Living Donors Act that was introduced on a bipartisan basis at the very end of the 118th Congress and will be reintroduced in the 119th. It's basically looking to support living donors' expenses, as they're donating the gift of life. There is a fund to help reimburse potential living donors for expenses they incur as part of the donation process; this bill increases the total reimbursement that you can give people and increases the income eligibility.

Q: The Centers for Medicare & Medicaid Services' (CMS's) Increasing Organ Transplant Access (IOTA) model to increase access to kidney transplant will start in July. What are your thoughts on that?

A: I call the IOTA model version 3.0 of value-based care models in kidney care. It is mandatory for half of all transplant centers that [perform transplants on] more than 11 adult patients per year. It is going to incentivize three things: 1) achievement, meaning more kidneys transplanted; 2) efficiency, meaning decreasing nonuse or discards of kidneys, which have increased substantially over the last year; and 3) trying to improve quality, aiming to prolong the life of the [allograft]. These three areas are great because they're getting more people [to undergo transplants] and hopefully keeping them healthy with their [allograft] for a longer period of time. ASN responded with 40 pages of recommendations, many of which were used by CMS—for example, giving greater rewards and incentives. I'm very proud of us at ASN for all the work that we've done.

Q: Do you have a sense of how the new administration will support or impact kidney health policies?

A: Absolutely. Trump 1.0 was very supportive of kidney care. The father of [the] HHS Secretary at that time, Alex Azar, had kidney failure, and [Azar] saw his father go through various forms of kidney replacement therapy, including having a challenging time accessing kidney transplantation. Azar recognized [that] we needed to improve the system. During that administration, they introduced and signed the Advancing American Kidney Health (AAKH) Initiative, through which they supported slowing down progression of disease and detecting it earlier, trying to get more people with new kidney failure either transplanted or on home dialysis modalities, and trying to increase overall the number of patients who get transplanted. IOTA fits right in.

Some of the earlier value-based care models were also instrumental in the first Trump administration. We believe the intention with Trump 2.0 is to continue work that they've done previously with the AAKH Initiative. This administration may be supportive of not just addressing chronic disease but detecting it earlier.

Q: What priorities are you focusing on now?

A: We'll continue a nephroeconomics course [that] ASN began supporting last year to educate and promote issues that are important for our members. A lot of nephrologists want to improve understanding of issues around economics, value-based care, and even physician reimbursement. Next year, we intend to have this in person and to coordinate [Capitol] Hill visits as well so individuals who are attending can advocate. It's really nice for people who are on the front lines to be able to advocate for their patients and for the profession.

We'll be working on new portions of the OPTN Modernization Initiative. Transplant is the best treatment for people with kidney failure, so if they're eligible, we should be doing more transplants. We're also helping to lead, both with the ASN Policy Committee and the Quality Committee, an overhaul to the ESRD [End Stage Renal Disease] Prospective Payment System, aka the ESRD bundle, or how dialysis is paid for. The whole community recognizes that the current prospective payment system that started in 2011 really is based in 2008 health care. There's been a lot of changes since 2008 health care, and therefore, we really do need an overhaul to try to bring in innovative treatments and therapies, which have been lacking in our field. We're preparing materials for leaders on the legislative and regulatory sides.

Another important new initiative [that] we're leaning into is working on getting an officer of kidney health and transplantation in the Office of the Secretary at HHS—somebody who wakes up every morning thinking about kidney diseases and can help coordinate all of the different agencies that touch kidney diseases.

Q: You have been a proponent of efforts toward more environmentally friendly dialysis. What are some current highlights in this area?

A: Earlier this year, KidneyX announced seven winners of its first dialysis Sustainability Prize. That looked at improvements to reduce power and water used in dialysis, such as a portable, nearly waterless hemodialysis system. KDIGO [Kidney Disease: Improving Global Outcomes] has a conference in late April [that] I'll be attending, specifically on green dialysis. And we'll continue to champion improvements in dialysis care, which are deeply needed because there's been so little innovation. Dialysis doesn't look a lot different than it did 20 to 30 years ago, and that's a shame. That's not the case in many other areas of medicine. We need to do better in thinking about different ways of doing dialysis, especially if you have emergencies or disasters. How can we provide dialysis, for example, with online PD fluid, or a wearable artificial kidney, or reusable dialysate? ASN is a member of the International Society of Nephrology's global initiative called GREEN-K.

Q: What can nephrologists do to support these various initiatives?

A: It's important for nephrologists to support policies and improvements in policies to benefit their patients. One of the things they can do is understand what some of these issues are, what bills are currently being promoted, or what legislation is currently introduced. They can reach out to their representatives and senators and schedule meetings locally with these people. You don't have to come to Washington, DC, to do that. Things that are important to you and your patients, we discuss in the various forums at ASN. Feel free to reach out to me at swatnick@asn-online.org any time to discuss issues of importance.

I'd also love to help people understand how they can advocate. Many hands make light work, they say, to get things over the finish line. You can bring an issue to the attention of a legislative staff member, but you need to actually have that conversation. There are so many important issues that need change in this country, so get a meeting with a legislative staff member, [and] take time to have a discussion and explain why this issue is so important to you, to your region, and to all [of] the constituents of this [congressional] member. You could potentially get new policies in place, new legislation, and new regulations to benefit you and your patients. ■

Following Fellowship: How to Approach a Career in Nephrology

By Cynthia Miracle and Scott Mullaney

https://doi.org/10.62716/kn.000162025

We have had the pleasure of being nephrology training program directors, who both began as junior faculty with research appointments at the institution in which we were fellows. We have held several titles throughout our careers and pivoted from the laboratory to develop successful careers as clinical educators. Through this role, we discovered that trainees are unfamiliar with all that our field offers and struggle with making decisions regarding their career path: Balance of personal and professional satisfaction, intellectual stimulation, autonomy, and finances. We have also been lucky to work closely with fellows through our involvement with Nephrology Business Leadership University, a week-long program tailored to second-year fellows preparing to begin a career in nephrology. Each year, we see the excitement of attendees grow as they learn of the varied roles available to them, which will allow a fulfilling career. This article's goal is to introduce a mindset by which nephrology trainees can approach their job search and develop a fulfilling career in nephrology.

The previous paradigm, dividing academic and private practice, is no longer applicable. Although still an early branch point, the individual components of a career (e.g., clinical practice, teaching, research, and practice leadership) exist in both (Figure). When looking at a job, trainees should look past the false dichotomy of "academic versus private practice," and instead, consider the activities they want to be doing in their job. The first step in finding the "right" job starts well before the job search. The first year of fellowship is overwhelming, but we encourage trainees to explore not only diverse clinical settings but also roles in medical education, hospital committees, and internships, available through ASN and the like. Toward the end of their first year, fellows should take some time to reflect on what they want their work to encompass. Do they want to teach; if so, whom? In what setting do they want to see patients—inpatient, clinic, dialysis, transplant, or all the above? Are they interested in leadership; administration? Taking an honest inventory allows a more focused job search and a more fulfilling start to a career as a nephrologist. It is important for fellows to remember that seeking a job is different than applying for a trainee position; a job will be long term. They should feel empowered to do research into the practice, ask questions regarding the issues important to them, seek input from those familiar with the practice, and enlist those familiar with contract negotiations.

