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Opportunities and Challenges Lie Ahead for the Nephrology Workforce

By Bridget M. Kuehn

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Growing satisfaction with the field of nephrology could help boost recruitment, especially as innovative new treatments, tools, and training strategies come online. However, compensation concerns and shifting immigration policies create serious uncertainty for the nephrology workforce.

These trends were among several discussed during the “Nephrology Workforce: The Future Is Now” session at ASN Kidney Week 2025. Panelists also emphasized the growing importance of quality of life in fellows’ decision-making, the potential role of advanced practice clinicians to help ease clinician burnout and improve nephrology training, the potential use of artificial intelligence (AI) to enhance nephrology training and help reduce administrative burden, and the evolution of nephrology training programs to help meet the demand for more subspecialization and to embrace emerging therapeutic advances.

Quality of life is king

ASN’s Nephrology Workforce and Training Committee 2025 Chair Robert Hoover, Jr., MD, FASN, highlighted the growing role that quality of life plays in fellows’ decisions about which jobs to accept. He noted that factors like call frequency (especially overnight call frequency), location, vacation time, and compensation were also listed as top considerations in the 2025 ASN Fellow Survey (1). He said that in 2014, some of the top factors were location, practice setting, and spouse’s employment prospects, but those factors have fallen in importance in recent surveys.

Nephrology fellows are also reporting greater satisfaction with the field than in previous eras. He noted that in 2015, just 60% of international medical graduates and 75% of US medical graduates reported that they would

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The Electronic Medical Record: Are We at a Blockbuster Moment?

By Katherine Kwon and Chirag Parikh

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Medicine is at the start of a profound change in how we envision and deliver patient care. Artificial intelligence (AI) will allow us to deliver precision medicine if we can unlock the insights buried within 10 or 20 years of notes, labs, and scans. We should take steps to ensure that the gains in productivity and improved outcomes are not all consumed by inefficient development spending. The current electronic medical record (EMR) marketplace is one of consolidation, and it can be difficult to imagine disruption of the major vendors. Consider, however, that in decades past, many Americans drove to Blockbuster Video stores to rent movies, and there was a store in almost every town. Today, streaming has replaced rental of physical media, and there is only

one Blockbuster Video store left (1). Companies that do not adapt to new technology are vulnerable, no matter how dominant they seem in the moment. Like Blockbuster facing Netflix, today’s EMRs may be approaching their own moment of disruption.

To understand where we are headed, it helps to understand where we have been. EMR programs have been growing and evolving for decades, and since much of that growth occurred while fee-for-service medicine was the dominant payment model, they are optimized for that function. In 2003, the US Department of Health and Human Services asked the Institute of Medicine to provide guidance on what

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recommend the field of nephrology, but that number has grown to 90% of fellows overall in 2025. "We've done a fantastic job improving how nephrology is perceived and educating and treating our fellows in such a way that they enjoy our specialty," Hoover said. He explained that it is critical because the fellows are often the key "salespeople" who encourage medical trainees to choose nephrology.

That improved satisfaction may help explain how the field has bounced back from a dramatic dip in the number of fellows—from more than 900 fellows to just over 800 from 2014 to 2015, with a rebound to approximately 865 in 2022. Hoover noted that the number of nephrology fellowship training programs also experienced a dip in the early 2000s but has since leveled off to about the same level as in 1991, with 150 programs in 2022.

There are currently approximately 12,000 practicing nephrologists in the United States, up from about 7550 in 2008, Hoover said. There are currently about 3.6 nephrologists per 100,000 people in the United States, an increase from 2.5 per 100,000 in 2008, helping the field keep up with rising rates of kidney failure, he said.

ASN Workforce and Training Committee 2026 Chair (member and vice chair in 2025) Ursula Brewster, MD, FASN, noted that people living with kidney diseases, however, have become more complex, increasing the demands on the existing workforce. It has also remained a challenge to recruit people to the field. Brewster noted that only 58% of nephrology training slots were filled in the Match, and only 73% were filled on Match Day. Thirty-six percent of those positions were filled by international medical graduates. "The most recent attacks on visas need to give us all pause," she said. "So far [in 2025], it is not necessarily a rosier picture."

The workforce's demographics still do not match the patient population. Hoover explained that 30% to 35% of people living with kidney failure are African American, despite these individuals making up 13% of the US population. Yet, only 6% of practicing nephrologists are African American. Hispanic practicing nephrologists are also under-represented. Having a workforce that is representative of the patient population is important, Hoover noted, because the evidence shows that having greater representation of race- and ethnicity-concordant physicians leads to better patient outcomes (2). He explained that having physicians who are the same race or ethnicity on the team helps build patient trust.

Yet, boosting diversity in the field could pose a challenge in the current political and policy environment, Hoover said. "There is an attack on the words themselves," he said. "Diversity, equity, inclusion, disparities—we cannot even use those words anymore."

Hoover explained that offices devoted to diversity, equity, and inclusion have been renamed, and the words have been removed from grants. In some cases, alternative words are being substituted to describe the necessary work. Additionally, grant funding for research on disparities has been canceled. "You have to work harder, you have to work better, you have to work smarter to overcome that loss," he said.

Women have finally achieved parity in medical school graduations, Brewster noted. However, internal medicine still lags in the number of women entering the field. There are also increasing numbers of women graduating from osteopathic schools, although parity has not yet been reached. She noted that although US medical graduates still make up the majority of internal medicine residents, osteopathic school graduates are making up a

growing share and may be another potential talent pool for nephrology. "[It's] an exciting trend [that] ASN has been trying to work with and capitalize on," Brewster expressed. She said the field is also continuing to recruit women to achieve parity.

Nephrology has come closer to salary parity between men and women, with men and women earning comparable wages per hour worked, Hoover noted. Women's salaries remain lower when hours are not calculated, which may reflect more women opting for reduced hours, he said. "We've done a good job in compensation equity."

Workforce headwinds

Despite some positive workforce trends, the field of nephrology is still facing recruitment challenges due to perceived salaries and a shifting immigration policy landscape. "There are perceptions among medical students and internal medicine students that nephrologists do not make money, that we are working hard and getting very little money for that work," Hoover said.

That is an important consideration, especially for US medical graduates who have an average of \$250,000 in student loan debt and may need substantial salaries to repay it, Hoover noted. That is less of a concern for international medical graduates, who have, on average, \$40,000 in student debt, he said.

"Importantly, we make more than hospitalists, even though [we] might have a similar salary coming out of fellowship," he said. Hoover noted that ASN continues to advocate for better compensation for nephrologists to help further boost the field.

Concern is also growing about the potential impact of new and proposed visa policies on the nephrology workforce. Brewster noted that 25% to 30% of nephrology fellows are currently on a J-1 visa, and 10% of nephrology fellows are on an H-1B visa.

Recent changes in federal policies include a previously unexpected month-long pause on J-1 visa interviews that occurred in May 2025 and a proposed \$100,000 employer filing fee for each H-1B visa application for a new hire. Brewster noted that there is a lot of uncertainty about how the proposed fee would affect current trainees and health care institutions and that more than 57 major medical organizations, including ASN, wrote to the Department of Homeland Security Secretary Kristi Noem urging her not to adopt the proposal (3). ASN Immediate Past President Prabir Roy-Chaudhury, MD, PhD, FASN, also wrote a separate letter while president to Secretary Noem urging against the proposed changes to the H-1B visa process (4).

"There has been a tremendous amount of pushback against this current chaotic plan," Brewster said. "There will be a massive health care crisis if this continues this way; particularly in jeopardy are going to be those hospitals that are in rural or underserved areas that really very much rely on H-1B visa workers."

There is also a proposal to cut the duration of J-1 visas. Currently, medical trainees can stay for the duration of their training from residency through fellowship. The proposal would cap the duration at 4 years or at the end of the training program, whichever comes first. That would require nephrology trainees to leave the country after 1 year of training, Brewster explained. They would have a 30-day grace period to return home after their visa expired, and then they could reapply or renew it. She said the disruption to training, patient care, and trainees' lives and career trajectories would be "absolutely devastating." Brewster noted that medical organizations are also opposing this proposal. "For fellowship programs and for trainees, there are a lot of unknowns out there," she said. "The mental health of our workforce has become an increasingly major concern because of these added stressors."

New standards and strategies

Brewster and other speakers also highlighted shifts in nephrology training standards, the growing roles of advanced practitioners in training and support, and the emerging use of AI in kidney care education. The emergence of new therapies and subspecialties in nephrology is creating both exciting opportunities and new challenges for training programs, according to Brewster. "The amount of knowledge we have to instill in them is expanding," she said.

Brewster noted that the American Board of Internal Medicine has changed its procedural competence requirements for nephrology trainees. The new standards require competency in acute and chronic hemodialysis, continual renal replacement therapy, and peritoneal dialysis. Trainees must also be provided an opportunity to learn about the placement of temporary vascular access, percutaneous kidney biopsies, and home dialysis, but it is up to the trainees to determine what they will pursue. "Some of these changes alleviated pressure points on the training programs, and some of them have created some other ones," Brewster said.

She explained that it has relieved some of the pressure on programs by reducing overall requirements, but she noted that smaller programs may have challenges meeting the requirement that a fellow attend at least eight peritoneal dialysis clinics and engage with multidisciplinary

"We've done a fantastic job improving how nephrology is perceived and educating and treating our fellows in such a way that they enjoy our specialty."

But the perception of low nephrology salaries does not always match reality. He noted that much salary data are based on the first year after fellowship, when both nephrologists and hospitalists may earn approximately \$240,000. But that fails to account for salary growth for nephrologists when they become partners in a practice or directors of a dialysis program. Such a promotion can boost their salary to a median of \$300,000, offering more salary growth opportunities than becoming a hospitalist, Hoover said. That places nephrologists' salaries in the middle range for specialists: lower than cardiologists' and gastroenterologists' salaries, roughly even with salaries of pulmonologists, but higher than endocrinologists' and geriatricians' salaries.

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staff during those trainings. ASN has created the Home Dialysis Scholarship program, a virtual education series, a home dialysis resource library, and Centers for Excellence in Home Dialysis to help support programs and trainees in meeting these requirements, she said.

ASN is also developing a framework to enhance competency-based training and allow trainees to individualize their career pathways, Brewster said. She explained that all programs would be required to meet current Accreditation Council for Graduate Medical Education requirements for essential competencies, but programs would also have the option to provide individualized competencies for subdisciplines such as glomerular disease. Fellows would also have the option to extend their fellowship for 1 year to complete a subspecialty, such as home dialysis or transplant. Brewster said that would allow programs to specialize in offering subdisciplines or subspecialties that align with their strengths.

Michelle Lard, APRN, RN, the advanced practice provider manager for the Department of Kidney Medicine at the Cleveland Clinic in Ohio, described the growing roles for advanced practice clinicians in nephrology training programs. She explained that advanced practice clinicians work alongside nephrologists in both inpatient services and outpatient clinics and help fill gaps, and they contribute to training and evaluating fellows in some skills in her department.

"It helps us decompress our staff and fellows' workloads," Lard said. It has helped improve wellness and work-life balance on the team and has helped the program recruit trainees, keeping it 100% filled, she said. The advanced practice clinicians help orient the fellows and train them on workflows. Working with advanced practice clinicians in multidisciplinary teams also helps the fellows develop interpersonal and communication skills and learn how to work in a team setting. She noted that integrating advanced practice clinicians into the program has improved patient safety and satisfaction, increased practice revenue, and reduced clinician burnout.

Jing Miao, MD, PhD, FASN, associate professor of medicine in the Division of Nephrology and Hypertension at the Mayo Clinic in Minnesota, discussed how the Mayo Clinic Nephrology Fellowship program has integrated AI tools into its training program. She highlighted the use of large language models to provide research summaries or generate discussion points for journal clubs, in curriculum development, and to support nephrologists' decision-making. "AI in health care and education isn't just a trend; it is becoming a necessity, especially with the rising burden of kidney disease[s] and the shortage of nephrologists," Miao said.

Miao noted that research suggests that as many as one in four nephrologists is experiencing burnout due to heavy workloads and overwhelming documentation. However, AI can potentially help reduce burnout by streamlining documentation and workflows and handling some administrative tasks. "By taking on these repetitive responsibilities, AI allows physicians to spend less time on paperwork but more time caring for patients and engaging meaningfully in clinical care," she said. She noted that ASN launched an AI-Powered Kidney Care Network in March 2025 to help develop kidney care-focused AI solutions.

But Miao also emphasized the importance of maintaining clinician oversight of any AI tools and of being mindful of their limitations. "In nephrology, AI holds great promise, but we must also consider limitations and the challenges, like

accuracy, hallucination, hidden biases, and the concerns with data privacy," she said. "That's why AI should support, not replace, health care professionals."

Brewster closed the talk by urging nephrologists to continue supporting each other and their teams during this time of great uncertainty and opportunity. "There is expanding science, and new treatments [for kidney diseases] offer a lot of new hope..." Brewster said. "We are innovating educational systems, and AI is allowing young physicians great opportunities to excel, to do something different, to be able to change things up." ■

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key capabilities should be included in an EMR. Read 23 years later, its report (2) holds up well. The authors delineated what they thought were key functions, as well as what they would like to see develop by 2010 (Table).

EMR current state

Although the Institute of Medicine's guidance did note that future capabilities in the EMR depended on good data architecture, subsequent EMR growth did not prioritize data hygiene. Instead, currently, there is a continued reliance on faxes and scans to convey information between disparate systems. Free text entry still cannot be automatically converted into discrete data fields. The systems still demand physician time and attention to characterize and sort data, such as diagnostic codes and medication orders.

Our current EMRs are well suited for fee-for-service medicine. They excel as repositories of information, dating back years, in which the clinician can search at their leisure. Fee-for-service care is reactive, occurring when the patient comes in for an encounter, and the EMR is able to passively serve up information at that time. Since billing is based on documentation, current EMRs offer facilitation of templated notes that capture all required elements, even at the expense of conciseness and readability. They also link to databases of both diagnostic and evaluation codes, so that the clinician can carry out coding and billing during or after the patient visit, and they allow seamless transmission of

orders to pharmacies and laboratories, as long as they are connected to the system that the physician is using.

With the shift to value-based care (VBC), however, shortcomings of current EMRs become apparent. VBC relies on population-level management, as well as the ability to analyze practice patterns to drive physician development. Consider the Johns Hopkins Patient Insight tool, which demonstrates how EMR data can drive quality improvement (3). The score tracks a number of quality metrics for people with chronic kidney disease, including whether they have had an albumin-creatinine ratio checked, along with blood pressure control, appropriate use of guideline-directed medical therapy, major events including hospitalizations and emergency department visits, and appropriate nephrology referrals. The Hopkins team aims to provide timely analysis for both the physician and patient to drive better care. An affiliated practice can create a report of its individual physician scores and compare it with its peers in endocrinology or primary care. It is the kind of insight that exemplifies the potential of AI set loose on the data-rich environment of modern health care.

Given the potential to improve outcomes, it is problematic that many current EMRs do not easily allow the creation of custom analytics such as the one developed at Johns Hopkins. Furthermore, the Hopkins dashboard cannot be easily transferred to other systems using the same EMR program, since each system's version is structured a little differently. The information technology investments required for each health system to replicate the dashboard are substantial. Although the nation's population could benefit from advanced analytics, forcing each hospital or clinic to shoulder the entire cost and effort of creating its own from scratch is a significant barrier. This scenario, repeated across hundreds of different optimization and improvement projects, represents an enormous drain on resources in an already strained health care system.

With the rapid development of AI, a host of companies are seeking to provide AI-powered enhancements to the current EMRs. Their services range from scribes to generate notes during the encounter to risk calculators to identify patients in need of prophylactic intervention or increased attention. Allowing the market to develop solutions will ensure that services provide adequate return on investment, for example, in enhanced clinician productivity or improved patient outcomes in a VBC model. A common underlying data architecture would be expected to decrease the cost of implementation, ensuring that patients widely can benefit from the best innovations. As long as implementation must be customized at great expense, AI care facilitation will remain sequestered in health care systems that can shoulder the upfront investment costs with hopes of later returns.

Barriers to EMR evolution

Existing EMRs currently have enormous legacy advantages. The cost of changing an EMR can be daunting (4). Planning and execution costs are substantial, whether performed in-house or hired out to contractors. Clinical operations are disrupted during the transition, and care can be compromised if data are lost between the old system and the new. Staff experience significant stress as they relearn workflows that touch almost every aspect of their daily duties. The costs of switching keep health care systems locked into their EMR, even if they find it lacking capabilities as practice evolves.

Market consolidation is occurring in the EMRs that serve large health care systems. As of January 2025, Epic commanded 42.3% of the acute care market in the United States, whereas the market share for Oracle Health (which purchased Cerner) fell slightly to 22.9% (5). However, society is not realizing the true potential of economies of scale related to this consolidation. EMRs are supposed to be interoperable (6), but so far, they have fallen far short of

Table. Key functionality of an EMR as defined in 2003

| Function | Comments from the Institute of Medicine |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Health information and data | Structure and coding derived from narrative data were targeted for 2010. |
| Results management | The focus was on getting test results to clinicians in a timely fashion. |
| Decision support management | There were mostly alerts about health care maintenance but also noted were early results of “artificial neural networks” improving diagnostic accuracy for certain conditions including breast cancer, myocardial infarction, and disease outbreaks. |
| Electronic communication and connectivity | It suggested “[both] within a setting and across settings and institutions,” but it included nothing specific about different EMRs “talking” to each other. |
| Patient support | It included education and also home monitoring, but it did not discuss patients seeing their own data. |
| Administrative processes | It specifically mentioned billing and coding, with the (perhaps optimistic) view that EMRs could avoid delays from “authorizations and prior approvals.” |
| Reporting and population health | It highlighted the importance of dashboards for clinical quality measures and that data would need to be reported with “standardized terminology and in machine readable format.” |

Twenty-three years later, many of these aspirational goals remain unmet, particularly in nephrology, in which complex care coordination across dialysis units, transplant centers, and primary care remains challenging.

seamless exchanges. This limits the sharing of innovation, as described earlier, even between two instances of the same EMR. A unified data architecture structure, common to all EMRs, would make it far easier for one system to adopt an analytics model developed elsewhere. Some specialties have already started to move toward a standardized data model and common ontology to facilitate interoperability (7).

Policy to assist EMR development

As our ability to extract insights from large databases continues to grow and as compensation models continue to move toward VBC, we will require new capabilities in our EMRs. The current market state contributes to costly and duplicative efforts to build modern analytics into programs that were not built to support them. Health care is too important to the nation’s economy and to the population to miss out on the potential advances that could be unlocked by improved data analytics. Policy solutions are therefore indicated to facilitate efficient investment and deployment for all patients’ benefit.

Currently, much of the policy around the sharing of health information across systems is driven by the 21st Century Cures Act (“the Cures Act”), which mandated the use of a specific data exchange standard called Fast Healthcare Interoperability Resources (FHIR) (8). FHIR was developed by an international standards organization called Health Level Seven International (HL7) (9). FHIR includes standards for discrete data elements, termed resources, that include meaningful categories such as laboratory results or patient demographics. FHIR also standardizes the exchange of information using pre-existing frameworks called application programming interfaces (10). By mandating the use of FHIR, Congress tried to ensure that patients could access their own data about their health.