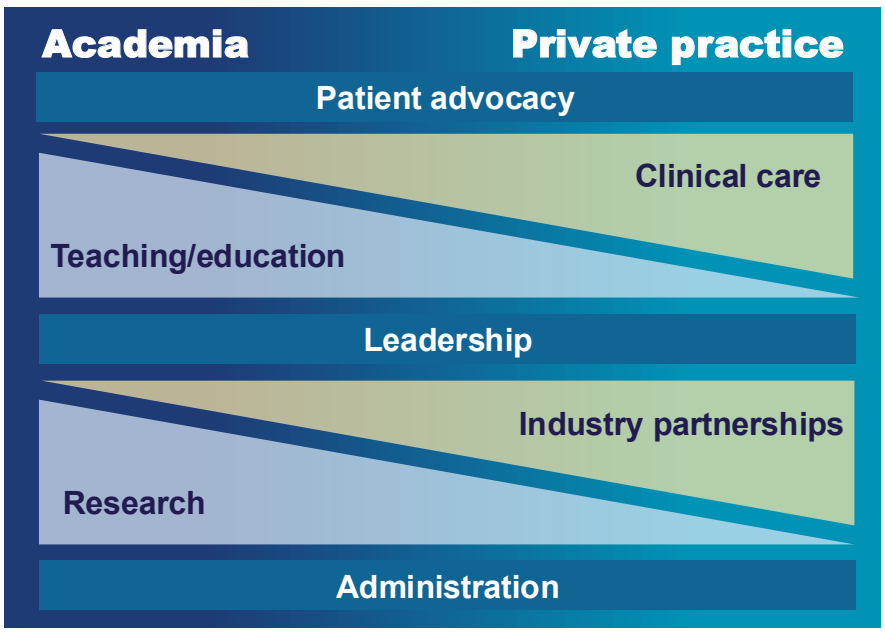
Once a fellow has entered the workforce, they will find that new opportunities will continue to present themselves as their career progresses. These opportunities from colleagues, industry, academia, and hospitals allow them to try out distinct roles to see what is a good "fit" and what is fulfilling. Each patient's case, teaching event, and administrative role are chances to demonstrate their work ethic, innovative spirit, and commitment to the mission. It is said, "Be kind; you never know who is watching." We should also be engaged, thoughtful, and thorough. A career will grow unexpected branches as a result.

By saying "yes" to countless opportunities, we have organized teaching conferences, directed services for the division, and carved out careers centered around education. Now as (near) senior faculty, we relish the opportunity to help guide those coming after us to carve their paths based on an honest introspection of their career interests. We hope this helps graduating fellows see the opportunities that exist as they complete their training and join us as nephrologists. A great reference for meetings and conferences that can help our new colleagues develop their career interests is maintained at the Renal Fellows Network (www.renalfellow.org/conferences). ■

Cynthia Miracle, MD, and Scott Mullaney, MD, MBA, FASN, are nephrologists at the University of California San Diego.

The authors report no conflicts of interest.

Figure. Opportunities available in academia and private practice



Finding

Study Maps Effectiveness and Risks of GLP-1RAs

https://doi.org/10.62716/kn.000302025

Glucagon-like peptide-1 receptor agonists (GLP-1RAs) may have a wide range of potential benefits, including a reduced risk of Alzheimer disease and dementia but also previously unrecognized risks, according to a report in *Nature Medicine*.

Using US Department of Veterans Affairs databases, the researchers identified 215,970 patients with diabetes who started treatment with GLP-1RAs between 2017 and 2023. The study included comparison groups of patients with diabetes initiating treatment with sulfonylureas, dipeptidyl peptidase 4 inhibitors, or sodium-glucose cotransporter-2 inhibitors, as well as a usual-care group with continued use of non-GLP-1RA antihyperglycemics. The investigators followed a discovery approach to "systematically map an atlas" of the effectiveness and risks of incident GLP-1RA treatment on a set of 175 health outcomes.

Findings suggested a range of beneficial effects involving the nervous system, including reductions in alcohol use disorders as well as suicidal ideation and self-harm: hazard ratio (HR), 0.89 and 0.90, respectively. There was also a reduced risk of neurocognitive disorders, driven by reductions in dementia and Alzheimer disease: HR, 0.92 and 0.88, respectively. Other potential benefits of GLP-1RA use included reductions in myocardial infarction; bacterial infections, particularly pneumonia; as well as liver failure, inflammatory bowel disease, and liver cancer.

Risks of GLP-1RA treatment included gastrointestinal disorders, such as nausea and vomiting and gastroesophageal reflux disease; hypotension and syncope; and arthritis. Kidney health risks included kidney stones (HR, 1.15) and interstitial nephritis (HR, 1.06). A targeted analysis suggested more than a twofold increase in the risk of drug-induced acute pancreatitis (HR, 2.46).

"[C]ompared to several controls, GLP-1RA use was associated with broad pleiotropic effects, encompassing effectiveness and risks that extend beyond those currently recognized," the researchers write. They discuss the need for further clinical studies, including research into the mechanisms and potential effectiveness of these medications for a wide range of other conditions [Xie Y, et al. Mapping the effectiveness and risks of GLP-1 receptor agonists. *Nat Med*, published online January 20, 2025. doi: 10.1038/s41591-024-03412-w; Erratum: *Nat Med*, published online January 31, 2025. doi: 10.1038/s41591-025-03542-9]. ■

A Rapid Diagnostic Point-of-Care Test for Peritoneal Dialysis-Associated Peritonitis

By Jaymin Patel and Prakash Gudsoorkar

https://doi.org/10.62716/kn.000412024

The management of peritoneal dialysis (PD) is fraught with challenges, and among the most serious is peritonitis—a complication that threatens not only patient outcomes but also the viability of PD as a modality. Delayed diagnosis of peritonitis can lead to poor outcomes, including infection-related hospitalization, transfer to hemodialysis, and increased mortality (1). Periplex**,** a novel rapid point-of-care test that detects inflammatory biomarkers, interleukin-6 (IL-6), and matrix metalloproteinase-8 (MMP-8), offers hope for improved early detection and monitoring of this critical complication.

A recent single-center study was conducted at the Singapore General Hospital for 3 years (2019–2022) and included 120 patients with suspected peritonitis (2). The researchers measured outcomes using traditional laboratory parameters, including leukocyte counts, cultures, and differential counts, providing a comprehensive analysis of the Periplex test's effectiveness against conventional diagnostic standards. Periplex demonstrated a sensitivity of 100% in detecting infective peritonitis. Its ability to rule out infection is underscored by a negative predictive value of 100%. However, the test's specificity of 50%, driven by false positives in cases of eosinophilic peritonitis, highlights the need for clinical discernment when interpreting results.