Although FHIR represents progress toward standardization of data, there are still significant gaps. The US Core Data for Interoperability lists the types of information that must be categorized by FHIR standards (11), but the list is far from comprehensive. EMRs have their own legacy data structures, including past HL7 frameworks, and conversion to FHIR is projected to take years or even decades (12). In the meantime, there is a variety of different strategies to convert health care data to FHIR on demand, but the conversion process always risks imperfect results. All of these changes to how data are stored and characterized take money to implement. The Cures Act did not provide any funding to help EMR companies or their customers make the change. Vendors are able to pass on costs of upgrades to their customers as long as they are “not excessive,” although that cost threshold is not defined. Providing funding, for example, through low-cost loans, grants, or incentive payments would help rebuild the nation’s fragmented health care data into a format that supports next-level analytics and AI-driven insights.

The Center for Medicare and Medicaid Innovation, which develops VBC payment models, could start collecting data on information technology costs associated with the delivery of care within their models. Private companies will be reluctant to divulge details of their operating expenses, but with guardrails around deidentification, this information can help guide future policy decisions. The Centers for Medicare & Medicaid Services could also make claims data available to those participating in VBC pilots in a more timely fashion and shift toward using a common data architecture. Finally, as EMRs continue to meet certification requirements, future levels of certification could include mandates around data architecture, shareability of analytic algorithms, and less reliance on manual entry of discrete data points.

As we stand at this potential Blockbuster moment for EMRs, the nephrology community must advocate for system changes that truly serve our patients’ complex needs. Our existing EMR systems are built on large and complex legacy systems that have not been updated to capture new AI-driven capabilities. Wholesale change is required, but right now, the cost burdens are inefficiently allocated, while each customer invests in creating workarounds. We would all benefit from strong federal policy to update standards, allow true interoperability, and level the playing field for outstanding innovators to win customers.

Netflix used the new innovation of the internet to improve the way people rented movies and in doing so, drove the Blockbuster behemoth out of business. Similarly, the next generation of EMRs must reimagine how we capture, analyze, and act on clinical information. Policy must make room in the marketplace for new innovations to thrive. For nephrology, this evolution cannot come soon enough. ■

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ASN Executive Vice President's Update

CKM Syndrome, a New Superspecialty, and the Love Your Kidneys! Campaign

By Tod Ibrahim

<https://doi.org/10.62716/kn.002922026>



Kidney diseases are “very [underrepresented] in the news” (1). The media covers kidney diseases an estimated six times less often than the number of Americans who die annually from kidney failure. By comparison, the media reports on homicides and terrorism 43 times and 18,000 times more often, respectively, than the number of Americans killed annually from either. Clearly, part of the challenge with media attention is that “we’re much more likely to click on a news story about the latest murder or disaster than one about heart or kidney disease,” which are among the top 10 leading causes of death in the United States (1).

Even among illnesses, kidney diseases trail Alzheimer disease, diabetes, and influenza in media coverage. Why has the kidney community struggled to raise awareness about kidney diseases or increase interest in the importance of kidney health? In February 2013, Bruce Skyer—then the chief executive officer of the National Kidney Foundation (NKF)—shared three reasons with *The New York Times*: “Among those at risk, and those who actually have the disease, their knowledge is very low...”; “...the kidney is a difficult organ to understand”; and “...kidney disease is called a [comorbidity], because its two leading causes are diabetes and high blood pressure” (2).

The connection to diabetes, high blood pressure, and cardiovascular diseases now offers an opportunity to raise awareness about and increase interest in kidney health. The American Heart Association (AHA) issued a presidential advisory in October 2023 on cardiovascular-kidney-metabolic (CKM) syndrome, advocating for “a multifaceted, concerted and patient-centered effort involving multilevel partnerships among clinical entities, policymakers, [payors], and numerous stakeholders, as well as the enhancement of education and research related to CKM syndrome” (3).

Given the attention to heart and metabolic diseases, kidney health is the largest unmet need in CKM syndrome. The current strategies largely focus on identifying kidney diseases after a cardiovascular risk is diagnosed. AHA’s emphasis on CKM syndrome provides ASN and the kidney community an opportunity to elevate the importance of kidney health and possibly even to prevent kidney diseases in the future.

According to AHA, this effort “will also necessitate changes to clinical workflows, care team composition, insurance coverage and reimbursement strategies to support interdisciplinary care, integrated obesity management, consideration of [social determinants of health] and equitable access to pharmacotherapies, and application of proven strategies to support implementation of CKM guidance within and across health centers” (3).

Since October 2023, ASN has been a proud collaborator of AHA’s CKM Health Initiative, along with other members of the kidney community—particularly the American Kidney Fund (AKF) and NKF (4). This 4-year effort includes partnering

with more than 150 sites across 15 regions to improve clinical practice, certify centers of excellence, produce resources for health professionals (including nephrologists), provide educational material for both health professionals and the public, and attempt to incorporate CKM factors into the Predicting Risk of Cardiovascular Disease EVENTS (PREVENT) risk calculator.

ASN has also embraced this opportunity to save kidneys, hearts, and lives. Cosponsored by AHA, ASN held a workshop in March 2025 to bring together diverse stakeholders, including nephrologists and other health professionals, across academic and community-based backgrounds; researchers; and people living with kidney diseases. The workshop helped focus ASN’s goals in this arena on:

- ▶ improving care for people living with kidney diseases and CKM conditions;
- ▶ strengthening research across the CKM health continuum;
- ▶ invigorating the workforce by upgrading health professional, graduate, and continuing education in nephrology;
- ▶ overcoming policy and financial hurdles by promoting legislative and regulatory priorities for the kidney community;
- ▶ supporting collaborative guidelines to sustain coordinated care of CKM conditions; and
- ▶ promoting the centrality of the kidney in CKM health by changes in terminology and communications about CKM health.

Additionally, AHA, jointly with the American College of Cardiology, will publish a clinical practice guideline on CKM syndrome this year, and ASN plans to issue kidney health guidance on the kidney-specific aspects of this syndrome during the summer.

In December 2025, the Centers for Medicare & Medicaid Services Innovation Center invited ASN to participate in the unveiling of the Advancing Chronic Care With Effective, Scalable Solutions (ACCESS) model (5). This 10-year voluntary model relies on outcome-aligned payments for technology-enabled chronic care prevention and management within the original Medicare system. With two of its four clinical tracks focused on CKM syndrome, ACCESS is intended to replace traditional fee-for-service billing with fixed payments tied directly to measurable clinical outcomes.

The excitement around CKM syndrome provides ASN and the rest of the kidney community with at least two opportunities.

First, the kidney community should use CKM to raise awareness about and increase interest in kidney health. This is the time to overcome the triad identified by the former NKF chief executive officer (Mr. Skyer) of low knowledge among those most at risk; poor lexicon and messaging; and tricky connections to diabetes, high blood pressure, and cardiovascular diseases.

The kidney community should own the media landscape between Valentine’s Day (February 14)—which is also National Donor Day—and World Kidney Day (March 12). During that month, we should convince the public, the press, policymakers, and primary care clinicians to Love Your Kidneys! and promote this new campaign.

For this campaign to succeed, the kidney community should pursue the following five initiatives:

- 1 Partner with the American Diabetes Association (ADA), AHA, and Breakthrough Type 1D (BT1D) to broadcast Love Your Kidneys! on all available channels. As illustrated in Table 1, these three voluntary health organizations (also called patient groups) have the financial resources needed to raise awareness about and increase interest in kidney health (6).
- 2 Join forces with the National Basketball Association (NBA) in a promotional effort similar to the National Football League’s “Crucial Catch” initiative, in which players, coaches, and stadium fans wear pink and other colors in October to promote early cancer detection and raise money for research, primarily partnering with the American Cancer Society (7). The NBA All-Star Game often takes place between Valentine’s Day and World Kidney Day (this year, it’s on February 15), which is perfect timing to celebrate former NBA greats who have undergone kidney transplant like Sean Elliott, Alonzo Mourning, and most recently Nate Robinson.
- 3 Use the final report from the Transforming Kidney Health Research Blue Ribbon Panel to accelerate discovery, early detection, prevention, and new therapies (8). In partnership with the American Association of Kidney Patients (AAKP), AKF, the American Society of Pediatric Nephrology, and NKF, ASN in 2025 issued recommendations to improve kidney health through greater federal funding (\$1.8 billion annually) for kidney research. As demonstrated in Table 2, current funding from the National Institutes of Health (NIH) for kidney research is much less than for research into cardiovascular diseases or diabetes (9).

Table 1. Total assets as reported on Internal Revenue Service form 990^a

| Organization | Specialty | Total assets |
|-----------------------------------------|---------------|------------------------|
| American Association of Kidney Patients | Nephrology | \$4,327,398 |
| American Diabetes Association | Endocrinology | \$231,397,688 |
| American Heart Association | Cardiology | \$1,926,864,938 |
| American Kidney Fund | Nephrology | \$175,543,171 |
| Breakthrough Type 1D | Endocrinology | \$488,117,647 |
| KidneyCure | Nephrology | \$59,012,612 |
| National Kidney Foundation | Nephrology | \$52,473,755 |
| Total | | \$2,937,737,209 |

^aMost current data publicly available (fiscal year [FY] 2023 or FY 2024) (6).

Table 2. Total NIH funding in FY 2024

| Disease | Total NIH funding (rounded) |
|----------------|-----------------------------|
| Cardiovascular | \$2,589,000,000 |
| Diabetes | \$1,036,000,000 |
| Kidney | \$703,000,000 |
| Total | \$4,328,000,000 |

Summarized from NIH (9).

- 4 Screen every member of Congress for kidney diseases (and perhaps even the US president and cabinet secretaries). A total of 535 members serve in the House of Representatives and the Senate. Conservatively, more than 50 of these legislators may have kidney diseases, but many of them may not know it, just like the 9 out of 10 Americans living with kidney diseases who do not know they are at risk for kidney failure (10). Recently, Former Representative Donald M. Payne, Jr. (D-NJ)—“a true kidney warrior”—died of kidney failure (11).
- 5 Incentivize further innovation through prize competitions like KidneyX (Kidney Innovation Accelerator), a public-private partnership between the US Department of Health and Human Services and ASN to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases (12).

These steps are the beginning of a much larger vision. Each year, ASN, KidneyCure (the ASN Foundation for Kidney Research), and the rest of the kidney community—particularly patient groups such as AAKP, AKF, and NKF—should build on the incredible stature, media platforms, and resources of ADA, AHA, and BT1D to raise awareness about kidney diseases and to increase interest in the importance of kidney health as a key component of CKM syndrome. The month between Valentine’s Day and World Kidney Day presents a unique opportunity for the Love Your Kidneys! campaign.

The second opportunity involves using CKM syndrome to reposition the specialty of nephrology. CKM syndrome has the potential to evolve into the first “superspecialty” in the modern history of medicine, pulling together the talents of cardiologists, nephrologists, and endocrinologists, as well as, potentially, hepatologists (if CKM expands to include liver diseases) and other specialists. Like musical “supergroups”—such as Cream, Traveling Wilburys, and Temple of the Dog—this new superspecialty could redefine how we consider medical specialties today and in the future (13).

During the past 50 years, the American Board of Medical Specialties has added two new specialties (emergency medicine in 1979 and medical genetics and genomics in 1991) (14). Since 1987, the American Board of Internal Medicine has used “added qualifications,” “focused practice,” and certification to add more than 10 new subspecialties, including critical care medicine (added qualifications in 1987 and certification in 2006), hospital medicine (focused practice in 2010), and adult congenital heart disease (certification in 2015) (15). These new specialties and subspecialties are either defined by the location of practice (e.g., emergency and hospital medicine) or seceded from existing specialties (e.g., critical cardiac electrophysiology or transplant hepatology).

A new superspecialty focused on saving kidneys, hearts, and lives has the potential to transform kidney care by shifting the focus from kidney failure to prevention and early kidney care intervention, ultimately improving the lives of people living with kidney diseases. By demonstrating value and generating excitement, a new superspecialty would also appeal to future generations of physicians and other health professionals.

Together, the Love Your Kidneys! campaign and new superspecialty would raise awareness about kidney diseases, increase interest in the importance of kidney health, and reposition nephrology as a specialty and key part of a larger, collaborative superspecialty. More

importantly, these initiatives would improve the lives of more than 850 million people worldwide living with kidney diseases, including 37 million Americans. ■

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Kidney News Business Round-Ups

Bringing together the key commercial activities shaping kidney care



Read more: <https://www.kidneynews.org/page/special-series-business> and on pages 10–11 of this issue.

Atacicept in IgA Nephropathy: Analysis of the Interim Phase 3 Data

By Ayman Al Jundi

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There has long been an unmet need for better treatments in immunoglobulin A nephropathy (IgAN). This became more of a concern when we realized that even people with IgAN and less than 1 g/g of proteinuria still have a significant long-term risk of kidney failure (1). Because of that, we have been awaiting the approval of effective disease-modifying treatments for IgAN. One of the most exciting treatment options is atacicept, which is a human transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI)-Fc fusion protein. Atacicept binds the cytokines B cell activating factor (BAFF) and a proliferation-inducing ligand (APRIL), preventing them from interacting with their receptors on B cells. The result of that is reduced IgA class-switching, reduced plasma cell survival, and therefore a decrease in the levels of galactose-deficient IgA1 (2–5).

A prespecified interim analysis of a phase 3 clinical trial for atacicept (Atacicept in Subjects With IgA Nephropathy [ORIGIN 3]) was recently published (6). ORIGIN 3 is a multicenter, double-blind, randomized clinical trial that randomized people with IgAN to receive atacicept or placebo in a 1:1 ratio. The main inclusion criteria were: aged ≥ 18 years, urine protein-to-creatinine ratio (UPCR) ≥ 1.0 g/g, and estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m². Individuals with secondary IgAN and those with rapidly progressive glomerulonephritis were excluded. The primary endpoint for this interim analysis was the percentage change in proteinuria at week 36 compared with baseline. Proteinuria was assessed as the UPCR from a 24-hour urine collection.

There were 203 individuals included in the interim analysis. The groups were balanced overall. On average, the trial participants were 40 years old, 2.5 years out from biopsy, with an eGFR of approximately 65 mL/min/1.73 m² and a UPCR of 1.7–1.8 g/g. Almost all participants were treated with a maximum-tolerated dose of a renin-angiotensin system inhibitor, and half were treated with a sodium-glucose cotransporter-2 inhibitor. Here is the punch line: The average percent

reduction in the 24-hour UPCR was 45.7% in the atacicept group versus 6.8% in the placebo group. The geometric mean between-group difference was 41.8%, which was statistically significant and is clinically significant. In individuals with baseline hematuria, hematuria resolved in 81.0% and 20.7% of individuals in the atacicept and placebo groups, respectively.

These are impressive results. We need to see how these will translate into an eGFR slope difference at 2 years. It would be surprising if they did not. It would be interesting to know if the baseline levels of or the magnitude of reduction in galactose-deficient IgA1, which occurs quickly after treatment, can predict future UPCR and eGFR responses to atacicept and other APRIL/BAFF inhibitors. This needs to be investigated further.

Now, let us talk about safety. Adverse events were similar between the two groups and were mostly mild to moderate. Injection-site reactions were more common in the atacicept group. There was no signal for a difference in infection risk with short-term use of atacicept, but whether there is a difference with long-term use is not yet known. The decrease in IgG levels is not insignificant (35.5% at 36 weeks), and people treated with atacicept should likely have IgG levels checked periodically to monitor for hypogammaglobulinemia. We will need to investigate the impact of long-term atacicept use on infectious risk and on vaccine responses, especially since this is likely to be used long term. Will the dosing and frequency be fixed throughout treatment? Or could there be a higher induction dose/frequency and a lower maintenance dose/frequency, as we see with some other immunosuppressive therapies (7–9)? Could the dose or frequency be adjusted if hypogammaglobulinemia develops?

In summary, the interim analysis of ORIGIN 3 showed significant improvements in proteinuria and microscopic hematuria, comparable with sibireprenlimab (10). Although the relative reduction in proteinuria compared with placebo was numerically higher in the sibireprenlimab trial than the atacicept trial, that cannot be interpreted as sibireprenlimab being more effective

than atacicept. These were separate trials and had groups with differences in baseline characteristics, such as baseline proteinuria. The best way to compare the two medications would be a head-to-head trial, which is unlikely to be done, or more realistically with well-designed real-world studies after approval.

If durability and safety of atacicept for IgAN are confirmed in the final analysis, atacicept may reshape the therapeutic backbone of IgAN management. It is very exciting to have more options for people living with IgAN. ■

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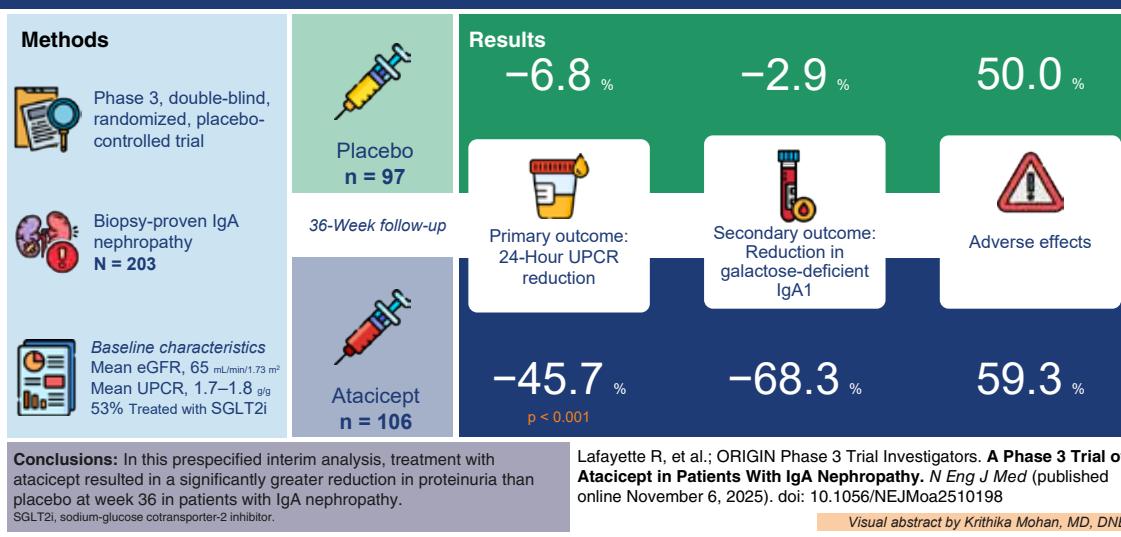
The author reports no conflicts of interest.

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ORIGIN 3 trial: Does atacicept reduce proteinuria in patients with IgA nephropathy?