- The utility of Periplex extends beyond diagnosis.
- When used in the recovery phase of peritonitis, it achieved a specificity of 93.6%, demonstrating its capability to confirm infection resolution after treatment.
- This dual functionality underscores its potential to streamline the diagnosis and management of peritonitis. One key finding was the superior sensitivity of MMP-8 over IL-6 in detecting peritonitis, providing insights into biomarker-driven diagnostic strategies.

Additionally, Periplex performed consistently across different PD solutions, enhancing its applicability in diverse patient populations.

Practical implications for clinical practice

The implementation of Periplex could transform the management of peritonitis in patients undergoing PD by facilitating earlier detection and intervention. In current practice, diagnosing peritonitis relies on presenting symptom, effluent cloudiness, and laboratory analyses, which can be delayed and are resource intensive. A point-of-care test like Periplex could empower patients to self-test at home, which is particularly beneficial for those with limited access to health care facilities or for those who are uncertain about the presence of peritonitis due to subtle symptoms.

In the recovery phase, Periplex could serve as a reliable confirmation of infection clearance, reducing the need for repeated in-center visits and allowing patients to resume regular PD without prolonged disruptions. For patients living in remote areas, this could mean fewer hospital admissions, lower health care costs, and a better quality of life.

Key points for current practice

1 Enhanced diagnostic speed.
Periplex enables rapid detection of peritonitis, supporting timely treatment decisions and potentially reducing hospitalizations.

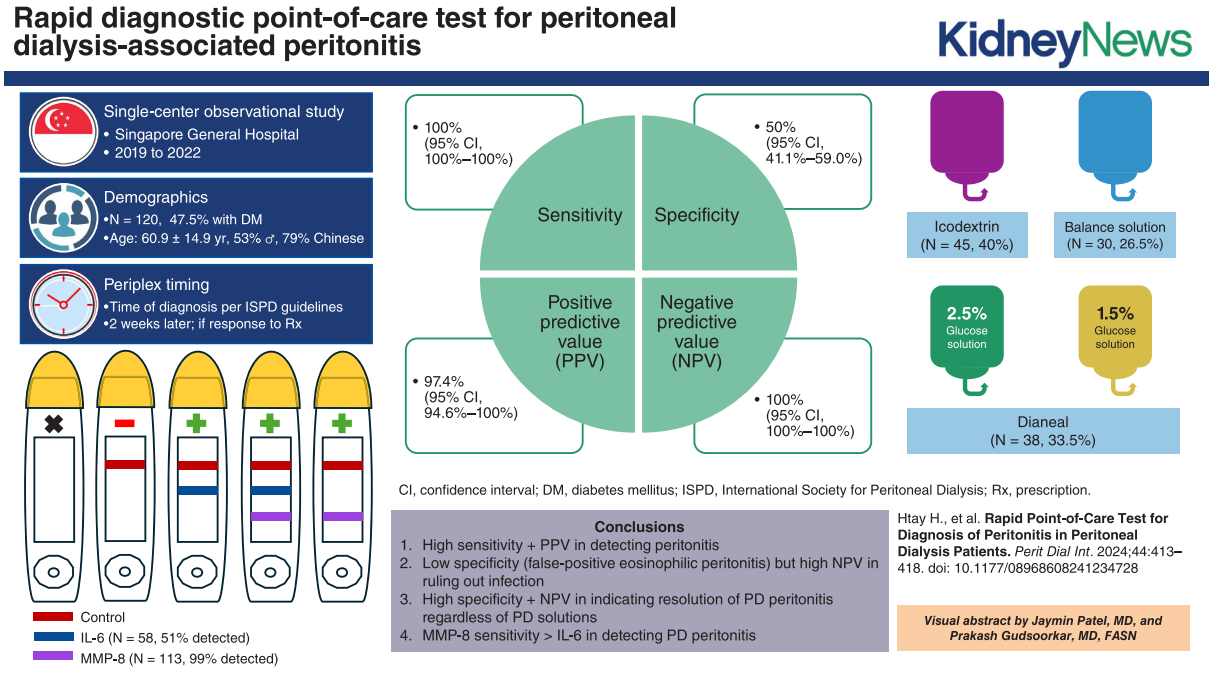
2 Reliable in-home settings.
The test's high sensitivity and negative predictive value make it a suitable tool for patient-administered testing, fostering patient autonomy and reducing health care visits.

3 Utility in confirming recovery.
High specificity in the recovery phase offers reassurance that the infection has resolved, streamlining post-treatment care.

4 Focused biomarker performance.
The superior sensitivity of MMP-8 over IL-6 could guide future point-of-care test development for inflammation markers in PD effluent.

Jaymin Patel, MD, is a nephrology fellow, and Prakash Gudsoorkar, MD, FASN, is an associate professor of medicine in the Division of Nephrology at the University of Cincinnati, OH. Dr. Gudsoorkar is a deputy editor for Kidney News.

The authors report no conflicts of interest.



References

1. Bello AK, et al. Epidemiology of peritoneal dialysis outcomes. *Nat Rev Nephrol* 2022; 18:779–793. doi: 10.1038/s41581-022-00623-7
2. Htay H, et al. Rapid point-of-care test for diagnosis of peritonitis in peritoneal dialysis patients. *Perit Dial Int* 2024; 44:413–418. doi: 10.1177/08968608241234728

IMGs Interested in Nephrology Need Additional Support

By Karen Blum

https://doi.org/10.62716/kn.000192025

International medical graduates (IMGs)—individuals who earn medical degrees in other countries and come to the United States for residencies and/or fellowships—are key to caring for an increasing population with kidney diseases, speakers said during a Kidney Week 2024 presentation. However, they can benefit from more support from training directors and other nephrologist mentors to succeed.

One in seven adults in the United States has kidney diseases, and nearly 14% of patients have chronic kidney disease (1); furthermore, the incidence of kidney failure is rising, said Koyal Jain, MD, MPH, FASN, an associate professor of medicine and director of the nephrology and hypertension training program at the University of North Carolina School of Medicine in Chapel Hill.

Who will care for these patients is a challenge, she said. Approximately 11,000–13,000 nephrologists practice nationwide, but nephrology has been declining in recent match trends. Just 66% of fellowships were filled in academic year (AY) 2024, and the ratio of candidates-to-nephrology positions was 0.67 (2). These numbers were slightly better in the AY2025 match, with 73% of fellowships filled and the ratio of candidates to positions at 0.74 (3).

IMGs are interested in nephrology, Jain said. Of 321 physicians who matched in nephrology for AY2024, 117 were foreign-born IMGs. Among 362 who matched in AY2025, 131 were foreign-born IMGs. Many are going to underserved areas, she said. Still, more than 56% of new IMGs reported difficulties finding a satisfactory position, compared with just 22% of US graduates (4).