KidneyNews



Fish Oil Supplements Put to the Test in Patients at High Risk on Dialysis

By Rebecca Lightman, Greg Garsuta, and Hassan Mahmoud

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According to a recently published study in *The New England Journal of Medicine*, fatty acid supplementation in patients on maintenance hemodialysis (HD) is associated with fewer serious cardiovascular events compared with placebo (1).

Cardiovascular disease remains the dominant cause of death for people receiving HD, with a 10- to 20-fold higher risk of cardiovascular mortality than the general population (2, 3). There is evidence that supplementation with n-3 omega fatty acids may be associated with cardiovascular benefit in the general population. However, blood levels of these fatty acids are generally lower in patients receiving HD (4). A newly published randomized controlled trial, the Protection Against Incidences of Serious Cardiovascular Events Study With Daily Fish Oil Supplementation in Dialysis Patients (PISCES), investigated the effects of n-3 fatty acid supplementation on cardiovascular events specifically within the population undergoing HD (1).

In this double-blind study, 1228 adults receiving maintenance HD, three to four times weekly at 26 sites across Canada and Australia, were randomized to a daily fish oil supplement (4 g containing 1.6 g eicosapentaenoic acid [EPA] and 0.8 g docosahexaenoic acid [DHA]) or corn oil placebo. Patients who were already taking n-3 fatty acid supplements at the time of randomization were excluded. Patients were followed for a median of 3.5 years, and adherence to supplementation was confirmed biochemically through plasma phospholipid measurements.

The primary endpoint of the study was total serious cardiovascular events: cardiac death, myocardial infarction, stroke, and peripheral vascular disease leading to amputation. Among the fish oil group, these events occurred at a rate of 0.31 per 1000 patient-days versus 0.61 in the placebo group (hazard ratio [HR], 0.57 [95% confidence interval, [CI], 0.47–0.70]; $p < 0.001$). Every component of the composite favored fish oil, with HRs clustering between 0.37 and 0.57. Of note, safety profiles were similar between groups; bleeding concerns, which have historically been associated with high-dose n-3s, did not occur more frequently within the fish oil group (4.8%) compared with placebo (7.6%).

Why did this intervention succeed, whereas others have been equivocal? The 4-g dose substantially exceeds the amount commonly available in standard over-the-counter formulations, helping correct the markedly lower n-3 fatty acids seen in patients undergoing dialysis. The authors propose several mechanisms by which the EPA and DHA may protect this specific population:

- ▶ Antiarrhythmic effects: Direct inhibition of cardiomyocyte sodium and calcium currents may stabilize electrical activity, countering the proarrhythmic milieu caused by rapid fluid and electrolyte shifts in HD.
- ▶ Anti-inflammatory action: n-3 Fatty acids may mitigate the distinct proinflammatory profile of kidney failure.
- ▶ Cardiovascular remodeling and antithrombotic effects: Potential benefits include favorable vascular remodeling and antithrombotic effects without a significant increase in bleeding risk.



- ▶ Lipid modulation: High-dose supplementation exerts beneficial antilipid effects, thus improving the metabolic profile.

The PISCES trial was well-designed overall, although a notable limitation to the generalizability of these results is the exclusion of patients on peritoneal dialysis or who no longer require HD treatments due to kidney transplantation. Additionally, less than 60% of the PISCES participants were being treated with statins, which may have amplified the apparent benefit of fish oil supplementation. Despite these limitations, the clinical implications of this trial are substantial. Of course, it is essential that these results prove replicable in future studies. Furthermore, real-world patient barriers should also be considered, as increasing pill burden can be frustrating and negatively affect adherence.

Although replication of these results would be ideal, a trial of this magnitude may take years to reproduce. Given the profound risk reduction and the reassuring safety profile demonstrated in the PISCES trial, it is difficult to justify waiting to change clinical practices. Clinicians may consider recommending this high-dose fish oil formulation to eligible patients receiving maintenance HD, using shared decision-making to navigate safety, costs, and adherence. ■

Rebecca Lightman, MD, and Greg Garsuta, DO, internal medicine residents, and Hassan Mahmoud, MD, are with the Division of Nephrology and Transplantation, Maine Medical Center, Portland.

The authors report no conflicts of interest.

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Fish oil and cardiovascular events in patients receiving hemodialysis

KidneyNews

| RANDOMIZATION | Cardiovascular events (PRIMARY ENDPOINT) | | Noncardiac death (SECONDARY ENDPOINT) |
|---------------|--------------------------------------------------------------------|--------------------------------------|---------------------------------------|
| | Fish oil 4 g of n-3 PUFA (1.6 g EPA 0.8 g DHA) n = 610 | Corn oil (placebo) n = 618 | per 1000 patient-days |
| | 0.31 per 1000 patient-days | 0.52 per 1000 patient-days | |
| | HR, 0.57 95% CI, 0.47–0.70 | HR, 0.77 95% CI, 0.65–0.90 | |
| | 0.61 per 1000 patient-days | 0.76 per 1000 patient-days | |

Conclusions: The rate of serious cardiovascular events among participants receiving maintenance hemodialysis was lower with daily supplementation with n-3 fatty acids than with placebo. PUFA, polyunsaturated fatty acid.

Lok CE et al., PISCES Investigators. Fish-Oil Supplementation and Cardiovascular Events in Patients Receiving Hemodialysis. *N Engl J Med* 2026; 394:128–137. doi: 10.1056/NEJMoa2513032

Visual Abstract by Edgar Lerma, MD, FASN

Business Round-Up: Q3–Q4 2025 Activity in the Nephrology Industry

By Melissa West

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Twice a year, *Kidney News* publishes a high-level review of US Food and Drug Administration (FDA) regulatory approvals, scientific results from industry, investments, and mergers and acquisitions to ensure the ASN membership is well-informed.

More than 500 data points, collected from July 1 to December 31, 2025, generated the following analysis and summaries.

The commitment of researchers, industry, clinical trials, and most importantly, patients should be applauded for their efforts to develop innovative diagnostics, drugs, devices, and biologics for people living with kidney diseases. This year begins with three additional drug approvals for the kidney community that occurred in the second half of 2025, and there is a robust pipeline of therapies advancing to commercialization. ASN leadership and staff are monitoring these developments closely to better advocate for implementation strategies that will bring these new therapies to patients.

When this article was written, investors were gathered in San Francisco, CA, for the 44th Annual J.P. Morgan Healthcare Conference. The presence of kidney companies has increased significantly since ASN established the Kidney Health Initiative in 2012 and KidneyX (Kidney Innovation Accelerator) in 2018. Kidney diseases have the attention of investors, thanks to the nephrologists and businesspeople who articulate areas for innovation all along the patient journey, protect kidney health, treat kidney failure and its complications, or ensure a successful transplant. As the past three Business Round-Ups show, investment in kidney-focused companies has grown and diversified since this ongoing series began in 2024, although it continues to trail other areas of medicine.

One area gaining investment focuses on artificial intelligence (AI) in health care. Nearly 10% of ASN's data points, focused on news and media, is concentrated on AI, not because

AI is "trendy" but because it is a significant part of the health care strategy. ASN is concentrating on how AI impacts acute kidney injury, dialysis, chronic kidney disease, transplant, and genetic kidney diseases with new models and approaches. Additionally, ASN wants the workforce to be prepared, competent, and responsible when it comes to integrating new approaches into clinical care. In Q3–Q4 2025, the Center for Medicare and Medicaid Innovation announced a model to test prior authorization, and the White House released an AI Action Plan. Researchers were awarded over \$10 million by the American Heart Association to study the use of AI in cardiovascular disease. AI governance and regulation continued to be discussed, debated, and supported with toolkits and state legislation.

Relationships between non-kidney-specific technology companies and nephrology practices, kidney companies, or health systems are actively being established. To support the kidney community in this regard, ASN launched an online discussion community—the AI-Powered Kidney Care Network—which provides regular posts on notable articles covering AI tools or research. (You can join this community as an ASN member through the ASN Communities page: <https://community asn-online.org/home>. Remember to set your ASN Communities notifications to receive new posts.)

As the business of nephrology evolves, kidney diseases are being discussed more in the public and lay media, which helps to raise awareness. This year, you may notice the news and social media activity related to kidney awareness, supported by patient organizations, foundations, and industry. ASN encourages members to notify their patients and engage with them on the day(s) that may be of interest, including but not limited to:

- ▶ National Kidney Month: Starting March 1
- ▶ World Kidney Day: March 12
- ▶ APO11 [Apolipoprotein 1] Awareness Day: April 28
- ▶ IgAN [Immunoglobulin A Nephropathy] Awareness Day: May 14
- ▶ FSGS [Focal Segmental Glomerulosclerosis] Awareness Day: June 10

ASN continues to be excited about the opportunity to secure a significant voice in the cardiovascular, kidney, and metabolic care landscape. These patients are a part of nephrology practices and centers, and the new therapies provide an opportunity to intervene in kidney diseases earlier. Cell and gene therapy, as well as xenotransplantation, provide an additional opportunity for the business of nephrology to evolve with additional focus on immune-mediated diseases and nephrologists as experts in immunosuppression. Finally, knowledgeable nephrologists are leading the value-based kidney care companies, which will ensure the best kidney outcomes for Americans. ASN continues to engage in policy and advocacy activities as kidney health leaders navigate federal research funding, vaccine recommendations, and drug-pricing strategies. (For the latest information on ASN advocacy and public policy, visit the Kidney Health Advocacy page: <https://www.asn-online.org/policy/kidney-health.aspx>.)

Melissa West is the senior director, Strategic Relations and Patient Engagement at ASN. She previously was the project director for the Kidney Health Initiative. With over 20 years' experience working in the kidney community, Ms. West tracks the trends in business and kidney care for ASN Council and staff. Please contact Ms. West at mwest@asn-online.org to share publicly available information that may have been missed in this article.

Summary: Biologic, drug, and device approvals and label extensions

| Approval | Category | Product | Company | Reference |
|------------------|----------|-------------------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Label extension | Drug | Kerendia (finerenone) | Bayer | Bayer's Kerendia wins FDA label expansion to treat 2 types of heart failure (July 14, 2025). https://www.fiercepharma.com/pharma/bayer-scores-fda-expansion-kerendia-heart-failure |
| Approval | Drug | EMPAVELI® (pegcetacoplan) | Apellis | FDA approves Apellis' EMPAVELI® (pegcetacoplan) as the first C3G and primary IC-MPGN treatment for patients 12 and older (July 28, 2025). https://investors.apellis.com/news-releases/news-release-details/fda-approves-apellis-empavelir-pegcetacoplan-first-c3g-and |
| 510(k) Clearance | Device | Archimedes™ | Simergent | Simergent Archimedes™ PD cycler receives FDA 510(k) clearance (October 7, 2025). https://www.simergent.com/blog/fdaclearance |
| Approval | Drug | Gazyva® (obinutuzumab) | Genentech | FDA approves Genentech's Gazyva for the treatment of lupus nephritis (October 19, 2025). https://www.gen.com/media/press-releases/15085/2025-10-19/fda-approves-genentechs-gazyva-for-the |
| Approval | Drug | VOYXACT® (sibemprelimab-szsi) | Otsuka | Otsuka receives FDA accelerated approval for VOYXACT® (sibemprelimab-szsi) for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression (November 25, 2025). https://www.otsuka-us.com/news/otsuka-receives-fda-accelerated-approval-voyxactr-sibemprelimab-szsi-reduction-proteinuria |
| Oral formulation | Drug | Wegovy® (semaglutide) | Novo Nordisk | Novo Nordisk's Wegovy® pill, the first and only oral GLP-1 for weight loss in adults, now broadly available across America (January 5, 2026; approved December 22, 2025). https://www.prnewswire.com/news-releases/novo-nordisks-wegovy-pill-the-first-and-only-oral-glp-1-for-weight-loss-in-adults-now-broadly-available-across-america-302652205.html |

C3G, complement 3 glomerulopathy; GLP-1, glucagon-like peptide-1; IC-MPGN, immune complex-mediated membranoproliferative glomerulonephritis; PD, peritoneal dialysis.

Do you have an opinion
about a story published
in *Kidney News*?

Email kidneynews@asn-online.org
to submit a brief Letter to the Editor.
Letters will be considered for
publication in an upcoming issue.

Summary: Biologic, drug, and device development

| Approval | Category | Product | Company | Reference |
|------------------------------------------------|--------------|----------------------------------------------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Phase 2 | Cell therapy | Rilparencel | ProKidney | ProKidney reports statistically and clinically significant topline results for the phase 2 RGEN-007 trial evaluating rilparencel in patients with chronic kidney disease and diabetes (July 8, 2025). https://www.globenewswire.com/news-release/2025/07/08/3111596/0/en/ProKidney-Reports-Statistically-and-Clinically-Significant-Topline-Results-for-the-Phase-2-REGEN-007-Trial-Evaluating-Rilparencel-in-Patients-with-Chronic-Kidney-Disease-and-Diabet.html |
| Phase 2 | Drug | Potravitug | Memo Therapeutics | Memo Therapeutics AG announces phase II trial results for potravitug in kidney transplant recipients with BKPyV infection (July 25, 2025). https://memo-therapeutics.com/2025/07/25/memo-therapeutics-ag-announces-phase-ii-trial-results-for-potravitug-in-kidney-transplant-recipients-with-bkpyv-infection/ |
| FDA breakthrough device designation | Device | Room temperature machine perfusion (RTMP) platform | BMI OrganBank | BMI OrganBank® secures FDA breakthrough device designation for innovative kidney transplant technology (August 4, 2025). https://bmiorganbank.com/bmi-organbank-secures-fda-breakthrough-device-designation-for-innovative-kidney-transplant-technology/ |
| Investigational new drug application clearance | Biologic | EGEN-2784 | eGenesis | eGenesis announces IND clearance for EGEN-2784 in kidney transplant and landmark patient updates in ongoing expanded access study (September 8, 2025). https://egenesisbio.com/press-releases/egenesis-announces-ind-clearance-for-egen-2784-in-kidney-transplant-and-landmark-patient-updates-in-ongoing-expanded-access-study/ |
| Phase 1 | Drug | MZE782 | Maze Therapeutics | Maze Therapeutics announces positive first-in-human results from phase 1 trial of MZE782, establishing proof of mechanism for a potent, oral SLC6A19 inhibitor with potential to treat phenylketonuria (PKU) and chronic kidney disease (CKD) (September 11, 2025). https://ir.mazetx.com/news-releases/news-release-details/maze-therapeutics-announces-positive-first-human-results-phase-1 |
| Phase 3 | Biologic | Imlifidase | Hansa Biopharma | Imlifidase successfully meets primary endpoint in pivotal US phase 3 ConfldeS trial in kidney transplantation (September 24, 2025). https://www.hansabiopharma.com/media/press-releases/2025/imlifidase-successfully-meets-primary-endpoint-in-pivotal-us-phase-3-confides-trial-in-kidney-transplantation/ |
| FDA fast track designation | Biologic | ABBV-CLS-628 | Calico Life Sciences | Calico Life Sciences announces U.S. FDA fast track designation for investigational treatment of autosomal dominant polycystic kidney disease (October 2, 2025). https://www.calicolabs.com/press/calico-life-sciences-announces-u-s-fda-fast-track-designation-for-investigational-treatment-of-autosomal-dominant-polycystic-kidney-disease/ |
| Phase 3 | Drug | Fabhalta® (iptacopan) | Novartis | Novartis Fabhalta® (iptacopan) meets phase III primary endpoint, slows kidney function decline in patients with IgA nephropathy (IgAN) (October 16, 2025). https://www.novartis.com/news/media-releases/novartis-fabhalta-iptacopan-meets-phase-iii-primary-endpoint-slows-kidney-function-decline-patients-iga-nephropathy-igan |
| Phase 1/2 | Cell therapy | Resecabtagene autoleucel (rese-cel) | Cabaletta Bio | Cabaletta Bio presents positive clinical data and development updates for rese-cel at ACR Convergence 2025 (October 27, 2025). https://www.cabalettabio.com/news-media/press-releases/detail/137/cabaletta-bio-presents-positive-clinical-data-and |
| Phase 3 | Biologic | Atacicept | Vera Therapeutics | Vera Therapeutics announces positive ORIGIN phase 3 data for atacicept in IgA nephropathy presented at ASN Kidney Week 2025 and published in <i>The New England Journal of Medicine</i> (November 6, 2025). https://ir.veratx.com/news-releases/news-release-details/vera-therapeutics-announces-positive-origin-phase-3-data |

ACR, American College of Rheumatology; BKPyV, BK polyomavirus; IND, investigational new drug.

Summary: Investments

| Company | Amount, \$ | Type | Reference |
|---------------------|----------------|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Renasant Bio | 54.5 Million | Seed | Renasant Bio, an underdog in the race to develop kidney disease therapies, raises \$54.5 million (July 10, 2025). https://www.statnews.com/2025/07/10/renasant-adpkd-kidney-disease/ |
| United Therapeutics | 1 Billion | Share repurpose | United Therapeutics Corporation announces \$1 billion accelerated share repurchase program (August 1, 2025). https://ir.unither.com/press-releases/2025/08-01-2025-120038780 |
| Strive Health | 550 Million | Series D | Strive Health raises \$550 million in Series D funding (September 9, 2025). https://strivehealth.com/news/strive-health-raises-550-million-in-series-d-funding/ |
| BMI OrganBank | Not applicable | National Kidney Foundation Innovation Fund | NKF Innovation Fund invests in BMI OrganBank to advance breakthrough kidney transplant technology (September 22, 2025). https://www.kidney.org/press-room/nkf-innovation-fund-invests-bmi-organbank-to-advance-breakthrough-kidney-transplant |

NKF, National Kidney Foundation.

Summary: Mergers, acquisitions, and partnerships

| Company | Amount, \$ | Type | Reference |
|-------------------------|-------------------------------------------|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Matchpoint Therapeutics | 60 Million (eligible for up to 1 billion) | Option and license agreement with Novartis | Matchpoint Therapeutics announces exclusive option and license agreement with Novartis to develop oral inhibitors for multiple inflammatory diseases (July 24, 2025). https://matchpointtx.com/news/matchpoint-therapeutics-announces-exclusive-option-and-license-agreement-with-novartis-to-develop-oral-inhibitors-for-multiple-inflammatory-diseases/ |
| Keenova Therapeutics | Not applicable | New company from branded business of Mallinckrodt and Endo, Inc. | Mallinckrodt completes spin-off of Par Health, introduces Keenova Therapeutics (November 10, 2025). https://mallinckrodt.mediарoom.com/2025-11-10-Mallinckrodt-Completes-Spin-Off-of-Par-Health,-Introduces-Keenova-Therapeutics |
| Akebia Therapeutics | 592 Million | Acquisition of Q32 Bio asset | Q32 Bio sells complement inhibitor ADX-097 (December 1, 2025). https://ir.q32bio.com/news-releases/news-release-details/q32-bio-sells-complement-inhibitor-adx-097 |
| Novo Nordisk | 2.1 Billion | Acquisition of Omeros Corporation asset | Omeros Corporation announces closing of asset purchase and license agreement with Novo Nordisk for Omeros' clinical-stage MASP-3 inhibitor zaltenibart (OMS906) (December 1, 2025). https://investor.omeros.com/news-releases/news-release-details/omeros-corporation-announces-closing-asset-purchase-and-license |
| BioMarin | 4.8 Billion | Aquisition of Amicus Therapeutics | BioMarin to acquire Amicus Therapeutics for \$4.8 billion, expanding position as a leader in rare diseases, accelerating revenue growth and strengthening financial outlook (December 19, 2025). https://www.biomarin.com/news/press-releases/biomarin-to-acquire-amicus-therapeutics-for-4-8-billion-expanding-position-as-a-leader-in-rare-diseases-accelerating-revenue-growth-and-strengthening-financial-outlook/ |
| Rectify Pharmaceuticals | 448 Million | Strategic research and licensing agreement with Boehringer Ingelheim | Rectify and Boehringer Ingelheim collaborate and advance first-in-class treatments for chronic kidney disease (December 22, 2025). https://rectifypharma.com/press_release/rectify-and-boehringer-ingelheim-collaborate-to-advance-first-in-class-treatments-for-chronic-kidney-disease/ |

MASP-3, mannose-binding lectin-associated serine protease 3.

Findings

Preventive Strategy Lowers AKI Risk After Major Surgery

<https://doi.org/10.62716/kn.002862026>

A strategy consisting of guideline-recommended nephroprotective measures reduces the incidence of moderate or severe acute kidney injury (AKI) in patients at high risk undergoing major surgery, concludes a randomized clinical trial in *Lancet (London, England)*.

The Biomarker-Guided Intervention to Prevent Acute Kidney Injury (BigpAK-2) trial enrolled adult patients undergoing major surgery at 34 hospitals in 8 European countries. All participants were considered at high risk for AKI, based on clinical risk factors and biomarkers of tubular stress (urinary tissue inhibitor of metalloproteinases 2 and insulin-like growth factor-binding factor 7).

Patients assigned to the intervention group received a preventive care strategy, incorporating recommendations from the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines: advanced hemodynamic monitoring, optimized volume and hemodynamic status, avoidance of nephrotoxic drugs and radiocontrast agents, and tight glycemic control. Patients in the control group received usual care.

Of 7873 screened patients, 1180 were randomized, and 1176 were available for analysis of the primary outcome: moderate or severe AKI within 72 hours after surgery. The mean age was 71 years; two-thirds of patients were men. Most patients were classified as having “severe general illness” and were undergoing abdominal/general or cardiac surgery.

Patients assigned to the preventive care strategy were less likely to develop moderate or severe AKI: 14.4% versus 22.3%; odds ratio, 0.57. The number needed to treat to prevent one case of moderate or severe AKI was 12. About half of the patients in the intervention group received all KDIGO-recommended nephroprotective steps.

Prevention of hypotension and discontinuation of angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers were the measures most strongly related to reducing AKI. Adverse events—most commonly atrial fibrillation, hemodynamically relevant arrhythmias, significant bleeding, and an unplanned return to the operating room—were similar between groups.

Despite the high frequency and morbidity associated with AKI after major surgery, recommended preventive steps are rarely followed. The BigpAK-2 findings show a reduction in moderate or severe AKI among patients at high risk receiving a KDIGO-based preventive care strategy. The researchers note, “The preventive strategy consists of interventions that are not resource intensive and can be easily implemented in patients at high risk in lower-resource hospitals” [Zarbock A, et al.; BigpAK-2 study group. A preventive care strategy to reduce moderate or severe acute kidney injury after major surgery (BigpAK-2); a multinational, randomised clinical trial. *Lancet* 2025; 406:2782–2791. doi: 10.1016/S0140-6736(25)01717-9].

Weight Loss Interventions Lead to Cardiorenal Benefits in CKD and T2D

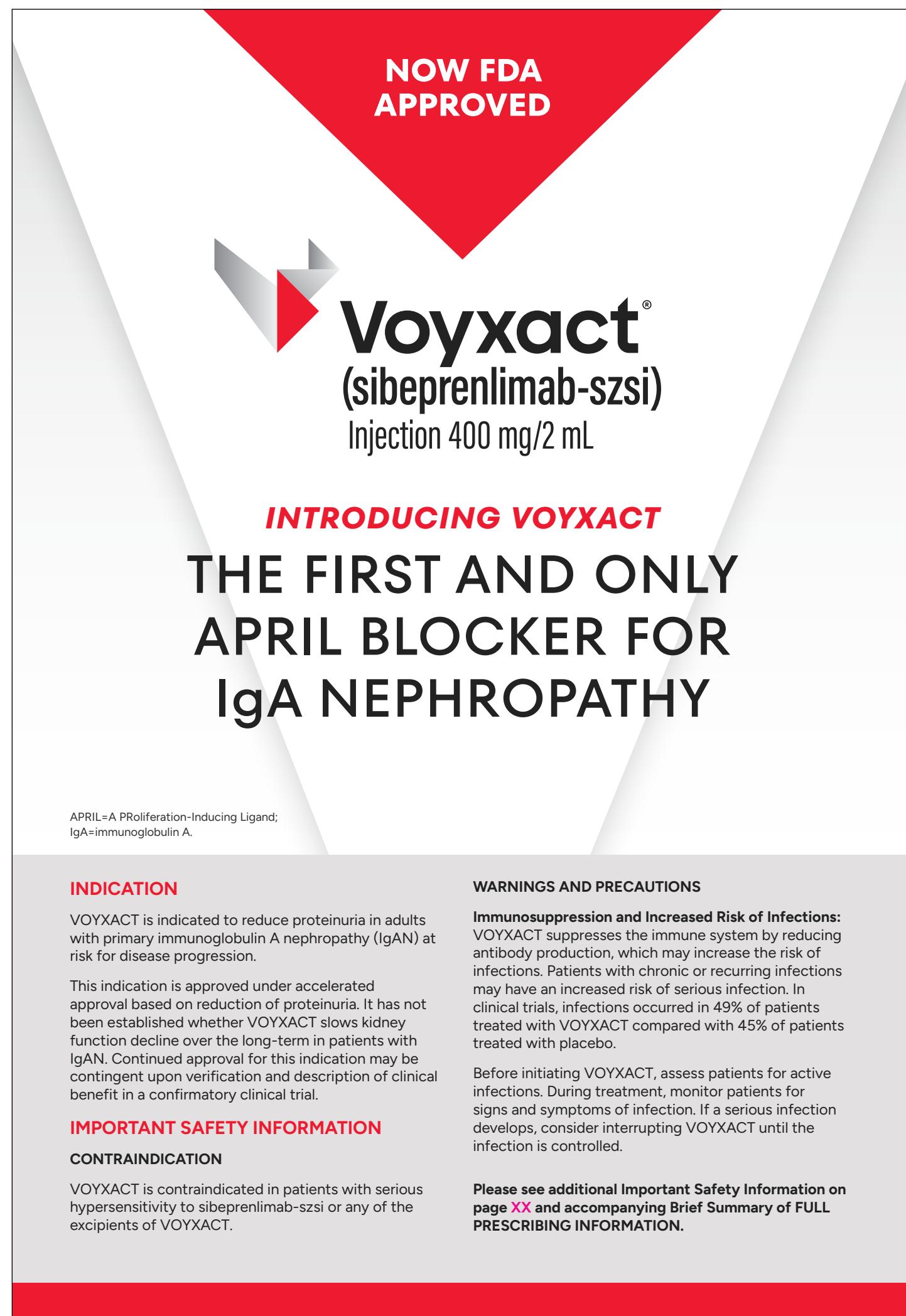
<https://doi.org/10.62716/kn.002872026>

For people with type 2 diabetes (T2D), chronic kidney disease (CKD), and overweight or obesity, interventions to promote weight loss—glucagon-like peptide-1 medications or bariatric surgery—are associated with a range of

cardiorenal benefits, reports a study in *Nephrology, Dialysis, Transplantation*.

Using the TriNetX US Collaborative Network, the researchers identified three cohorts of patients with T2D, CKD, and overweight or obesity who

had been prescribed semaglutide or tirzepatide or who had undergone bariatric surgery. Each cohort was propensity score matched to patients receiving dipeptidyl peptidase-4 inhibitors (DPP4i), a class of oral hypoglycemic



NOW FDA APPROVED

VOYXACT®
(sibemprelimab-szsi)
Injection 400 mg/2 mL

INTRODUCING VOYXACT

THE FIRST AND ONLY
APRIL BLOCKER FOR
IgA NEPHROPATHY

APRIL=A PRoiferation-Inducing Ligand;
IgA=immunoglobulin A.

INDICATION

VOYXACT is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether VOYXACT slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

VOYXACT is contraindicated in patients with serious hypersensitivity to sibemprelimab-szsi or any of the excipients of VOYXACT.

WARNINGS AND PRECAUTIONS

Immunosuppression and Increased Risk of Infections: VOYXACT suppresses the immune system by reducing antibody production, which may increase the risk of infections. Patients with chronic or recurring infections may have an increased risk of serious infection. In clinical trials, infections occurred in 49% of patients treated with VOYXACT compared with 45% of patients treated with placebo.

Before initiating VOYXACT, assess patients for active infections. During treatment, monitor patients for signs and symptoms of infection. If a serious infection develops, consider interrupting VOYXACT until the infection is controlled.

Please see additional Important Safety Information on page XX and accompanying Brief Summary of FULL PRESCRIBING INFORMATION.



VOYXACT® (sibemprelinab-szsi) binds to APRIL, blocking signaling at the BCMA and TACI receptors. Inhibition of APRIL results in reduced levels of Gd-IgA1, which is implicated in the pathogenesis of IgA nephropathy.

BCMA=B-cell maturation antigen; Gd-IgA1=galactose-deficient IgA1; TACI=transmembrane activator and calcium modulator and cyclophilin ligand interactor.

SIGNIFICANT PROTEINURIA REDUCTION

Primary Endpoint: Relative Change From Baseline in uPCR-24h at Month 9*

-50% **vs** **+2%**

VOYXACT

(n=152)

vs

+2%

PLACEBO

(n=168)

51% placebo-adjusted treatment effect at 9 months
(96.5% CI, [†] 43%, 58%; P<0.0001)

*Estimated geometric mean percentage change at 9 months compared with baseline. Data were included in the analysis regardless of early treatment discontinuation and initiation of confounding therapy (treatment policy strategy). Missing data were imputed using multiple imputation.

[†]96.5% CI corresponds to the two-sided significance level of 0.035 for the interim analysis.

SAFETY PROFILE IN VISIONARY

Adverse Reactions in ≥10% of Patients Treated With VOYXACT and at a Higher Incidence Than Placebo

| | VOYXACT (n=259) | Placebo (n=251) |
|---------------------------------|-----------------|-----------------|
| Infections | | |
| Upper respiratory infection | 49% | 45% |
| | 15% | 14% |
| Injection site reactions | | |
| Erythema | 24% | 23% |
| | 13% | 12% |

SELF-ADMINISTERED DOSING

VOYXACT is dosed every 4 weeks by subcutaneous injection.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Immunosuppression and Immunization Risks: Because of its mechanism of action, VOYXACT may interfere with immune responses to vaccines and increase the risk of infection from live vaccines. Live vaccines are not recommended within 30 days prior to initiation of VOYXACT or during treatment with VOYXACT as safety has not been established. No data

are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving VOYXACT or on the efficacy of immunizations administered while receiving VOYXACT.

medications with neutral effects on body weight.

Four cardiorenal outcomes—kidney failure, myocardial infarction, stroke, or death from any cause—were compared between the matched cohorts. The analysis included 17,749 patients treated with semaglutide, 4211 treated with tirzepatide, and 2603 who had undergone bariatric surgery. In all three treatment

groups, most patients were women. The mean age was 64 years for patients receiving weight-loss medications and 56 years for those undergoing bariatric surgery.

All four adverse cardiorenal outcomes were less frequent in the cohorts receiving weight-loss interventions compared with DPP4i. Hazard ratios (HRs) for kidney

Continued on page 14 >

VISIONARY Study Design

- VISIONARY is a randomized, double-blind, placebo-controlled study of 510 adults with biopsy-confirmed IgA nephropathy, an eGFR ≥ 30 mL/min/1.73 m², and proteinuria (defined as either uPCR based on 24-hour urine collections ≥ 0.75 g/g or urine protein ≥ 1.0 g/day)
- Patients were randomized 1:1 to receive VOYXACT (n=259) or placebo (n=251) subcutaneously every 4 weeks and remained on a stable and maximally tolerated dose of ACE inhibitors and/or ARBs with or without an SGLT2 inhibitor throughout the study
- An interim analysis for efficacy was conducted on the first 320 randomized patients who reached the Month 9 visit (VOYXACT, n=152; placebo, n=168)

ACE=angiotensin-converting enzyme; ARB=angiotensin receptor blocker; CI=confidence interval; SGLT2=sodium-glucose cotransporter 2; uPCR=urine protein-creatinine ratio.

- Most adverse reactions were reported as mild or moderate in severity and resolved without treatment interruption or discontinuation
- VOYXACT suppresses the immune system by reducing antibody production, which may increase the risk of infections



Scan to learn if VOYXACT is right for your patients

Findings

Weight Loss Interventions

Continued from page 13

failure were 0.78 for patients receiving semaglutide, 0.58 for those receiving tirzepatide, and 0.79 for those undergoing bariatric surgery.

Semaglutide was also associated with reductions in myocardial infarction and stroke: HR, 0.80 and 0.85, respectively. For tirzepatide, HRs were 0.76 for both myocardial infarction and stroke. All three treatments were associated with reduced all-cause mortality: HR, 0.64 with semaglutide, 0.47 with tirzepatide, and 0.68 with bariatric surgery.

The study adds new evidence on cardiorenal benefits of contemporary weight-loss interventions for people with T2D and CKD. Risks of kidney failure, myocardial infarction, stroke, and death from any cause were substantially lower than in matched patients receiving DPP4i. "Further investigation into tirzepatide's dual GIP [gastric inhibitory polypeptide]/GLP-1 [glucagon-like peptide-1]

receptor activation and its direct kidney-protective mechanisms may refine therapeutic strategies for T2DM and CKD," the researchers write [Wilkinson TJ, et al. Cardiorenal outcomes of weight loss interventions in people with CKD and type 2 diabetes. *Nephrol Dial Transplant*, published online December 4, 2025. doi: 10.1093/ndt/gfaf258]. ■

INDICATION

VOYXACT is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether VOYXACT slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

VOYXACT is contraindicated in patients with serious hypersensitivity to sibemprelimab-szsi or any of the excipients of VOYXACT.

WARNINGS AND PRECAUTIONS

Immunosuppression and Increased Risk of Infections: VOYXACT suppresses the immune system by reducing antibody production, which may increase the risk of infections. Patients with chronic or recurring infections may have an increased risk of serious infection. In clinical trials, infections occurred in 49% of patients treated with VOYXACT compared with 45% of patients treated with placebo.

Before initiating VOYXACT, assess patients for active infections. During treatment, monitor patients for signs and symptoms of infection. If a serious infection develops, consider interrupting VOYXACT until the infection is controlled.

Immunosuppression and Immunization Risks:

Because of its mechanism of action, VOYXACT may interfere with immune responses to vaccines and increase the risk of infection from live vaccines. Live vaccines are not recommended within 30 days prior to initiation of VOYXACT or during treatment with VOYXACT as safety has not been established. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving VOYXACT or on the efficacy of immunizations administered while receiving VOYXACT.

Common Adverse Reactions: The most common adverse reactions (reported in ≥10% of patients treated with VOYXACT and at a higher incidence than placebo) in patients treated with VOYXACT and placebo, respectively, were infections (49% versus 45%) and injection site reactions (24% versus 23%). The most common infection was upper respiratory infection (15% versus 14%), and the most common injection site reaction was injection site erythema (13% versus 12%). Most adverse reactions were reported as mild or moderate in severity and resolved without treatment interruption or discontinuation.

Pregnancy: There are no available data on VOYXACT use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Monoclonal antibodies, such as sibemprelimab-szsi, can be actively transported across the placenta as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy.

Lactation: There are no data on the presence of sibemprelimab-szsi in human milk, the effects of sibemprelimab-szsi on the breastfed infant, or the effects of sibemprelimab-szsi on milk production.

Pediatric Use: Safety and effectiveness of VOYXACT in pediatric patients have not been established.

Geriatric Use: Clinical studies of VOYXACT did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger adult patients.

Pregnant women exposed to VOYXACT, or their healthcare providers, should report VOYXACT exposure by calling **1-833-869-9228** or visiting www.VOYXACT.com

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at **1-800-438-9927** or FDA at **1-800-FDA-1088** (www.fda.gov/medwatch).

Please see Brief Summary of FULL PRESCRIBING INFORMATION on the following page.

Neighborhood Disadvantage and Kidney Transplant Disparities

<https://doi.org/10.62716/kn.002892026>

People living in disadvantaged neighborhoods may face disparities in access to waitlisting and kidney transplantation (KT), reports a study in *JAMA Network Open*.

Using a national registry, the researchers identified 501,444 US adults with kidney

failure who initiated dialysis from 2015 through 2021. Residential neighborhood disadvantage was evaluated using a validated measure comprising nine factors. Cause-specific hazard models were used to estimate differences in waitlisting and KT

across tertiles of residential neighborhood disadvantage scores. The analysis included interaction terms to examine associations with race and ethnicity.

Patients initiating dialysis had a mean age of 64 years. About 59% of patients were



VOYXACT® (sibemprelimab-szsi) injection, for subcutaneous use

BRIEF SUMMARY OF PRESCRIBING INFORMATION

(For complete details, please see *Full Prescribing Information and Patient Information*.)

INDICATIONS AND USAGE: VOYXACT is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether VOYXACT slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

CONTRAINdications: VOYXACT is contraindicated in patients with serious hypersensitivity to sibemprelimab-szsi or any of the excipients of VOYXACT.

WARNINGS AND PRECAUTIONS

Immunosuppression and Increased Risk of Infections: VOYXACT suppresses the immune system by reducing antibody production, which may increase the risk of infections. Patients with chronic recurring infections may have an increased risk of serious infection. In clinical trials, infections occurred in 49% of patients treated with VOYXACT compared with 45% of patients treated with placebo.

Before initiating VOYXACT, assess patients for active infections. During treatment, monitor patients for signs and symptoms of infection. If a serious infection develops, consider interrupting VOYXACT until the infection is controlled.

There are limited clinical study data with concomitant use of VOYXACT and systemic immuno-suppressants. Consider the potential for increased immunosuppression when coadministering VOYXACT and immuno-suppressants or when initiating VOYXACT either before or after immuno-suppressive therapy.

Immunosuppression and Immunization Risks: Because of its mechanism of action, VOYXACT may interfere with immune responses to vaccines and increase the risk of infection from live vaccines. Live vaccines are not recommended within 30 days prior to initiation of VOYXACT or during treatment with VOYXACT as safety has not been established. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving VOYXACT or on the efficacy of immunizations administered while receiving VOYXACT.