"It's tough for international medical graduates, I feel, because nobody knows your medical school," said Jain, a native of India who came to the United States in 2009 for a residency. "Your medical school might be great where you're coming from, but people don't necessarily know it here. [Second], you have to prove that you're good enough to be considered. [Third], the whole process is expensive and time-consuming, and there's not a lot of information or support available."

Without connections, it can be difficult to get requisite experience, she added. For example, Jain sent over 100 emails to nephrologists in the Houston, Texas, area looking for clinical observerships before hearing from one doctor. That person's support was enough to enable her to gain experience and connections.

Nephrology was the second-highest specialty among the percentages of Accreditation Council for Graduate Medical Education (ACGME)-accredited positions filled by non-US IMGs, making up 36.4% of matches, according to the 2024 fellowship match (5). This was second to endocrinology, with 37.7% of positions filled by non-US IMGs.

Jain mentioned several ways that training program directors and others can support IMGs, which translates into benefits for all learners:

- **Personal support.** Institute flexible vacation-leave policies. IMGs sometimes need to travel around the world to see family, so a 1-week break may not afford them enough time. Have a family-friendly work environment to support work-life balance, and allow trainees time off to care for a sick child or to take them to a medical appointment. Offer a space for new mothers to pump breast milk. Provide a safe space and resources for trainees to discuss any stressors.
- **Cultural support.** Include all fellows and the holidays that they observe when celebrating holidays. If trainees have family in town, allow them to bring family members to celebrations so they feel included. If global conflicts occur in a trainees' home country, check in with them to see how they are doing.
- **Biases and microaggressions.** Ensure IMGs have faculty members in whom they can confide and trust to help support them through negative experiences. Patients refusing to see physicians from a certain country of origin or comments made about people's food choices, clothing, accents, or skin color all can be demoralizing. "I have had many of these things happen to me personally or [have] seen it happen to somebody [who] I was close to," Jain said. "Everybody needs a safe space."
- **Mentorship and sponsorship.** Recognize that IMG fellows may not have as much research experience because they may not have had opportunities. Understand their career goals, and support them in helping forge connections in academia or research. Encourage them to take courses about the business of medicine. Ensure that individuals coming from a non-ACGME residency program have extra support, like helping them obtain a driver's license or other state identification card.

After fellowship, program directors can continue to support IMGs, Jain said, such as by encouraging individuals to apply for a green card and teaching them to negotiate salaries. Jain said that when she interviews fellowship candidates now, she shares with them that she is an IMG who went through a J-1 nonimmigrant visa and exchange visitor waiver. "It's just made their lives easier to know that I understand the process, and they can brainstorm things with me," she said.

The J-1 visa requires individuals to return to their home country for 2 years following their training in the United States unless the requirement is waived. This can be done through several means, Jain said, such as being offered a job by a federal agency like the Veterans Administration or being hired by a state public health department or equivalent through the Conrad 30 waiver program.

Through that program, if a physician works 40 clinical hours per week for 3 years in a health professional-shortage or medically underserved area, they do not need to return to their country. Only 30 slots are available in the United States, mainly for primary care, although nephrologists who care for patients from underserved areas can make that argument based on the primary care they provide, Jain said. Timing is critical, she said. Faculty members should advise candidates who they support to apply in September or October the year before they will graduate. In addition, she advised, they should contact an immigration lawyer for assistance.

Additional opportunities for J-1 visa holders to obtain waivers exist within the Appalachian Regional Commission, the Department of Health and Human Services, and other areas including the Delta Regional Authority. IMGs also can apply for O-1 nonimmigrant visas if they meet criteria such as having an extraordinary ability in the sciences; these visas can be extended forever. IMG fellows who have not completed an ACGME residency can stay on for an extra year of training, be hired as an assistant professor for 3 years, and then become specialty-board eligible. At the time of writing, it is unclear how these options will be affected under the Trump administration.

Trainees holding J-1 visas do not qualify for National Institutes of Health grants, but "that doesn't mean they can't go into research," Jain said. "There are lots of grants and private funding available" from sources that include ASN, the American Kidney Fund, the National Kidney Foundation, the American Diabetes Association, the American Heart Association, and the Polycystic Kidney Disease (PKD) Foundation (6).

Seeing IMGs in positions of leadership also is important to encourage trainees, Jain said. Approximately 43% of people practicing internal medicine are now IMGs compared with only 11% of internal medicine program directors (5).

"It's very important that ASN hosts this type of session focusing on IMGs," commented Javier Neyra, MD, MS, FASN, an associate professor of medicine at The University of Alabama at Birmingham, who moderated the session. Neyra, a native of Peru, trained for 7 years on a J-1 visa and transitioned through the Conrad 30 program in Kentucky to obtain permanent residency and a green card. When he started the process in 2016, there was not a lot of information available to help, but things have since changed for the positive, he said.

"Now, program directors and division chiefs have much more understanding of the process and type of visas, so they can support their trainees in this transition from training to practice," Neyra said. "But there is still a lot of work ahead to not only support these individuals but create policy changes that allow them to transition successfully [to] both academic and private practice careers." ■

References

1. U.S. Centers for Disease Control and Prevention. Kidney disease surveillance system: Trends in prevalence of CKD stages among U.S. adults. https://nccd.cdc.gov/CKD/detail.aspx?Qnum=Q372
2. Pivert KA.; American Society of Nephrology. ASN Data. First look: AY2024 Match. November 29, 2023. https://data.asn-online.org/posts/ay_2024_match/
3. Pivert KA.; American Society of Nephrology. ASN Data. First look: AY2025 Match. December 4, 2024. https://data.asn-online.org/posts/ay_2025_match/
4. Beasley E. 7 Things to know about the nephrologist shortage. *Healthgrades for Professionals*. https://resources.healthgrades.com/pro/7-things-to-know-about-the-nephrologist-shortage
5. McElvaney OJ, McMahon GT. International medical graduates and the physician workforce. *JAMA* 2024; 332:490–496. doi: 10.1001/jama.2024.7656
6. Neyra JA, et al. International medical graduates in nephrology: A guide for trainees and programs. *Adv Chronic Kidney Dis* 2020; 27:297–304.e1. doi: 10.1053/j.ackd.2020.05.003

Mouth and Kidneys: Unveiling the Crosstalk Between Oral and Kidney Health

By Priyanka Gudsoorkar, Sujay Mehta, and Prakash Gudsoorkar

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Chronic kidney disease (CKD) affects multiple body systems, yet oral health often remains overlooked in nephrology care despite its significant implications. People living with CKD commonly experience oral manifestations such as xerostomia, candidal infections, gingival inflammation, and tooth erosion, typically resulting from uremia-related metabolic, immune, and hormonal imbalances (1). These symptoms contribute to systemic inflammation, heightened infection risk, and complications like protein-energy wasting and cardiovascular disease, which worsen clinical outcomes. Studies emphasize that these oral health issues are not minor but play a crucial role in patient health, advocating for routine oral assessments and collaboration between nephrologists and dental professionals to enhance CKD management and patient quality of life.