ADVERSE REACTIONS

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

The safety of VOYXACT was evaluated in a randomized, double-blind, placebo-controlled, clinical study in patients with IgAN (VISIONARY). The median duration of exposure was 44 weeks in the 259 patients treated with VOYXACT and 48 weeks in the 251 patients administered placebo. The most common adverse reactions (reported in $\geq 10\%$ of patients treated with VOYXACT and at a higher incidence than placebo) in patients treated with VOYXACT and placebo, respectively, were infection (49% versus 45%) and injection site reactions (24% versus 23%). The most common infection was upper respiratory infection (15% versus 14%), and the most common injection site reaction was injection site erythema (13% versus 12%). Most adverse reactions were reported as mild or moderate in severity and resolved without treatment interruption or discontinuation.

USE IN SPECIFIC POPULATIONS

Pregnancy: *Risk Summary* There are no available data on VOYXACT use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Monoclonal antibodies, such as sibemprelimab-szsi, can be actively transported across the placenta as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy. In an enhanced prenatal and postnatal development (ePPND) toxicity study, administration of sibemprelimab-szsi subcutaneously to pregnant monkeys did not result in any adverse effects on embryofetal or postnatal development at exposures approximately 10-times the clinical exposure at the maximum recommended human dose (MRHD) based on area under the curve (AUC).

Clinical Considerations Disease-Associated Maternal and/or Embryo/Fetal Risk IgA nephropathy is associated with adverse maternal outcomes, including increased rates of cesarean section, pregnancy-induced hypertension, pre-eclampsia and preterm delivery, and adverse fetal/neonatal outcomes, including stillbirth and low birth weight. *Fetal/Neonatal Adverse Reactions* Transport of endogenous IgG antibodies across the placenta increases as pregnancy progresses, and peaks during the third trimester. Therefore, VOYXACT may be present in infants exposed *in utero*. Consider the potential clinical impact of VOYXACT exposure in infants who are exposed to VOYXACT *in utero*.

Lactation: *Risk Summary* There are no data on the presence of sibemprelimab-szsi in human milk, the effects of sibemprelimab-szsi on the breastfed infant, or the effects of sibemprelimab-szsi on milk production. Endogenous maternal IgG and monoclonal antibodies are transferred into human milk. The effects of local gastrointestinal exposure on sibemprelimab-szsi in the breastfed infant are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VOYXACT and any potential adverse effects on the breastfed child from VOYXACT or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness of VOYXACT in pediatric patients have not been established.

Geriatric Use: Clinical studies of VOYXACT did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger adult patients. No clinically meaningful differences in the pharmacokinetics of VOYXACT were observed in patients aged 65 and over compared to younger adult patients.

PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling (Patient Information and Instructions for Use). Pregnant women exposed to VOYXACT, or their healthcare providers, should report VOYXACT exposure by calling [1-833-869-9228] or visiting www.VOXACT.com

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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male; 5% were Asian, 27% were Black, 13% were Hispanic, and 55% were White. Of patients waitlisted for KT, the mean age was 54 years; 64% were male; and 7% were Asian, 27% were Black, 17% were Hispanic, and 50% were White. Overall, 35% of people with kidney failure and 28% of KT candidates resided in high-disadvantage neighborhoods.

On adjusted analysis, patients living in high-disadvantage neighborhoods were less likely to be waitlisted for KT (hazard ratio [HR], 0.71), compared with those in low-disadvantage neighborhoods. By race and ethnicity, HRs for waitlisting associated with high-neighborhood disadvantage were 0.87 for Asian patients, 0.68 for both Black and White patients, and 0.89 for Hispanic patients, and all were less likely to be waitlisted for KT than White patients in low-disadvantage neighborhoods.

High-neighborhood disadvantage was also associated with a lower likelihood of KT overall (HR, 0.89), as well as living-donor KT (HR, 0.65) and pre-emptive KT (HR, 0.62). All KT access outcomes were less likely for Black patients in high-disadvantage neighborhoods than for White patients in low-disadvantage neighborhoods: HR, 0.60 for any KT; 0.23 for living-donor KT; and 0.22 for pre-emptive KT.

Previous studies have linked racial and ethnic disparities in chronic disease diagnosis and management to residence in a disadvantaged neighborhood. The present study explored how neighborhood disadvantage may influence access to waitlisting and KT for people with kidney failure.

The results show reduced access to waitlisting and KT for US adults living in neighborhoods in the lowest tertile on a neighborhood-disadvantage score. “[N]eighborhood disadvantage may contribute to persistent racial and ethnic disparities in access to LDKT [living-donor KT] and pre-emptive KT,” the researchers write. They call for “urgent, multifaceted interventions” to address structural factors contributing to neighborhood disadvantage [Li Y, et al. Residential neighborhood disadvantage and access to kidney transplantation. *JAMA Netw Open* 2025; 8:e2549679. doi: 10.1001/jam-anetworkopen.2025.49679].

Disaster Preparedness, Collaboration Key to Maintaining Patient Health During Crises

By Karen Blum

<https://doi.org/10.62716/kn.002812025>

From earthquakes to floods and heat waves to political unrest or war conflicts, all have the potential to disrupt kidney care, putting patients at risk for worsening health.

Many factors associated with disasters increase the risk of acute kidney injury (AKI), said Mehmet Şükrü Sever, MD, emeritus professor of nephrology at Istanbul University School of Medicine in Turkey and chair of the European Renal Association's Kidney Relief in Disasters Task Force, during a presentation at ASN Kidney Week 2025 in Houston, TX.

People with chronic kidney disease (CKD) have a higher risk of injury compared with healthy individuals, and the survival of people with AKI or CKD in disasters depends on factors such as functional infrastructure, advanced technology, the availability of particular drugs, and well-trained medical personnel, Sever said. He and others discussed the role of nephrology teams—in partnership with local authorities and other agencies—in protecting patient health. “All kidney health [practitioners]—and our patients—should have training in what to do in the case of a disaster,” Sever said. “We should all know what to do at the moment of a disaster and what we are going to do if we can survive.”



Role of nephrology teams

Nephrology teams play a key role during acute crises, in the postdisaster period, and in preparing for the next disaster, Sever said. They may endure many challenges, including an increase in the number of patients, due to disaster-related etiologies or as patients are transferred from nonfunctioning to functioning nephrology units, and difficulties in making diagnoses, with limited laboratory testing or an inability to perform kidney biopsies, he said (1).

During a disaster, Sever recommended the following actions for nephrology team members:

- ▶ If your present location is dangerous, try to move to a safe place.
- ▶ Check your and your relatives' health status. Try to get medical help if needed, and inform third parties, such as coordinators or authorities, if you cannot take part in the disaster response.
- ▶ Try to contact the disaster-relief coordinator to get instructions. If you cannot, try to get to your own workplace to help out. If neither option is possible, intervene by your own initiative, locally.

There are three major management strategies that nephrologists can use for patients in predictable emergencies like weather events: predisaster evacuation, local management of people with AKI and CKD, and postdisaster evacuation (2), he said. However, if patients are older, frail, or have many comorbidities, evacuation may not be possible.

Common etiologies seen with disasters include dehydration, hypovolemic shock, nephrotoxicity, and sepsis, he said. Some are specific to particular types of disasters. For example, destructive disasters can lead to crush injuries, whereas floods can cause malaria or leptospirosis (1).

Those with CKD experience various risks during disasters, he added. People not undergoing dialysis may have inadequate treatment or insufficient medications and become at risk of progressing to kidney failure, whereas transplant recipients face an increased risk of

rejection if immunosuppressive treatment is not available or due to increased risk of life-threatening infections from unhygienic conditions (1, 3).

During crises, use diet to help patients not undergoing dialysis if appropriate healthy foods are available, he advised. Ask patients to adhere to their treatments and stock medications, and train them about self-management or where they can go if they cannot reach their doctors. For patients undergoing hemodialysis, decrease the frequency of dialysis sessions from thrice weekly to once or twice, or consider shortening dialysis sessions to increase the number of shifts per day. Patients also could be switched to peritoneal dialysis if appropriate.

For patients undergoing peritoneal dialysis, decrease the number of exchanges, apply longer dwell times, or consider switching to hemodialysis. For transplant recipients, modify treatment regimens if there is a lack of immunosuppressants, and train patients about self-treatment for mild complications. In the case of serious complications, try to refer patients as soon as possible from the disaster zone to other regions of the country.

Evacuations come with their own concerns, said Sever. There may be unhealthy and unsecured environments; a lack of dialysis during the journey or first days in the new environment; increased risks of infections or other complications; and medical, social, or economic difficulties in a host country, he said (4).

When a crisis strikes, patients should try to contact their medical facility or physician. If they cannot make contact, they should try to treat themselves. If their health worsens, they should contact authorities to be evacuated. One of the worst-case scenarios is being connected to a hemodialysis machine at the active phase of a disaster, like tremors of an earthquake, when health care staff may be busy, said Sever. Therefore, patients should be trained about how to stop the machine and self-disconnect.

Following a disaster, screen all patients for medical problems that may have gone undetected during the crisis, and treat them as soon as possible, Sever said (5). Restore damaged infrastructure, and replenish supply stocks as soon as possible. Additionally, hold debriefing meetings in which nephrology team members can discuss what went well and what went wrong. “This is so important in order to avoid repetition of the same mistakes in future disasters,” he noted.

In preparing for the next possible disaster, consider facility preparations like securing shelves or furniture to the walls, he said. Develop emergency-response plans so all nephrology team members know what to do and how. Develop generator plans, and create a communication plan with emergency telephone numbers including for fire and police departments. Prepare health care practitioners and patients through training courses and drills (5). Logistical planning for health care provision should be organized by disaster-relief coordinators, but nephrology teams can prepare medical documents for patients and patient educational materials (6), he said, and look for alternative facilities in case the present one becomes nonoperational.

Handling water disruptions

Interruptions in water flow, whether from a natural disaster or a water main break, can impact dialysis provision, said Sarrah Johnson, DNP, MBA, RN, chief diversity and inclusion officer for US Renal Care, Brandywine, MD. Nephrology teams can prepare in several ways, she said.

- ▶ Have and activate an emergency plan. Identify the cause of water interruption to determine what resources you need. Can you get portable water tanks and connect those to your dialysis facility? How long will it take to get those on-site? Will you need portable fuel for generators? Communicate the information with your staff and with patients to lessen their anxiety, and indicate if you know when you can return to normal operations.
- ▶ Execute clinical leadership. Can you run shortened dialysis sessions, or use medications as an interim treatment? Validate water safety at your backup clinic location. If that, too, is impacted, where can you relocate patients? Educate patients about other considerations like diet and fluid intake, and provide guidance about when to go to an emergency department. Conduct home or virtual visits if needed to assess patients' supplies.
- ▶ Use clear, frequent communication to your teams and patients. Include other stakeholders, such as staff at your backup facility, patient caregivers or family members, transportation agencies, and your local municipality. If the local government is informed that you are impacted, the decision-makers may prioritize restoring water supply to your facility, she suggested.

Disaster resources

Several organizations have emerged over the past couple of decades to help nephrology groups maintain care for patients. In December 2023, ASN partnered with the European Renal Association, the International Society of Nephrology, and Direct Relief to form the Global Humanitarian Kidney Support Initiative to ensure continuity of care for people with kidney diseases during disasters and conflicts and in regions where access to essential health

services is limited, said Jeffrey Silberzweig, MD, FASN, chair of ASN's Emergency Preparedness and Response Workgroup and professor of clinical medicine at Weill Cornell Medical College in New York City. The initiative uses tools like emergency support for clinics and hospitals, provision of essential medicines and supplies, training for health care workers, and patient education.

When Hurricane Melissa was expected to hit the Caribbean in October 2025, ASN contacted all members in Jamaica to offer assistance, Silberzweig said. Direct Relief prepositioned some personnel and supplies. After the hurricane hit, Montego Bay had no water or power, but a government hospital in Kingston offered to provide additional shifts for patients who could be transported there. Working with Renal Dynamics, a company supplying dialysis equipment, the hospital was able to get supplies to those in need, he said.

The Kidney Community Emergency Response (KCER) program, formed in 2006, under a Centers for Medicare & Medicaid Services contract, helps provide technical assistance to End Stage Renal Disease Networks in disaster preparedness, response, and recovery, Silberzweig explained. Prior to Hurricane Sandy making landfall in the New York City area in 2012, KCER and New York and New Jersey state health departments advocated for early dialysis, which helped lower hospitalization and mortality rates, he said (7).

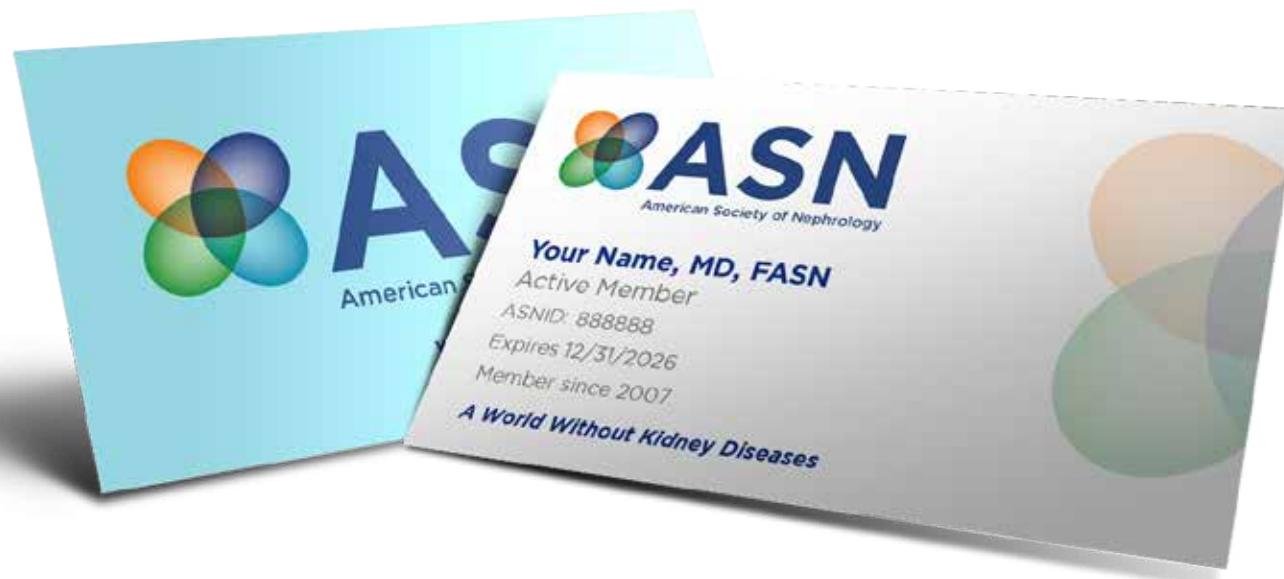
The International Society of Nephrology has a Renal Disaster Preparedness Working Group, said Ali Abu-Alfa, MD, FASN, professor of medicine at the American University of Beirut in Lebanon. Among its disaster-relief efforts, the group has reached out to countries such as Taiwan and Japan following earthquakes.

In addition to providing direct assistance during disasters, many of these workgroups and organizations offer preparedness resources for nephrology teams and people living with

kidney diseases, including kidney-specific and disaster-specific resources and links to other partner organizations and agencies (8, 9). ■

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Kidney Watch 2026 continues in this issue with two additional perspectives on acute kidney injury and glomerular diseases. Building on the themes introduced last month, these articles highlight emerging research, evolving clinical challenges, and areas poised to shape nephrology in the year ahead.

Explore the entire Kidney Watch collection: <https://www.kidneynews.org/page/kidney-watch>.

The Illusion of Progress in AKI Research

By Jia Hwei Ng

<https://doi.org/10.62716/kn.002842026>

Over the past few years, patterns emerging from conference abstracts, scientific sessions, and peer-reviewed publications in acute kidney injury (AKI) have been strikingly consistent. From 2023 through 2025, predictive modeling aimed at identifying AKI earlier has dominated the landscape, alongside biomarker discovery and increasingly refined AKI subtypes. In basic science, work has continued to focus on inflammatory signaling, cell death, and pathways of tubular injury and recovery. More recently, there has also been growing recognition of the importance of post-AKI care, including follow-up, medication management, and patient education.

On the surface, this looks like progress (Figure). Yet, AKI outcomes remain largely unchanged.

The persistence of these themes raises an uncomfortable question: If the field is advancing, why does AKI look the same clinically year after year? The issue is not a lack of effort. It is a misalignment between where energy is concentrated and where the true bottleneck lies.

In the current research environment, artificial intelligence (AI) has accelerated work in AKI prediction. Models can now be developed, validated, and deployed rapidly using electronic health record data. New tools promise earlier detection of injury, improved risk stratification, and increasingly granular phenotyping. This pace of

progress is real and highly visible, often overshadowing slower but more consequential advances in basic science.

Basic science moves differently. Understanding how kidneys respond to injury, how tubular cells decide between regeneration and maladaptive repair, and how fibrosis becomes established requires time. These processes cannot be compressed. They demand careful experimentation, longitudinal observation, and iterative validation.

A substantial proportion of AKI is neither unexpected nor preventable. Cardiac surgery, major vascular procedures, sepsis, shock, and exposure to lifesaving but nephrotoxic therapies are well-recognized high-risk scenarios. Earlier detection does not change the necessity of these interventions. We are not going to cancel surgery, withhold chemotherapy, or avoid contrast when those measures are required to save a patient's life.

Once AKI occurs, clinical care remains largely supportive. Management focuses on minimizing additional injury and optimizing physiology. Recovery, when it happens, depends largely on the patient's intrinsic biology.

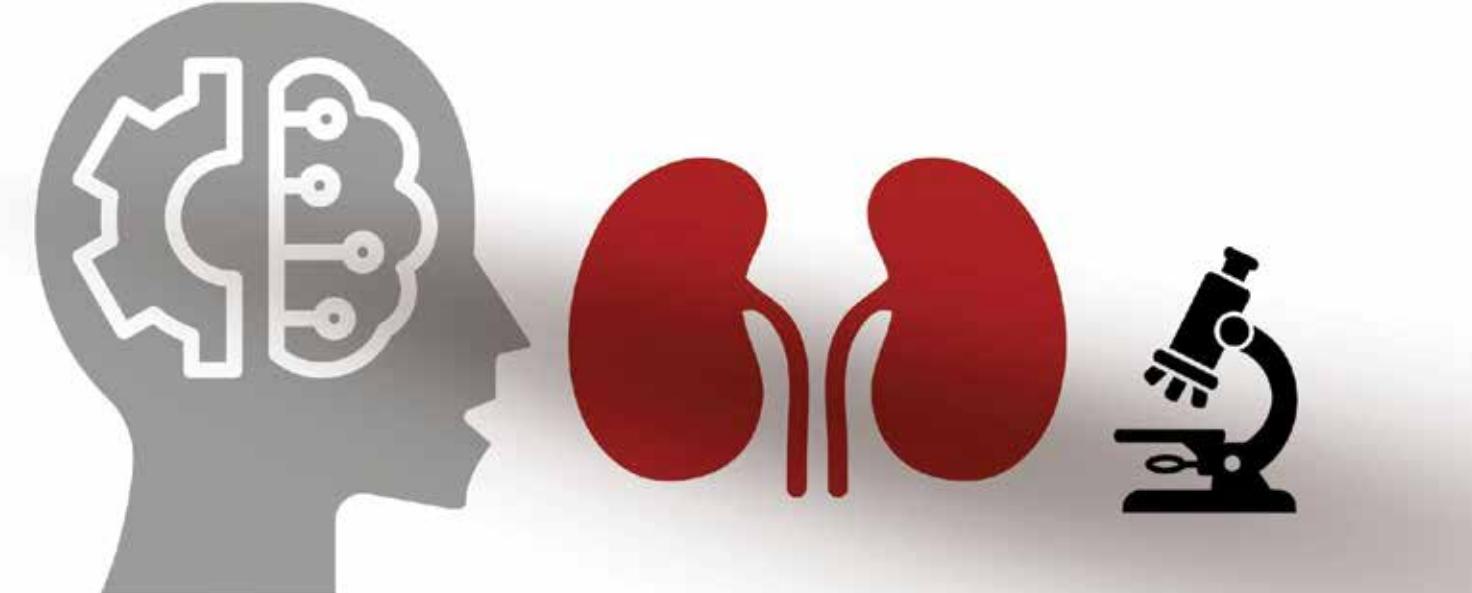
The most important unanswered question in AKI is not who will develop injury, but what happens afterward. Can ongoing cell death be halted? Can regeneration be promoted and fibrosis prevented? These are questions that cannot be solved quickly, but they are the questions that determine outcomes.

Looking ahead, the most predictable trend in AKI research is continued expansion of AI, i.e., more prediction models, more electronic health record integration, and more implementation efforts aimed at identifying risk earlier and more precisely. The challenge will be ensuring that speed and visibility translate into answers that ultimately change recovery, not just recognition. Until the biological determinants of repair after AKI can be altered, prediction alone will remain insufficient. ■

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The author reports no conflicts of interest.

Figure. The illusion of progress in AKI research



Highly visible advances in AI-driven prediction overshadow the biological processes that ultimately determine recovery after AKI.

GlomCon Hawaii and the Future of Glomerular Diseases

By Zohreh Gholizadeh Ghozloujeh, Sayna Norouzi, and Edgar Lerma

<https://doi.org/10.62716/kn.002702025>

Over the past few years, glomerular disease has been evolving rapidly and bringing optimism to the field. The recent Kidney Disease: Improving Global Outcomes (KDIGO) glomerular diseases guideline, spanning immunoglobulin A nephropathy (IgAN) and IgA vasculitis, lupus nephritis, antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis, and nephrotic syndrome in children, now provides a roadmap for how we describe and stage these conditions. The harder task is deciding how trials, clinics, and training structures will actually live inside that framework. GlomCon Hawaii 2025 was built around this challenge. It operated less as a lecture series and more as a working space in which the glomerular diseases community stress-tested what guideline-era care will demand in practice.

At the same time, clinical trials in glomerular diseases and nephrology more broadly have expanded in parallel. How we design those studies now, particularly the endpoints we choose to anchor them, will shape what counts as “good evidence” in the decade ahead. In that context, endpoints and surrogate markers in IgAN, lupus nephritis, complement 3 glomerulopathy (C3G), and related conditions are increasingly judged by a simple standard: Will regulators and payors see them as “reasonably likely” to predict long-term benefit, or not? (1, 2). Clinical trial literacy and translating trial data into day-to-day practice are now expected of glomerular specialists. In this landscape, small populations and rare mechanisms do not justify weak design; we need to force explicit tradeoffs around effect size, follow-up, and event rates and reward thoughtful enrichment and stratification (3). It is the time to consider basket, umbrella, platform, and pragmatic designs as a possible practical way to deal with the fragmentation of phenotypes and therapies. Postapproval registries and real-world evidence will help to inform long-term safety, durability, and generalizability of the newly approved medications (4–6).

The clinical content pointed in the same direction. Across IgAN, membranous nephropathy, podocytopathies, lupus nephritis, paraprotein-mediated disease, C3G, and ANCA or antiglomerular basement membrane (anti-GBM), a pattern is emerging that now defines mature glomerular practice: Start with rigorous pathology, place it in the context of current trials and emerging therapies, and then work through what that actually means for a real patient in clinic. In IgAN, for example, it is no longer sufficient simply to name the histologic lesion on kidney biopsy; complement biology, B-cell activating factor (BAFF) and a proliferation-inducing ligand (APRIL) signaling, broader autoantigen-driven mechanisms, the pathophysiologic implications of hematuria and proteinuria, and evolving outcome data from targeted trials increasingly shape how we think about risk and response (7).

In lupus nephritis and vasculitis, the real concerns are now how to reconcile steroid-minimizing, de-escalation-oriented language with high chronicity scores, pregnancy planning, relapsing, and organ-threatening diseases in front of us (6). Questions about how much pathologic nuance in IgAN truly guides treatment selection and how far genomics or biomarkers can substitute for repeat biopsies are likely to shape the next decade of glomerular disease care rather than the outcomes of a single meeting.

Structurally, it may also be time to acknowledge glomerulonephritis (GN) as more than a set of diagnoses. Given the burden of glomerular diseases and the pace at which trials and targeted therapies are appearing, the case for formal GN clinics and centers of excellence is becoming harder to ignore: clinics with standardized pathology review, embedded genetic evaluation, protocolized access to trials and registries, and deliberate training pathways, rather than complex cases accumulating informally in a few hands (7–9). At the same time, any vision for GN subspecialization has to grapple with workforce constraints, equity, and wide global variation in resources. Translation of GN guidelines into daily practice in the face of differing biopsy access, drug availability, cultural context, and the constraints of pediatric and adolescent care is more important than ever and will require a coordinated response from the community.

Finally, equity and community are no longer optional extras in this conversation. Any credible glomerular disease agenda now has to treat trust, recruitment, and access to costly therapies in minority and underserved communities and in other historically excluded groups as core design questions for both care and trials.

GlomCon Hawaii is a glimpse of where glomerular disease care is heading after the new wave of guidelines and clinical trials: toward a discipline that not only understands endpoints and mechanisms but translates them into day-to-day decisions (Figure). More broadly, glomerular disease education is expanding across the nephrology community, from dedicated programming at ASN Kidney Week to focused courses at the National Kidney Foundation Spring Clinical Meetings and

disease-specific offerings through the International Society of Glomerular Disease, as well as primer courses alongside the International Society of Nephrology World Congress of Nephrology. Ultimately, the value of this work will be judged by whether it improves care at the bedside and prevents complications for the patients we serve. ■

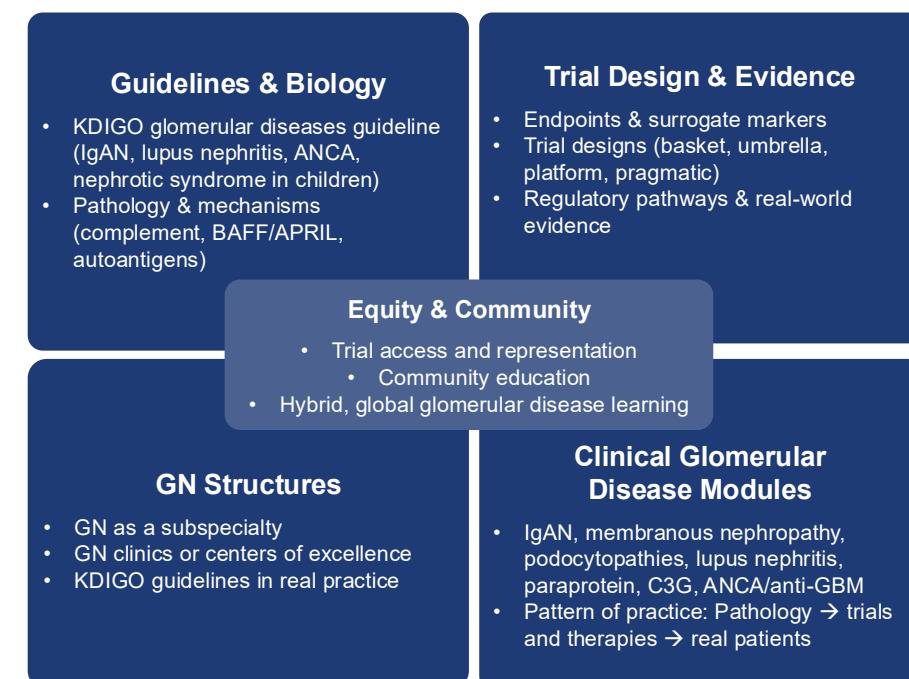
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The authors report no conflicts of interest.

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Figure. Thematic map of GlomCon Hawaii 2025



New Payment Models Critical to Improving Patient-Centered Kidney Care

By Bridget M. Kuehn

<https://doi.org/10.62716/kn.002712025>



New payment models that prioritize patient-centered kidney care, help slow progression, and support new technologies or therapies for kidney diseases are needed, according to panellists at an ASN Kidney Week 2025 session, titled “Better Kidney Care Requires Better Payment Systems.”

The session brought together a panel of experts who outlined the history of kidney disease payment models, ongoing changes in federal payment models, and the need for new models designed to improve care and embrace innovation. The talks emphasized the need to revise the existing End-Stage Renal Disease (ESRD) bundle, recent changes in the Centers for Medicare & Medicaid Services’ (CMS) payment models, and the growing role of private insurer Medicare Advantage plans in kidney care. The session also provided examples of how one system is engaging with current payment models.

There are already several changes to federal payment models underway: the eminent cancellation of the ESRD Treatment Choices Model, recent changes to the Kidney Care Choices Model, and the recent announcement of a new payment model that would help patients access health-tracking technology (1). But a major revamp of kidney care models is needed akin to the congressional action that led to the creation of the original ESRD bundle, said Suzanne Watnick, MD, FASN, professor of medicine in the Division of Nephrology at the University of Washington in Seattle and the ASN Health Policy Scholar. “We need major disruption,” she said. “We do need an act of Congress.”

Redesigning the bundle

During her Kidney Week presentation, Watnick focused on short-term and long-term fixes needed in the Medicare ESRD bundle. She noted that there has been very little innovation in the delivery of dialysis care in the past several decades, resulting in stagnation in patient survival. By contrast, she noted that other fields, such as oncology, have seen major improvements in patient survival from advanced malignancies over the past 20 years. “We need to improve the lives and well-being of our patients,” she said.

Watnick explained that an act of Congress in 1972 guaranteed coverage for people who require hemodialysis or transplant. The move was in response to the limited access to dialysis and a push to provide benefits to people with

disabilities more broadly. Since then, that mandate has been filled through a series of payment models. The first version of the ESRD bundle payment model was created in 1983, but certain medications were billed separately, which may have created an incentive to overuse such medications. In 2008, Congress passed the Medicare Improvements for Patients and Providers Act to curb excess expenditures through a single bundled payment, including for medications, tied to patient quality measures. The new bundle was implemented in 2011 and helped curb expenditures and increase home dialysis rates.

Yet, Medicare spending on kidney failure continues to account for a disproportionate share of mandatory federal health spending. Watnick explained that people with kidney failure on dialysis make up 1% of Medicare patients but 7% of Medicare’s budget. “We are dealing with a lot of focus on our patients because they are expensive,” she said.

The bundle itself may explain why innovation and improvements in patient care have lagged in kidney diseases. Watnick noted that there have been recent innovations in chronic kidney disease (CKD) and glomerular nephritis care, with a growing array of kidney-preserving therapies. Yet, investment by the National Institutes of Health in kidney disease research has lagged that in cancer. The single-payment structure of the bundle has also hampered private investment in kidney care innovation, as there is little financial incentive. She noted, by contrast, that oncology drugs are separately covered, creating a greater opportunity for their manufacturers to recoup development costs.

“It’s much easier to find a financially viable pathway,” she said. The Medicare Payment Advisory Commission recognized this several years ago and created the Transitional Drug Add-On Payment Adjustment and the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), which provided add-on payments to the bundle to incentivize innovation. Yet, the time-limited nature of these programs and the fact that just one technology has qualified for TPNIES have minimized their impact, Watnick said. “This is just a band-aid on a gaping wound,” she said.

Watnick said changes are needed to increase the base payment rate per dialysis session and to design new payment adjusters to incentivize care quality. She suggested payment adjustments to keep up with increased costs and to

account for geographic and other cost differences across dialysis facilities. For example, she noted that rural facilities pay more to transport dialysis supplies. Better quality metrics tied to patient-centered outcomes are also needed. She noted that differences in patients’ access to transplantation and outcomes also need to be addressed. Better patient engagement in designing metrics and greater transparency are also needed. “Patient experience measures are so important,” she said. “Emphasizing outcome-based and care coordination metrics [is] important too, not just the easily gamed ones.”

Some of these changes can be made in the short term, but others may be longer-term endeavors that take until 2050. Watnick expressed that major changes will require federal advocacy. She noted that the 2019 Advancing American Kidney Health Executive Order and other ongoing programs are working to increase transplant access and home dialysis (2). Yet, she said that substantive changes are needed to payment models to continue progress.

CMS shifts

One of the biggest policy shifts currently underway is the growing proportion of people receiving dialysis moving to Medicare Advantage plans. But smaller shifts are already in progress with revisions to some existing models of chronic disease care. Shortly after Kidney Week, the Center for Medicare and Medicaid Innovation (the CMS Innovation Center) also announced a new Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model (1).

The 10-year voluntary model will pay incentives to ACCESS organizations that make technology available to help patients with chronic diseases manage their conditions. The model aims to improve patients’ access to technologies such as telehealth, wearable health-tracking devices, and apps to help manage chronic diseases. Targeted conditions include hypertension, CKD, prediabetes or diabetes, dyslipidemia, obesity or overweight, chronic musculoskeletal pain, or depression or anxiety. It will include a track called Early Cardio-Kidney-Metabolic, focused on risk factors such as hypertension, elevated cholesterol, overweight or obesity, and prediabetes, to promote the prevention of kidney diseases and related chronic conditions. Another track, Cardio-Kidney-Metabolic, will focus on diabetes, CKD, and atherosclerotic heart disease, again shifting the focus to upstream care for kidney diseases and their contributors. The other two tracks will focus on behavioral health and musculoskeletal pain.

The ACCESS Model will be available without a copay for patients with Medicare Fee-for-Service starting in July 2026 and will last for 10 years, with evaluations for quality and spending impact. Participating ACCESS organizations will receive predictable payments to help patients manage chronic disease, with full payments tied to health outcomes, such as improved blood pressure control, rather than to a particular set of services. It will also emphasize care coordination with primary care and referring clinicians, as well as the use of technology to share information and data between patients and clinicians. Limited details were available at press time, but Watnick said that the ACCESS organizations would work with coordinating physicians, who would receive payments of \$100 per patient. She was waiting for more details on how nephrologists might participate.

“It will get tools into the hands of our patients to help either prevent or slow down progression through novel technologies in conjunction with a managing clinician, [who] may be able to be a nephrologist,” Watnick said in a

follow-up interview after the ACCESS Model announcement.

Eugene Lin, MD, MS, FASN, assistant professor of medicine and resident fellow at the Schaeffer Center for Health Policy and Economics at the University of Southern California in Los Angeles, said the growing number of Medicare Advantage individuals on dialysis is likely to be highly impactful. He noted that the 21st Century Cures Act of 2016 gave all people on dialysis the option to select a Medicare Advantage plan offered by a private insurer instead of Medicare Fee-for-Service starting in 2021. In 2007, only about 19% of people on dialysis were enrolled in Medicare Advantage plans due to narrow exceptions that allowed it, but the number grew to about 30% in 2020. Since the passage of the act, that number has grown to more than half of people on dialysis, and it is expected to reach approximately 60% by 2030 (3).

"Medicare Advantage is hugely important," Lin said. "It's the plurality payor for dialysis. It's a story of heterogeneity [in payments and offerings]. We really need to understand the pros and cons if we want to have an informed discussion."

Those private plans must turn a profit—something they do by constructing narrow networks of dialysis companies who negotiate their rates with the insurer, Lin explained. This gives larger dialysis facilities an advantage by allowing them to negotiate better rates, while disadvantaging smaller dialysis centers. By comparison, Medicare Fee-for-Service pays the same rates for all facilities in a geographic area. This can also lead to higher-priced nephrologists being cut out of networks, he said. Some networks may have many high-quality centers, while others may have primarily low-quality facilities.

"Not all [dialysis centers] are created equal," Lin said. "Those narrow networks may come at the cost of quality or distance. The good news is that narrow network facilities tend to be, on average, closer to patients, but they also have a little bit higher mortality rate and lower [quality scores]."

Medicare Advantage plans may also limit access to certain therapies or require prior authorization to constrain costs. They may also steer patients toward less expensive medication options by offering lower or no copays, Lin explained. That may affect their access to or use of newer, more expensive medications, such as sodium-glucose cotransporter-2 inhibitors or specialty drugs, he said. However, he noted that the plans may also prioritize better care coordination to avoid costly complications or hospitalizations.

These private insurer plans may also offer lower out-of-pocket costs and more services that can be very appealing to patients. For example, Medicare Advantage plans may offer vision, hearing, and dental benefits that are not offered through Fee-for-Service. Fee-for-Service beneficiaries may purchase Medigap plans to help reduce out-of-pocket costs; however, these plans are not available to all beneficiaries. As a result, out-of-pocket costs for Medicare beneficiaries may top \$10,000 per year for outpatient dialysis alone, whereas Medicare Advantage plans are required to cap out-of-pocket costs at \$9300 per year, and many plans offer lower caps, such as \$3000 to \$4000, to attract participants, Lin said. "That's a huge difference for many people," Lin explained. Prescription drug plan deductibles are also lower in Medicare Advantage plans. In fact, 15% of people on dialysis on Fee-for-Service plans have no prescription coverage at all, Lin noted.

Lin noted that there is some evidence that dialysis facilities may be steering patients into Medicare Advantage plans due to higher dialysis reimbursement rates. However, this may not be advantageous for all dialysis companies. "There are a substantial number of facilities that are losing under this bargain, and they are probably the small, independent facilities," he said. "There is a threat [that] those smaller facilities may close or be acquired by the larger players."

However, cuts to Medicare Advantage plans' reimbursement rates and quality downgrades could make these plans less attractive to patients in the coming years, Lin said. That trend has already led some companies to pull back from the market. "There are going to be fewer ancillary benefits, increased out-of-pocket maximums, and increased drug costs," he surmised. ■

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From Marrow to Podocyte: Following the suPAR Trail

By Caitlyn Vlasschaert

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When we think about immune-mediated proteinuric kidney disease, autoantibodies are often front of mind: anti-phospholipase A2 receptor (PLA2R) and anti-thrombospondin type 1 domain-containing 7A (THSD7A) in membranous nephropathy, anti-nephrin in subsets of minimal change disease and focal segmental glomerulosclerosis (FSGS), and others that target distinct components of the glomerular filtration barrier. These discoveries have cemented the concept that autoantibody-mediated injury can directly compromise podocyte integrity. More recently, attention has turned to myeloid-derived factors. Circulating mediators produced by monocytes and their progenitors have long been suspected to contribute to glomerular injury, but their role has proven harder to define.