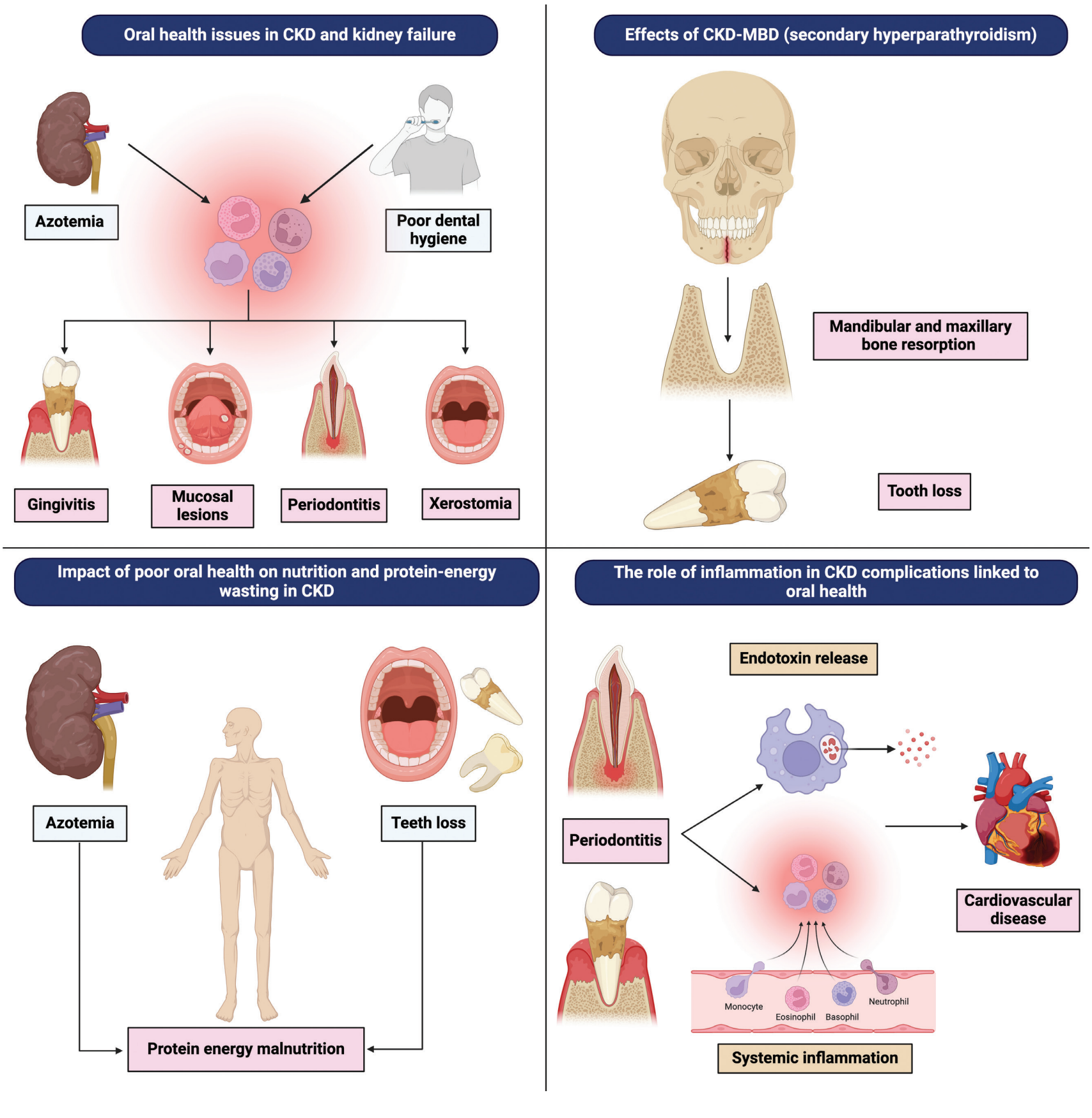
Oral pathologies and systemic impact in CKD

The prevalence of oral pathologies, such as xerostomia, mucosal lesions, and gingival inflammation, is notably higher among people living with CKD (Figure 1), especially those undergoing dialysis. This is attributed to elevated urea levels, immune dysfunction, and inflammatory responses, which increase susceptibility to periodontal infections and bacteremia. Gingivitis and periodontitis are also prevalent, highlighting the need for preventive oral health strategies from the early stages of CKD (2).

People living with CKD often have fewer teeth and advanced periodontal disease, which impair their ability to consume nutrient-rich foods. This exacerbates protein-energy wasting and accelerates malnutrition (3). Studies show a direct link between tooth loss and reduced protein intake in people living with CKD, underscoring how oral health significantly impacts nutrition and overall well-being.

Periodontitis and related oral inflammation contribute to systemic complications in CKD by harboring bacteria

Figure 1. Oral health manifestations in CKD



that release endotoxins, triggering an inflammatory response (4). Elevated levels of C-reactive protein and serum amyloid A in people living with CKD with periodontal disease correlate with increased cardiovascular risks, suggesting that periodontal treatment could mitigate inflammation and reduce cardiovascular complications—the leading cause of mortality in people with CKD.

CKD-mineral bone disorder (MBD) manifests in oral radiographs as demineralized structures, loss of the lamina dura, and mandibular bone resorption, particularly in those with secondary hyperparathyroidism (5). Addressing CKD-MBD may improve oral health, further supporting an integrated approach in CKD care.

Integrating oral health into CKD care: A call for interdisciplinary collaboration

Intervention studies suggest that regular dental check-ups, oral hygiene education, and periodontal care can improve nutritional status and reduce inflammation in people living with CKD. This evidence supports the role of routine dental care in managing CKD and enhancing patient quality of life and clinical outcomes.

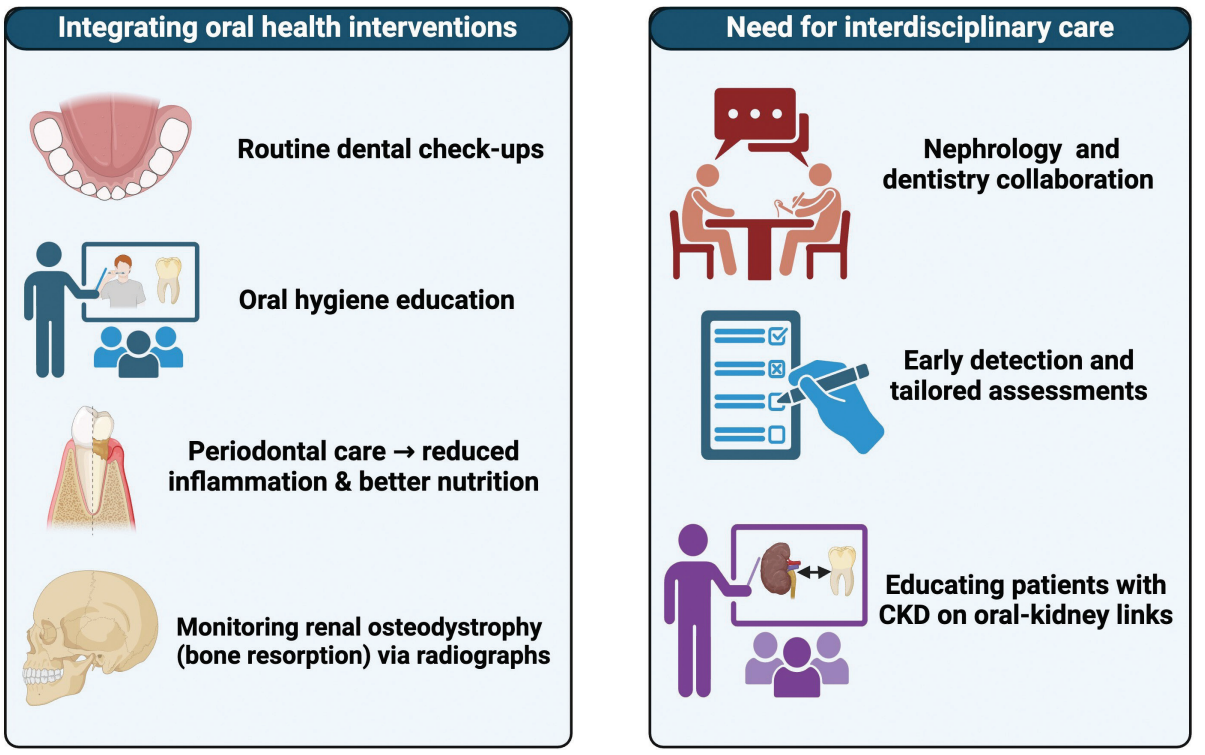
Compared with nephrology care alone, interdisciplinary care involving dental professionals enhances preparedness for kidney failure and improves health outcomes. A comprehensive approach—incorporating patient medical history, kidney function, and tailored oral assessments—empowers dental professionals to address CKD-related oral health manifestations, aiding early detection and management (Figure 2). Additionally, educating people living with CKD about the oral-kidney health link is vital. Dentists and nephrologists can complement each other by encouraging regular check-ups and facilitating integrated care, ultimately improving patient outcomes and quality of life.

Bridging nephrology and dentistry: Preventive oral health strategies to enhance CKD outcomes

The link between poor oral health and CKD complications, such as cardiovascular disease and infections, highlights the need for preventive oral health measures. Increased awareness, oral hygiene education, regular dental assessments, and timely periodontal treatment should be prioritized. Dental evaluations for patients on dialysis should ideally be scheduled on nondialysis days to reduce the risk of bacteremia, and baseline dental radiographs are recommended to monitor renal osteodystrophy.

Nephrology and dentistry must collaborate to address patients' health needs comprehensively. Poor oral health exacerbates CKD progression and complications, reduces quality of life, and raises health care costs (6). Future research should explore whether proactive oral health interventions can lower inflammation, improve nutrition, and decrease mortality from cardiovascular and infection-related complications. With open communication between oral clinicians and nephrologists, multidisciplinary care can support personalized treatment planning and adaptability as patients' health evolves, ultimately benefiting this population at high risk. ■

Figure 2. Oral health interventions in CKD management: A multidisciplinary approach



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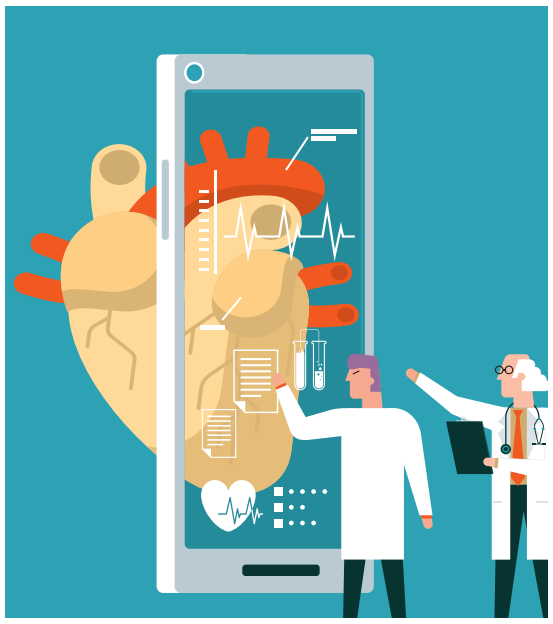
Dr. Priyanka Gudsoorkar cofounded the Solidarity Dental Foundation and serves as mentorship/membership chair of the Oral Health Section of the American Public Health Association. Dr. Mehta serves as chair of the Oral Health Interest Group at AcademyHealth and chair-elect of the American Public Health Association's Oral Health section. Dr. Prakash Gudsoorkar reports no conflicts of interest.

References

1. Martí Álamo S, et al. Dental considerations for the patient with renal disease. *J Clin Exp Dent* 2011; 3:e112–e119. http://www.medicinaoral.com/odo/volumenes/v3i2/jcedv3i2p112.pdf
2. Oliveira LM, et al. Periodontitis is associated with oral health-related quality of life in individuals with end-stage renal disease. *J Clin Periodontol* 2020; 47:319–329. doi: 10.1111/jcpe.13233
3. Akar H, et al. Systemic consequences of poor oral health in chronic kidney disease patients. *Clin J Am Soc Nephrol* 2011; 6:218–226. doi: 10.2215/CJN.05470610
4. Baciu SF, et al. Chronic kidney disease and periodontitis interplay—a narrative review. *Int J Environ Res Public Health* 2023; 20:1298. doi: 10.3390/ijerph20021298
5. Kanjevac T, et al. Impact of chronic kidney disease mineral and bone disorder on jaw and alveolar bone metabolism: A narrative review. *Oral Health Prev Dent* 2018; 16:79–85. doi: 10.3290/j.ohpd.a39858
6. Chapple ILC, et al. Interplay between periodontitis and chronic kidney disease. *Nat Rev Nephrol* (published online December 10, 2024). doi: 10.1038/s41581-024-00910-5



Peritoneal Dialysis Linked to Better Cardiac Surgery Outcomes

https://doi.org/10.62716/kn.000272025

Among patients on dialysis undergoing cardiovascular surgery, peritoneal dialysis (PD) is associated with reduced mortality and other adverse outcomes compared with hemodialysis (HD), reports a study in *Kidney360*.

From the National Inpatient Sample, the researchers identified 30,155 patients on HD or PD who underwent coronary artery bypass grafting or valve replacement surgery between 2016 and 2020. In-hospital mortality and a range of secondary morbidity outcomes were compared between dialysis groups, with adjustment for potential confounders.

Approximately 7% of patients were receiving PD. Coronary artery bypass surgery was performed in 78.5% of patients and valve replacement in 34.3%, with 12.8% undergoing combined surgery.