One of the most prominent—and most debated—candidates is the soluble urokinase plasminogen activator receptor (suPAR). In 2011, Wei and colleagues reported that suPAR, a cleaved form of the glycosylphosphatidylinositol-anchored receptor uPAR, was elevated in most patients with FSGS and could activate podocyte $\alpha v\beta 3$ integrins (1). Activation of this axis reorganized the podocyte actin cytoskeleton, with proteinuria in experimental systems. Patient serum collected before recurrent FSGS after transplant induced $\alpha v\beta 3$ activation, and plasmapheresis that reduced suPAR diminished this effect. Recombinant suPAR produced albuminuria and early FSGS-like lesions in uPAR-null mice. These observations, together with signals from large cohorts, generated substantial interest in suPAR as a circulating permeability factor (2).

Follow-up studies, however, painted a more complicated picture. In the NEPTUNE (Nephrotic Syndrome Study Network) cohort, Spinale et al. found that suPAR was not an independent predictor of FSGS after adjusting for the estimated glomerular filtration rate and proteinuria, and experimental models with elevated suPAR did not develop proteinuria (3). Harel et al. later showed that injection of recombinant uPAR/suPAR in wild-type and uPAR knockout mice failed to induce proteinuria, podocyte effacement, or cytoskeletal disruption, suggesting that suPAR by itself may not be sufficient to drive glomerular injury (4). The molecular heterogeneity of suPAR has been proposed as one explanation for discrepant findings: Multiple fragments exist, and it has been suggested that a hypoglycosylated form, not detected by standard enzyme-linked immunosorbent assays, might be pathogenic (5).

Most recently, Spear et al. reported in *JASN* on the role of bone marrow-derived factors in glomerular disease, with particular attention to the tumor necrosis factor (TNF)- α -suPAR axis (6). In prior work, this group had used bone marrow chimera and adoptive transfer experiments to suggest that immature myeloid cells could transmit proteinuria in mice (7). In the new study, the authors directly examined human bone marrow aspirates from 27

patients with chronic kidney disease (CKD), including 17 with biopsy-proven FSGS, and 11 healthy control patients (6). Hematopoietic stem and progenitor cells (HSPCs) showed a proinflammatory transcriptional skew, including TNF- α and interferon- γ pathways. When cultured *ex vivo*, these HSPCs generated monocytes that secreted higher levels of suPAR, which disrupted podocyte actin *in vitro* and caused proteinuria in mice—effects that are mitigated by suPAR neutralization. Inflammatory stimulation of HSPCs in mice similarly increased suPAR and was followed by proteinuria. Among people with CKD receiving corticosteroids, suPAR secretion from marrow-derived monocytes was modestly reduced, but the transcriptional skewing of HSPCs persisted, suggesting that conventional immunosuppression does not fully address this upstream driver. This finding aligns with the clinical experience, in which some patients relapse or remain refractory despite steroid therapy.

The implication is that TNF- α -driven marrow programming may enhance suPAR production and contribute to podocyte injury. Although the patient sample was small, and much of the functional evidence comes from *ex vivo* and animal models, the study nevertheless represents an important step in probing upstream sources of inflammatory mediators in CKD. For clinicians, the message is not that suPAR testing is ready for practice but rather that bone marrow-derived inflammatory signals may shape glomerular disease in ways that we are only beginning to understand. Bringing marrow biology into the picture broadens our view of immune-kidney cross talk and highlights new pathways worth investigating. ■

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An Increasing Kidney Transplant Burden Demands Improved Post-Transplant Care Models

By Veena Ganesan and Samira S. Farouk

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The 2019 Advancing American Kidney Health Executive Order outlined an ambitious goal: to significantly expand access to kidney transplant and achieve a target of 80% of patients starting kidney replacement therapy either receiving a transplant or initiating home dialysis by 2025 (1). Although this goal has not been met, the number of kidney transplant recipients (KTRs) in the United States reached a record high of 27,351 in 2023 (2), and the number of prevalent KTRs was 245,506, according to the 2023 US Renal Data System annual report (3).

With a recent estimate of only 800 transplant nephrologists in the United States (4), there is clearly a need for effective collaboration among transplant centers, referring nephrologists, and primary care physicians (PCPs)—particularly as the number of patients needing pretransplant evaluation and waitlist follow-up continues to rise. A recent publication in the *American Journal of Kidney Diseases* (5) summarizes a 2022 American Society of Transplantation Controversies Conference, in which the goal was to “identify major challenges and propose guidance for collaborative, safe, and standardized care transitions and longitudinal management of this population.” To meet these demands, the authors emphasize that general nephrologists and referring practitioners must work in tandem with transplant centers to ensure optimal care for post-transplant patients who might otherwise face inadequate access to services.

Even the first step in transitioning a KTR to a general nephrologist can be fraught with obstacles, including patient factors (e.g., reluctance, location), center factors (e.g., safeguarding outcomes), and nephrologist factors (e.g., comfort level). To support smoother transitions, the authors provide an example of a document delineating key recipient and donor data that can be manually completed and shared by the transplant center with the referring nephrologist (5). Incomplete records—particularly when electronic health record (EHR) systems are not universally shared—may leave patients vulnerable to preventable hospitalizations and allograft loss. As with all aspects of patient care, the authors underscore the importance of clear communication between transplant centers and referring nephrologists (5). Simple interventions, such as exchanging cell phone numbers, may greatly improve communication and care coordination. However, the time required to prepare such documents and communicate with practitioners outside of the transplant

team contributes to already well-described “unbillable work.” A more streamlined, universal EHR and compensation systems that more accurately capture unbillable and value-based work are needed to build sustainable care models (4).

The majority of the publication outlines clinical practice guidelines for long-term KTR care, including infectious complications, cardiometabolic disease, recurrence of glomerular disease, cancer risk and screening, and pregnancy (5). These sections highlight sometimes complex post-transplant care needs and underscore the importance of high-quality training in transplant nephrology during general nephrology fellowship—and suggest that transplant training for the general nephrologist perhaps should be expanded. Although these guidelines can aid in initial decision-making, it seems unlikely that referring nephrologists would feel empowered to make transplant-specific decisions without direct partnership with transplant centers, particularly in the early post-transplant period. The authors also note that even a seemingly straightforward question of when to transition a patient back to referring practitioners remains controversial.

Although care may be “transitioned,” a long-term partnership between practitioners is a more realistic goal rather than “graduation” from the transplant program. Ongoing challenges include resistance from general nephrologists, who face their own nontransplant demands and inadequate reimbursement models. PCPs are also critical members of the care team, although re-engaging them—especially after their role may have diminished during the dialysis period—can be difficult. The study also highlights the importance of patient empowerment: Transplant recipients who understand their medications, recognize warning signs, and know when and where to seek help are better prepared to manage their care beyond the transplant center (5).

The publication points to systems-level solutions, such as an interoperable EHR, telemedicine, and transition clinics, as strategies to improve continuity. Shared-care models, in which transplant centers oversee immunosuppression and transplant-specific needs, while community nephrologists manage routine monitoring, may balance resources effectively. Tailored education, culturally sensitive materials, and expanded use of digital tools can further support patients across diverse settings.

Ultimately, successful transitions and care partnerships will depend on close collaboration among transplant centers, general nephrologists, PCPs, patients, and care partners. Although expanding the KTR care team to include PCPs and general nephrologists may reduce some burden on transplant centers, the need to grow the transplant nephrology workforce remains. With more transplant recipients than ever before and not enough transplant nephrologists, building efficient, patient-centered care pathways is essential to safeguard long-term graft survival and patient well-being. ■

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ASN Comments on Emerging ESRD Measures and Advocates for Congress to Support the Kidney Community

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Reinforcing ASN's long-standing policy priorities: promoting patient-centered care, ensuring quality measures are evidence-based and feasible, and preventing unintended consequences for people living with kidney diseases and the professionals who care for them, ASN recently submitted two comment letters (1, 2) addressing kidney-related quality measures under review.

Quality measures increasingly shape how kidney care is delivered and reimbursed in the United States. Measures that are poorly designed or insufficiently tested can add administrative burden, distract from patient care, and create incentives that do not align with patient needs. ASN's comments reflect its ongoing commitment to ensuring that quality programs are grounded in strong evidence, promote truly patient-centered and actionable care, and account for real-world clinical and operational challenges. By engaging early and constructively, ASN aims to help ensure that quality measurement advances—rather than hinders—high-quality care for people living with kidney diseases.

ASN comments on the Partnership for Quality Measurement (PQM) fall 2025 Endorsement and Maintenance cycle

ASN submitted comments as part of PQM's Endorsement and Maintenance fall 2025 cycle, emphasizing ASN's core principle that quality measures used in federal programs must be rigorously evaluated, transparent, and supported by evidence (1). ASN addressed five End Stage Renal Disease (ESRD) facility-level measures, assigned by the Centers for Medicare & Medicaid Services (CMS) consensus-based entity identification number (CBE ID), that are up for endorsement or maintenance, providing input on each based on feasibility, clinical relevance, and alignment with quality goals.

CBE ID 5320: Percentage of Chronic Hyperphosphatemia in Dialysis Facilities

ASN expressed significant concerns about this proposed measure. While recognizing the intent to monitor phosphorus management in the context of payment reforms, ASN cautioned that the measure relies solely on observational data and lacks evidence tying specific serum phosphate thresholds to improved clinical outcomes. ASN recommended that CMS reconsider thresholds and exclusions for patients with complex nutritional needs, so the measure does not inadvertently penalize appropriate care.

CBE ID 2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

ASN supported this measure and the updated exclusion criteria, noting continuity with prior feedback. However, ASN urged additional exclusions for patients with limited life expectancy or those expected to receive a transplant soon and suggested explicitly incorporating frailty as part of the rationale.

CBE ID 1463: Standardized Hospitalization Ratio for Dialysis Facilities

ASN agreed that hospitalization rates are meaningful quality indicators but urged CMS to convert the measure from a simple ratio to a true risk-standardized rate. ASN raised concerns that conditions unrelated to kidney diseases (e.g., oncologic or surgical causes) may drive hospitalizations and distort comparisons between facilities.

CBE ID 2979: Standardized Transfusion Ratio for Dialysis Facilities

ASN appreciated improved exclusion and risk-adjustment criteria for this measure, including considerations for coagulation disorders and hereditary anemias. ASN also reiterated that the need for transfusions frequently reflects complex conditions outside the purview of dialysis care. ASN recommended transitioning the measure to a risk-standardized rate to improve benchmarking and interpretability.

CBE ID 0369: Standard Mortality Ratio for Dialysis Facilities

ASN reaffirmed support for this mortality measure but emphasized that deaths due to patient choice to withdraw from dialysis should be explicitly excluded. ASN further recommended modifying the measure into a true risk-standardized rate to better benchmark facility performance and to ensure that mortality metrics do not inadvertently discourage patients from making informed treatment decisions.

Across all five measures, ASN's feedback reflected its long-held policy priorities: measures should be grounded in evidence, reflect care that facilities can influence, and avoid penalizing patient choice or complex clinical realities.

ASN comments on the 2025 Measures Under Consideration (MUC) list

In a separate letter submitted in January, ASN provided detailed feedback on three ESRD-related measures included on the 2025 MUC list released by PQM (2). Although recognizing CMS's stated commitment to patient-centered care and the Meaningful Measures 2.0 initiative, ASN raised concerns about whether the proposed measures, as currently specified, would meaningfully advance those aims.

MUC2025-011: Dialysis Facility Discussion of Life Goals

ASN welcomed the intent of this measure, noting the importance of understanding patients' goals and values. However, ASN expressed significant reservations about the measure's readiness for implementation in the ESRD Quality Incentive Program. Key technical specifications, including the full survey instrument, were not available for review, limiting stakeholders' ability to assess validity and feasibility. ASN also noted the absence of facility-level testing of reliability and that the measure previously failed to receive consensus-based endorsement due to insufficient evidence. Importantly, ASN emphasized that documenting patient goals without requiring follow-up action—such as referrals to supportive services or care plan adjustments—risks turning meaningful conversations into a compliance exercise. ASN also raised concerns about survey fatigue in dialysis settings, in which patients are already asked to complete multiple surveys, potentially undermining data quality and patient engagement.

MUC2025-020: Advance Care Planning

ASN has long supported advance care planning for people with kidney failure and their families. However, ASN noted that this proposed measure was designed for inpatient hospital settings and depends on documentation that dialysis facilities often cannot access due to limited interoperability and nonstandardized transitions of care. Holding dialysis facilities accountable for processes outside their control, ASN cautioned, could create reporting challenges without improving patient care. ASN also questioned whether the age-based criteria used in the measure appropriately target patients most likely to benefit, suggesting that clinical indicators such as frailty or advanced illness may better align with patient-centered care.

MUC2025-064: Facility-Level Chronic Hyperphosphatemia in [Patients on Dialysis]

Regarding this proposed measure, ASN acknowledged CMS's rationale for proposing a quality measure focused on phosphate-lowering medications in patients on dialysis but did not express support for the measure in its current form due to limited evidence and potential unintended consequences. ASN raised concerns about reliance on observational data and expert opinion to define serum phosphorus thresholds, noting the lack of randomized clinical trial evidence linking specific targets to improved outcomes. ASN also highlighted the risk of unintended consequences, including discouraging adequate nutrition in some patients. Consistent with its emphasis on actionable and fair measures, ASN suggested that medication prescribing or adherence-based measures may better reflect quality of care, particularly given the many patient-level factors that influence phosphorus control.

ASN's congressional advocacy to close out 2025

Meanwhile, the society continues to encourage congressional efforts to enact a funding bill to support the research and patient care programs most essential to people with kidney diseases, their care teams, and the investigator community. Many of ASN's advocacy priorities (highlights below) were included in the draft spending bill, and as of press time, top congressional leaders were attempting to reach consensus on how to enact that bill before funding was to run out on January 30, 2026.

- ▶ calling for “robust support for kidney research at NIDDK [National Institute of Diabetes and Digestive and Kidney Diseases],” encouraging NIDDK research into chronic kidney disease and disparities in access to kidney transplantation
- ▶ prioritizing the development of a modern, dynamic organ candidate-matching technology system that better serves donor families and recipients; performs efficiently; allows for timely, systematic updates in allocation policy; and supports clinical innovation
- ▶ increasing funding to support living donors through the Health Resources and Services Administration's living donor reimbursement program
- ▶ expanding chronic kidney disease prevention and early detection and screening programs through the Centers for Disease Control and Prevention and CMS

- Using organ-tracking technology to allow organ procurement organizations real-time updates on an organ's location to help improve safety and efficiency in the transplant process

Together with the National Kidney Foundation, ASN urged congressional leaders to finalize these and other priorities. The letter and a timeline of ASN's policy activities can be found on ASN's Kidney Health Advocacy policy webpage at <https://www ASN-online.org/policy/kidney-health.aspx>. To keep track of ASN's policy efforts throughout the year, follow coverage in *Kidney News* and the ASN podcast feed, and follow @ASNAdvocacy on X for real-time policy updates. ■

Protecting Peer Review: A System in Crisis

By Lori-Ann Fisher and Bernard G. Jaar

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Peer review remains a crucial part of academic communication, with roots dating back to the 18th century when the editor of *Medical Essays and Observations* sent copies of articles to external experts prior to publication (1). Modern peer review is defined as the process by which grant applications and manuscripts are assessed by subject-matter experts (reviewers) (2). With the abundance of research that the scientific field now produces, a labor crisis exists due to too few reviewers, resulting in deficiencies in the peer-review process. In "The Peer Review Crisis: How to Fix an Overloaded System," the author describes the scope of this crisis, while offering solutions to both incentivize reviewers and improve the efficiency and quality of the peer-review process (3).

Both increased turnover times for submission to acceptance of manuscripts and more frequent invited reviewer rejections, in part due to "reviewer fatigue," have been cited as evidence of growing labor shortages (4). The consequence of an overloaded peer-review system is the inability to maintain scientific rigor, resulting in publication of poor-quality or flawed research. Indeed, based on data from The Retraction Watch Database, a publicly available website capturing data from scientific databases, an estimated 62,970 articles have been retracted since 2000 (Figure) (5).

Solutions to improve the peer-review process are not only needed to enhance research output but for trust in science, which is now under increasing public scrutiny. Financial reimbursement has been proposed to incentivize reviewers, with pilot data showing improvements in review time, but not to limit quality (6). Such financial interventions may not be sustainable without transferring costs to the authors in article-processing fees. Realistic incentives may include pathways allowing recognition of peer review for academic promotion. Public accolades may also incentivize reviewers, an example of which is the *American Journal of Kidney Diseases*' Reviewer Hall of Fame (7). However, this may not translate to more reviews, as some data suggest reduced reviews after receipt of such prizes (8).

Expanding the pool of reviewers may also be needed. One-fifth (20%) of scientists performed approximately 67%–94% of reviews, comprised of established academics from high-income countries (9). Approaches to enhance this pool could include: 1) partnering more experienced reviewers with early-career scientists, 2) recruiting academics from low- and middle-income countries, and 3) using artificial intelligence to better match reviewers to publications. These approaches may aid in addressing shortages, while not compromising quality. Selecting reviewers from a global pool may provide cultural context to and equity in reviews, especially in health sciences, reducing publication bias. Importantly, another use of artificial intelligence may be to reduce reviewer burden for grammar and content assessment (e.g., plagiarism). Furthermore, standardizing peer review through directed questions may improve congruence and validity in review and reviewer workload.

Rising popularity of preprint servers since the COVID-19 pandemic has allowed dissemination of research without peer review. Curation of manuscripts through these avenues may allow reductions in reviewer time, as selected research may undergo traditional peer review, whereas other research may experience less-formalized screening prior to publication.