PD was associated with lower rates of all outcomes of interest. In-hospital mortality was 4.4% in the PD group versus 7.8% in the HD group (odds ratio, 6.1 on adjusted analysis). PD was also associated with a lower incidence of prolonged ventilation (over 96 hours; odds ratio, 0.51) and a shorter average length of stay (incidence rate ratio, 0.85). Patients receiving PD also had lower hospital charges (mean difference, $–87,172).

Findings were "largely consistent" in subgroup and exploratory analyses. Approximately one-fourth of patients initially on PD switched to HD—a transition associated with substantial increases in prolonged ventilation, length of stay, and hospital charges. Patients who switched from PD to HD also had higher in-hospital mortality, although the difference was not statistically significant.

Patients on dialysis undergoing cardiovascular surgery are at greatly increased risk of adverse outcomes. Patients on PD have sometimes been electively converted to HD, historically, due to perceived higher complication rates.

This large, retrospective study suggests that patients on PD undergoing cardiovascular surgery have lower rates of adverse outcomes compared with those on HD. The researchers conclude: "Protocols should be developed to optimize the care of [patients on PD] undergoing cardiac surgery, with the goal of maintaining PD whenever possible" [Shah A, et al. Impact of dialysis modality on mortality and complications in cardiovascular surgery: Insights from a national retrospective cohort study. *Kidney360*, published online January 16, 2025. doi: 10.34067/KID.0000000701]. ■

New Prosthesis Improves Patency Rates in AVF Stenosis

https://doi.org/10.62716/kn.000282025

For patients on hemodialysis with arteriovenous fistula (AVF) stenosis, a new cell-impermeable endoprosthesis (CIE) provides higher patency rates compared with percutaneous transluminal angioplasty (PTA), according to randomized trial data reported in *Kidney International*.

The international WRAPSODY Arteriovenous Access Efficacy (WAVE) trial enrolled 245 patients on hemodialysis requiring treatment for stenosis within the peripheral venous outflow circuit. Most patients had brachiocephalic AVFs with repeat stenosis. Those assigned to the intervention group were treated with the novel CIE device, developed to prevent restenosis caused by neointimal hyperplasia and negative remodeling. Controls received standard treatment with PTA.

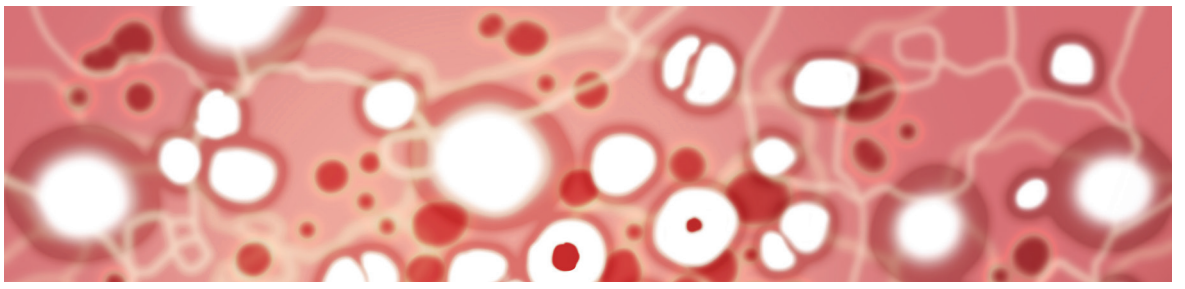
The primary efficacy outcome was 6-month target lesion primary patency, defined as freedom from clinically indicated target vessel revascularization or thrombosis. The study also evaluated safety events affecting the access circuit and leading to reintervention, hospitalization, or death within 30 days and, as a secondary efficacy outcome, access circuit primary patency.

The two groups had similarly high clinical and procedural success rates. Six months after treatment, target lesion primary patency was 89.6% for patients assigned to CIE placement versus 62.3% in the PTA group. The intervention group also needed fewer interventions to maintain target lesion patency: mean, 0.18 versus 0.47. The 30-day rate of freedom from safety events was 96.6% in the CIE group and 95.0% in the PTA group.

Access circuit primary patency was maintained in 72.2% of patients assigned to CIE versus 57.0% in the PTA group. The CIE group also had a lower rate of clinically driven target lesion revascularization: 10.4% versus 37.7%.

Although AVFs are preferred for vascular access in patients on hemodialysis, maintaining long-term AVF patency can be challenging. The CIE device was developed to overcome the limitations of available commercial devices, specifically by preventing transmural tissue growth.

Six-month data from the WAVE trial show higher patency rates among patients with AVF stenosis treated using CIE compared with standard PTA. The two treatments have similar safety profiles. In December 2024, the CIE device received premarket approval from the US Food and Drug Administration. The researchers plan further follow-up to assess 24-month clinical outcomes [Razavi MK, et al.; WAVE Trial Investigators. Six-month safety and efficacy outcomes from the randomized-controlled arm of the WRAPSODY Arteriovenous Access Efficacy (WAVE) trial. *Kidney Int*, published online January 23, 2025. https://www.kidney-international.org/article/S0085-2538(25)00063-8/fulltext]. ■



Kidney Outcomes in Pediatric ANCA-Associated Vasculitis

https://doi.org/10.62716/kn.000292025

One year after diagnosis, most patients with pediatric-onset antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) have inactive kidney disease, but nearly half have evidence of kidney damage, reports a study in *Arthritis & Rheumatology*.

Using data from ARChiVe (A Registry of Childhood Vasculitis), the researchers identified 145 patients diagnosed with granulomatosis with polyangiitis, microscopic polyangiitis, or ANCA-positive pauci-immune glomerulonephritis. All were 18 years or younger at diagnosis, had kidney disease based on biopsy or dialysis dependence, and had clinical data at diagnosis and at a 12- or 24-month follow-up.

Rates of inactive kidney disease, defined as a pediatric vasculitis activity score of 0 or 1, were compared at 12 or 24 months. Improvements in kidney function and evidence of kidney damage were assessed at 24 months. The study also evaluated the prognostic implications of initial kidney function, based on estimated glomerular filtration rate (eGFR) and Kidney Disease: Improving Global Outcomes (KDIGO) stage.

Sixty-eight percent of patients were female; the median age at baseline was 13.8 years. The diagnosis was granulomatosis with polyangiitis in 78% of patients. Seventy-one percent of patients initially had less than normal kidney function, and 25% were on dialysis. At 12 months, 83% of patients with available data were classified as having inactive kidney disease. By 24 months, this figure increased to 98%.

However, 42% of patients had evidence of permanent kidney damage at 12 months. Findings included an eGFR of 15 to 60 mL/min/1.73 m^2 in 31% of patients, kidney failure with an eGFR less than 15 mL/min/1.73 m^2 in 21%, and hypertension over the 95th percentile or antihypertensive medication in 15%.

The baseline KDIGO category showed a linear association with follow-up outcomes. Odds ratios for a non-normal KDIGO category at 12 months were 4.77 for moderately reduced kidney function, 8.62 for severely reduced kidney function, and 26.3 for kidney failure at baseline. An eGFR of 38 mL/min/1.73 m^2 appeared to be the optimal cutoff for identifying patients at risk of moderate to severely reduced kidney function.

Pediatric-onset AAV is a rare, relapsing disease, with blood vessel damage potentially leading to downstream involvement of the kidneys and other organ systems. The new study adds to previous evidence of early kidney damage, even with aggressive treatment.

The extent of reduction in kidney function at baseline may provide a simple and practical tool for outcome prediction in pediatric AAV. "Providing improved, individualized insights into anticipated outcomes will ultimately allow patients and their families to be more involved in shaping and participating in their own care," the investigators conclude [Toor KK, et al.; PedVas Investigators Network. Evaluating renal disease in pediatric-onset antineutrophil cytoplasmic antibody-associated vasculitis: Disease course, outcomes, and predictors of outcome. *Arthritis Rheumatol*, published online December 3, 2024. doi: 10.1002/art.43071]. ■

NephMadness 2025: Back to the Future

By Matthew Sparks

https://doi.org/10.62716/kn.000202025

Spring is here, and NephMadness is again ready to educate and entertain the nephrology community. Now in its 13th year, NephMadness 2025 features an intriguing lineup of teams across eight regions (Figure).

In the Resistant Hypertension region, we have Renal Denervation versus Novel Medications (Rx) for Hypertension (HTN), focusing on innovative treatments for high blood pressure. The Green House region includes Tubular Toxins versus Oxalate Offenders, highlighting dietary impacts of common herbal medications and foods on kidney health. Genetics in nephrology is represented by Genetics in Focal Segmental Glomerulosclerosis (FSGS) versus Genetic Counseling, emphasizing the role of genetic factors and patient guidance. The Hemodialysis region features Hemodiafiltration versus Incremental Dialysis, showcasing advancements in dialysis techniques. In the Chimeric Antigen Receptor T Cell (CAR-T) for Kidney Disease (Dz) region, CAR-T for Autoimmune Disease versus CAR-T Side Effects explores the potential and challenges of CAR-T cell therapy. The Minimal Change Disease (MCD) region includes the Diagnosis (Dx) and Pathogenesis of MCD versus MCD Relapse, focusing on understanding and managing this condition. Disaster Nephrology covers kidney care during Natural Disasters versus kidney care during Conflicts. Lastly, the Obesity in Kidney Transplant region features Obesity in Donors versus Obesity in Recipients, discussing the impact of obesity on both donors and recipients in kidney transplantation. This diverse array of topics promises to provide valuable insights and stimulate engaging discussions among nephrology professionals.

NephMadness is a single-elimination tournament consisting of 16 nephrology concepts divided into 8 distinct regions. The purpose of the tournament is to learn, discuss, and debate each topic, with a little friendly competition! We encourage you and your group to throw a NephMadness party, and we made it easy with a PowerPoint presentation describing each of the concepts. You can engage with the online nephrology community on social media using the hashtag #NephMadness on X or Bluesky. NephMadness will also feature eight podcasts covering each of the regions in what is called a PodCrawl, featuring podcasts by The Nephron Segment, Freely Filtered, GN in Ten, The Curbsiders, Life as a Nephrology Professional Podcast, Kidney Chronicles, RheumMadness, and The Poison Lab.

Do you have what it takes to match the Blue Ribbon Panel? Head to https://ajkdblog.org/ to find more information and enter your bracket.

Matthew Sparks, MD, FASN, is an associate professor of medicine at Duke University, Durham, NC. He is a cocreator of NephMadness and serves on the NephMadness 2025 Executive Team.

Figure. 2025 NephMadness tournament bracket

CME, Continuing Medical Education; MOC, Maintenance of Certification.

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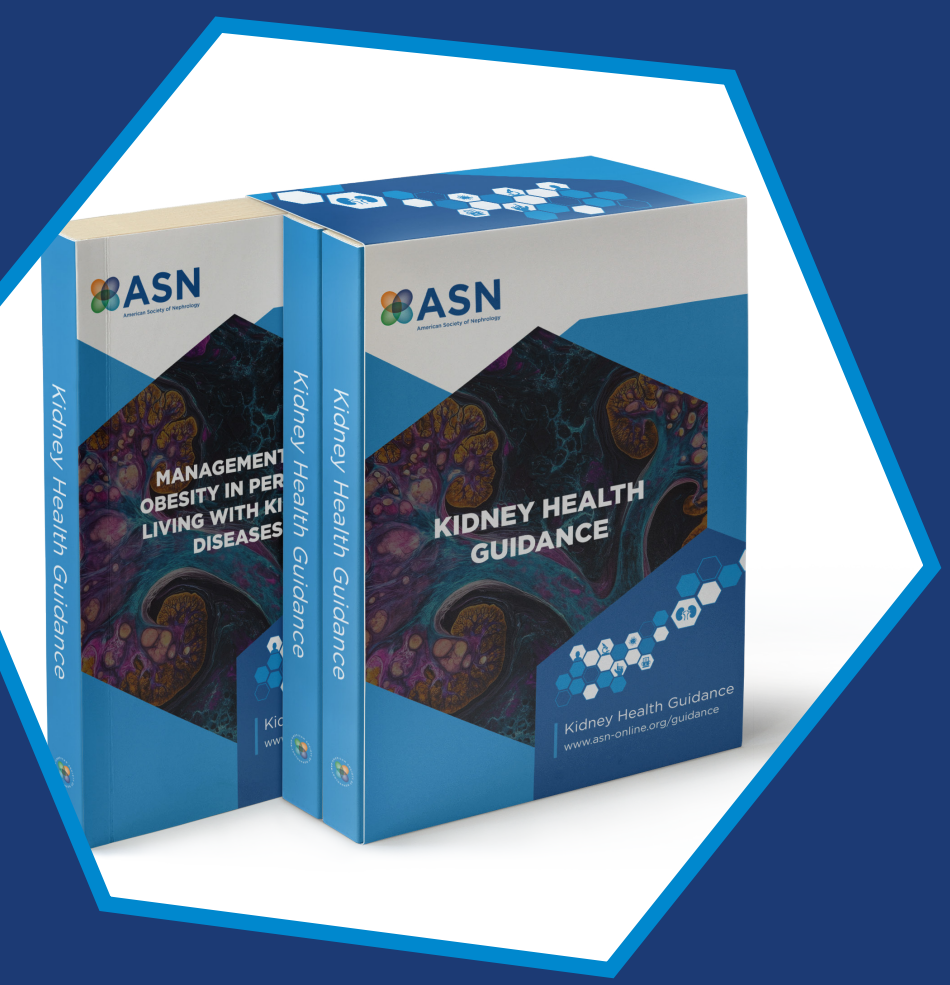

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