Despite ongoing challenges, peer review remains the gatekeeper for science. To protect this mechanism, innovations are rapidly needed from editors, journals, funding agencies, and academic institutions. ■

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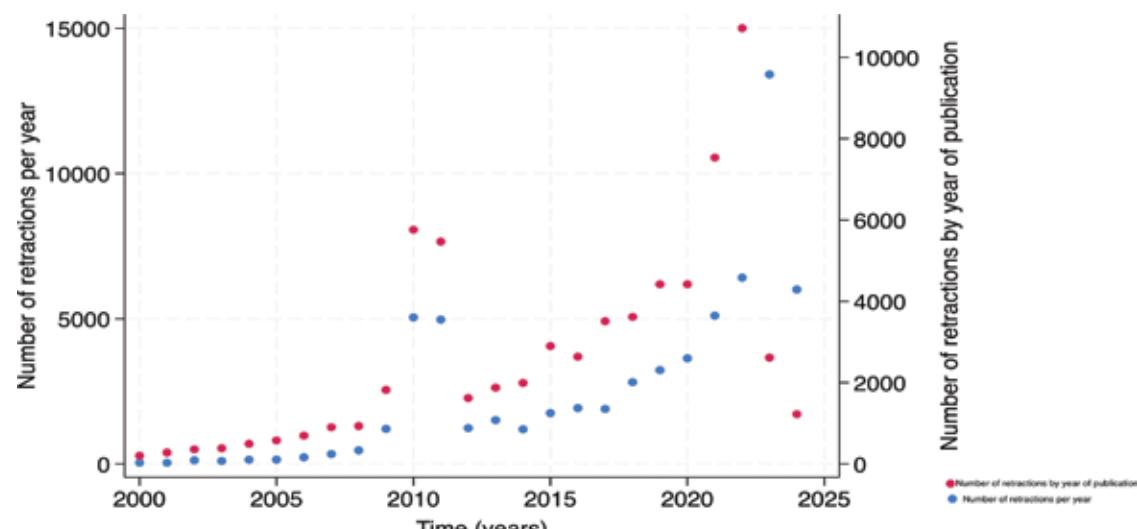
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Figure. Number of retractions per year and number of retractions by year of publication over a 25-year period (2000–2024)



The Silent Crisis in Transplant Nephrology: A Call for Recognition, Respect, and Reward

By Mona Doshi, Prince Mohan Anand, Neeraj Singh, Gaurav Gupta, Amit Govil, Nadiesda Costa, and Bekir Tanriover

<https://doi.org/10.62716/kn.002512025>

Although kidney transplantation is the preferred treatment for advanced kidney disease, its recent success is accompanied by emerging challenges. The transplant volume in the United States reached a record 27,000 in 2024 (1), driven by the expansion of donor and recipient eligibility. However, the broader geographic organ sharing, mandated by the 2021 allocation policy, has increased cold ischemia times, elevated the organ nonuse rate, and contributed to a rate of delayed graft function affecting one-third of deceased-donor kidney transplants (2).

The clinical consequences of this shift are reflected in recent outcome data, which show a slight but concerning decline in graft survival. According to the 2023 Scientific Registry of Transplant Recipients report (2), the proportion of recipients achieving a 1-year estimated glomerular filtration rate ≥ 45 mL/min/1.73 m² (a key surrogate for long-term function) decreased from 67.8% to 64.9% between 2016 and 2022. Concurrently, the US Renal Data System 2024 report documents a dip in 5-year graft survival (1). A heightened emphasis on long-term patient management is imperative to halt or reverse these unfavorable trends.

Raising awareness of the crucial role of transplant nephrologists

Kidney transplantation is a complex, multistep journey for people living with kidney diseases, spanning from initial referral and evaluation to waitlisting and long-term post-transplant care. While general nephrologists initiate the process, the subsequent navigation is led by transplant nephrologists. Supported by a multidisciplinary team, these specialists guide patients through the waitlist period and are essential for maintaining positive long-term outcomes.

However, the transplant community faces a critical workforce challenge. Over the past 2 decades, the annual number of kidney transplants has doubled, but the number of transplant nephrologists has not kept pace. Today, approximately 800 transplant nephrologists in the United States manage a vast and growing patient population, including nearly 27,000 new transplant recipients per year, 140,000 patients on the waitlist, and a prevalent population of about 300,000 existing recipients (a workload of approximately 450 patients per transplant nephrologist) (3, 4).

Compounding this shortage is an impending “silver tsunami.” One-third of practicing transplant nephrologists are aged 55 years or older and are likely to retire within the next decade. With fellowship programs training only 30 to 40 new transplant nephrologists annually, there is an urgent need to expand the workforce pipeline to replace retiring physicians and meet rising clinical demand (5, 6).

Beyond direct patient care, transplant nephrologists also play a crucial role in educating the next generation, including general and transplant fellows, as well as allied health professionals. Sustaining this educational mission is fundamental to addressing the systemic workforce shortage.

The leading causes of long-term graft loss have shifted to chronic antibody-mediated rejection and recurrence of native kidney diseases, even as acute rejection rates have fallen to their lowest levels thanks to advances in immunosuppression. Progress in finding

new treatments is hampered by two key factors: the low incidence of these conditions at individual centers and the absence of standardized diagnostic and treatment criteria. Conducting multicenter prospective clinical trials through collaborations among transplant nephrologists, industry, and the US Food and Drug Administration is therefore critical to developing solutions for these persistent challenges.

junior faculty; and engaging in research and scholarly activities

- 4 Leadership, quality, and program development: leading quality improvement and patient-safety initiatives; contributing to program development and regulatory compliance; and advancing the field of transplantation through innovation, policy, and advocacy

Systemic challenges and a path forward

Although the needs of the transplant nephrology community overlap with their general nephrology colleagues, transplant nephrologists face two dominant, systemic challenges that threaten the field's sustainability:

- 1 Systemic failure to recognize and reward its true value. The prevailing relative value unit-based compensation model shortsightedly focuses on billable procedures, systematically excluding the critical nonbillable work—from complex care coordination to regulatory compliance—that forms the backbone of a successful program (7–9). Additionally, no relative value unit codes currently exist for transplant nephrology. These financial disincentives are exacerbated by a striking leadership gap: With surgeons leading over 90% of programs, the priorities and financial flows within transplant centers are naturally skewed toward surgical interventions (10). This combination has created an environment in which the physicians responsible for the health of waitlisted and transplant patients lack the institutional influence and financial support to match their responsibilities.
- 2 A critical workforce shortage. The field faces a worsening deficit of specialists, fueled by three primary factors:
 - A shrinking pipeline: broader declining interest in nephrology
 - Training and financial disincentives: an extra year of fellowship training without a significant increase in compensation
 - Poor work-life balance: the intensely demanding nature of the role exacerbated by the lack of benchmarking for staffing ratios

Several mitigation strategies exist to help address these challenges. Recognizing transplant nephrologists as key players in the ecosystem and mandating dual medical and surgical leadership at hospital-reporting meetings; establishing benchmarks for workload and adequate compensation of a transplant nephrologist; delegating stable patient care to referring nephrologists and advanced practice providers; and enhancing transplant exposure in general fellowships are necessary but insufficient to replace the need for dedicated transplant nephrologists. The entire nephrology community must come together to support transplant nephrology.

A call to action: ASN's commitment to “Supporting Transplant Nephrology Together”

To address these challenges, ASN recently convened a meeting of key stakeholders, including the present authors, titled “Supporting Transplant Nephrology Together,” to outline a concrete action plan. This initiative directly tackles the core strategic questions of compensation, training, and visibility through immediate next steps.



The entire nephrology community must come together to support transplant nephrology.

The role of the transplant nephrologist encompasses four key pillars:

- 1 Clinical care: providing comprehensive, longitudinal care for kidney transplant candidates and recipients, including pretransplant evaluation, peritransplant management, long-term allograft surveillance, and management of immunosuppression and transplant-related complications
- 2 Multidisciplinary collaboration: working closely with transplant surgeons, coordinators, pharmacists, nurses, social workers, and other specialists to ensure integrated, patient-centered transplant care and optimal outcomes
- 3 Training and research: educating trainees, allied health professionals, and patients; mentoring fellows and

Action plan on compensation and reimbursement

Convene a dedicated ASN Transplant Compensation Toolkit Task Force charged with developing and implementing a toolkit (or other work product) that helps articulate the value of transplant nephrology and transplant nephrologists, creates a comprehensive document outlining the issue and key work areas, and develops and disseminates a comprehensive business case that quantifies the full economic value of transplant nephrologists. If successful in achieving its charge, the task force will create an opportunity for additional steps, such as:

- ▶ identifying ideal data, creating a plan to overcome existing gaps, and establishing a goal of generating and improving these data on a regular basis;
- ▶ defining necessary staffing ratios;
- ▶ scoping opportunities for valuation advances (e.g., through the American Medical Association Relative Value Scale Update Committee);
- ▶ developing educational forums, such as webinars or courses, to educate the community on the toolkit and data-collection efforts; and
- ▶ providing practical advice on compensation models and career planning to graduating transplant nephrologists, using forums such as the Nephrology Business Leadership University.

Action plan on training and workforce

Leverage the success of the ASN–American Society of Transplantation Task Force on Accreditation Council for Graduate Medical Education Accreditation to advance key strategic initiatives. Below are some concepts that could be considered:

- ▶ Formalize professional identity. The Centers for Medicare & Medicaid Services should formally recognize transplant nephrologists as a distinct physician type in the Provider Enrollment, Chain, and Ownership System, which would make a Center for Medicare and Medicaid Innovation payment model for post-transplant care possible. For example, this model could be analogous to the dialysis payment system, appropriately funding the comprehensive care team.
- ▶ Customize continuing certification (previously called Maintenance of Certification). Collaborate with the American Board of Internal Medicine to develop a tailored continuing certification pathway for physicians specializing in transplant nephrology to allow

them to demonstrate their skills in their focused area of expertise.

- ▶ Enhance fellowship training. Mandate and standardize robust, longitudinal clinical experiences in transplant recipient care within general nephrology fellowship curricula to ensure baseline competency.

Action plan on visibility and integration

Continue to strengthen ASN's commitment to transplant nephrology, which includes making ASN Kidney Week even more "transplant-forward" by:

- ▶ bolstering transplant nephrologist representation on ASN committees and the Kidney Week Education Committee;
- ▶ adding more transplant-related sessions to Kidney Week;
- ▶ establishing new forums at Kidney Week for transplant nephrology fellowship program directors and transplant medical directors to meet;
- ▶ ensuring that transplant nephrology is included in all programming for division chiefs and fellowship training program directors; and
- ▶ inviting the transplant community to propose a specific project within the ASN Excellence in Patient Care platform, serving as a universal guidance document streamlining transfer of care between transplant nephrologists and community partners.

These coordinated efforts, many now formally underway, are critical to equitably recognize transplant nephrologists, preserve workforce stability, and strengthen the foundation of transplant care for the future. ■

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The authors report no conflicts of interest.

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Integrating Clinical Care and Research for Pediatric Glomerular Diseases Through the BRIDGE Program

By Kiran Z. Naqvi, Lucy C. Miller, Veronica Servin, Nikki N. Uditsky, Sherry L. Wilson, Andrew L. Schwaderer, and Myda Khalid

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Glomerular diseases (GDs) significantly contribute to the burden of chronic kidney disease in children, and recent evidence suggests that pediatric patients with GDs may experience a decline in kidney function similar to that seen in adults (1–3). Despite advances in therapeutic options for adults with GD, pediatric therapies remain limited. Although reasons for this are multifactorial, a major contributing factor is limited clinical research and trials focusing on pediatric GD (4, 5). To overcome these barriers and accelerate progress in early detection, staging, and interventions for pediatric GD, an integrated pediatric and young adult GD research clinic was established at Riley Hospital for Children, Indiana University School of Medicine, in Indianapolis. This program embeds longitudinal patient care with biorepository and registry development. By combining clinical visits with research activities, this program streamlines processes and fosters patient engagement and trust (6). This program, called BRIDGE (Biorepository, Registry, Integrated Clinic, Biomarker Discovery and Glomerular Disease Exploration), is designed to support the diagnosis and management of GD, enhance biomarker discovery, and provide infrastructure for the development and execution of novel clinical trials.

Children and young adults presenting with new-onset GD are enrolled into the GD registry and the BRIDGE research clinic. They are followed longitudinally, and during scheduled clinic visits, clinical parameters, biospecimens, and patient surveys are collected. Participants are also introduced to eligible clinical trials, within and outside of the institution, specific to their condition to give them access to cutting-edge therapies.

The objectives for this program include improved access to GD specialists and up-to-date care, the development of a longitudinal clinical data repository with corresponding biospecimens, patient engagement including patient input into clinical research priorities and design, and enhanced clinical trial recruitment and participation.

Improved access and clinical care

- **Clinic visits with a GD expert:** Consented and enrolled patients see a GD specialist, ensuring that the most current treatment options are offered.

- **Enhanced access:** The clinic prioritizes access for consented patients with newly diagnosed biopsy-proven GD, a critical time for care and intervention.
- **Patient education and familiarity with underlying disease:** Focused patient education and engagement improve understanding and familiarity with underlying GD and its impact. This naturally lends itself to better engagement with clinical trials.
- **Integrating clinical and research visits:** This process reduces patient burden, eliminates redundant procedures, and improves efficiency, thereby enhancing care while conserving time and resources.

Biomarker discovery and clinical research

- **Observational study cohorts:** Participants enroll in National Institutes of Health-funded observational studies including Cure Glomerulonephropathy (CureGN) and Nephrotic Syndrome Study Network (NEPTUNE).
- **Clinical registry:** The program collates longitudinal clinical trials to track disease progression, treatment response, and clinical outcomes.
- **Biorepository:** Longitudinal paired blood and urine samples are collected from the time of initial presentation through the disease course and/or the clinical follow-up duration with the goal of identifying diagnostic and predictive biomarkers.

Patient engagement

- **“One stop shop”** streamlines care by integrating clinic and research visits and phlebotomy and study lab processing in a single location.
- **Continuity of the physician** and the study team builds patient and caregiver trust.
- **Patient input** on research priorities and study design via a patient advisory panel is collected.

Enhancing clinical trial recruitment

- **Patient selection:** The study clinic comprises people with GD, thereby reducing the need to find eligible patients through laborious electronic health record data pulls.

- **Clinical trial recruitment:** Patients in the study clinic are more likely to enroll in clinical trials because of a better understanding of their kidney disease, trust in the care team, and ease of the same location for trial visits.
- **Diverse patient population for recruitment:** The program provides care to children across the state of Indiana with a socioeconomically and racially and ethnically diverse population.

Establishing such a program is not without challenges, however. Institutional leadership buy-in and investment are paramount for covering costs of the initial set-up, including but not limited to salary support for research staff, availability of clinical research facilities, funds for biospecimen processing and storage, as well as biostatistical support for establishing the data repository. GD specialists must be available for patient care. Often, care for new patients with GD is time and labor intensive. However, once these initial hurdles are crossed, such programs can be financially sustained through clinical trial and clinical research engagement. Moreover, such programs will accelerate the biomarker and drug discovery and development process, resulting in improved patient outcomes and lower disease burden. ■

All authors are with Riley Hospital for Children, Indiana University of School of Medicine, Indianapolis. Kiran Z. Naqvi, MD, MHA; Veronica Servin; Nikki N. Uditsky; Sherry L. Wilson, RN; and Myda Khalid, MD, FASN, are with the Clinical Research Program in Pediatric Nephrology; Lucy C. Miller, MD, is with the Children’s Clinical Research Center; and Andrew L. Schwaderer, MD, is with the Division of Pediatric Nephrology.

Drs. Schwaderer and Khalid hold National Institutes of Health funding. Dr. Khalid reports serving as a consultant for Boehringer Ingelheim, cochair of the IgAN Alliance with NephCure, on the advisory board for Apellis, and on the board of the Pediatric Nephrology Research Consortium. The other authors report no conflicts of interest.

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Study Brings New Questions About Lung Ultrasonography in Dialysis

By Simon A. Kashfi and Daniel W. Ross

Volume assessment and management are critical for the long-term safety and well-being of people living with kidney failure. The optimal method for assessing dry weight remains uncertain, with the timing and approach often up to the practitioner's clinical discretion. Traditional methods include a physical examination, analysis of patient symptoms, and review of blood pressure trends. Lung ultrasonography is a novel method used in nephrology to help assess volume status in patients on dialysis. Lung ultrasonography is an ideal tool because it is a quick and objective way to assess pulmonary congestion. Lung ultrasound B-line assessment has been shown to correlate tightly with other objective measures of cardiac filling pressures such as wedge pressure (1). A recent study by Kaysi and colleagues (2) presents intriguing data that raise further questions. This study uses midweek, postdialysis B-line assessment using lung ultrasound. Ultrafiltration was increased in patients with an elevated B-line score. Ultimately, dry weight decreased, but there were no statistically significant changes in blood pressure or medications. Echocardiographic parameters were not reported.

The study by Kaysi et al. (2) has several strengths. First, the authors' use of an eight-zone method to assess the B-line score is practical. This method was validated by Reisinger et al. (3) and is more consistent with clinical practice. In contrast, another study on lung ultrasonography in patients undergoing hemodialysis used the 28-zone method (4). Secondly, the Kaysi et al. study (2) demonstrated a significant reduction in dry weight, a finding not observed in the LUST study (NCT02310061) (5). This reduction is intuitive, as fluid removal is necessary to decrease pulmonary congestion. Interestingly, there was no increase in episodes of intradialytic hypotension. Finally, we commend the training and education of nurses in performing lung ultrasound, showing that this technique is accessible and feasible for a variety of cases.

In the 2021 LUST trial (5), lung ultrasound was performed before dialysis during a midweek session. Patients with moderate to severe lung congestion (>15 B-lines) were monitored weekly with lung ultrasound until the treatment goal (<15 B-lines) was achieved. Importantly, cardiac outcomes were also assessed with serial echocardiography. Interestingly, blood pressure, dry weight, and echocardiographic parameters were not significantly different between active and control groups. An analysis of a subset of patients in the LUST

trial revealed improvements in left atrial volume, left ventricular mass regression, left ventricular end-diastolic indexed volume, and left ventricular diastolic filling properties, primarily through the preservation of E/e' (6). These patients experienced a significant reduction in dry weight.

The trials by Zoccali et al. (5) and Kaysi et al. (2) leave us asking the following questions: When is the optimal time to perform lung ultrasonography on a patient undergoing hemodialysis? Immediately before dialysis? During? After? The following day? Kaysi et al. (2) performed their ultrasonography after dialysis, whereas ultrasonography was performed before dialysis in the LUST trial (5). Why did Kaysi et al. (2) show an effect on dry weight but not the LUST study? Should lung ultrasound B-line assessment be the sole method for evaluating volume status? Is it the most practical approach? Are we overlooking intravascular assessments of volume status such as VExUS (Venous Excess Ultrasound) and Doppler echocardiography?

Cardiac effects of hemodialysis may be important in answering these questions. Hemodialysis is associated with reductions in myocardial blood flow that cause myocardial stunning (7). These changes even occur in patients without significant large vessel coronary artery disease or diabetes (8). Although changes in myocardial perfusion and regional wall motion abnormalities improve, they do not fully resolve by 30 minutes after dialysis, which is when Kaysi et al. (2) performed their assessments.

Intuitively, predialysis lung ultrasonography should reveal B-lines, as patients are above their dry weight. Although patients who have completed dialysis may be at their dry weight, the presence of myocardial stunning may cause transient pulmonary edema. Myocardial stunning may also alter VExUS scoring and Doppler echocardiography. Future studies should consider B-line assessment at 30 minutes and 180 minutes after dialysis to evaluate changes in the B-line score as myocardial stunning resolves. ■

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Dr. Kashfi reports no conflicts of interest. Dr. Ross reports serving as the chair of the Ultrasound Committee at the American Society of Diagnostic and Interventional Nephrology. He also is the codirector of the annual Point-of-Care Ultrasonography (POCUS) for Nephrologists course at Columbia University, for which he receives honoraria.

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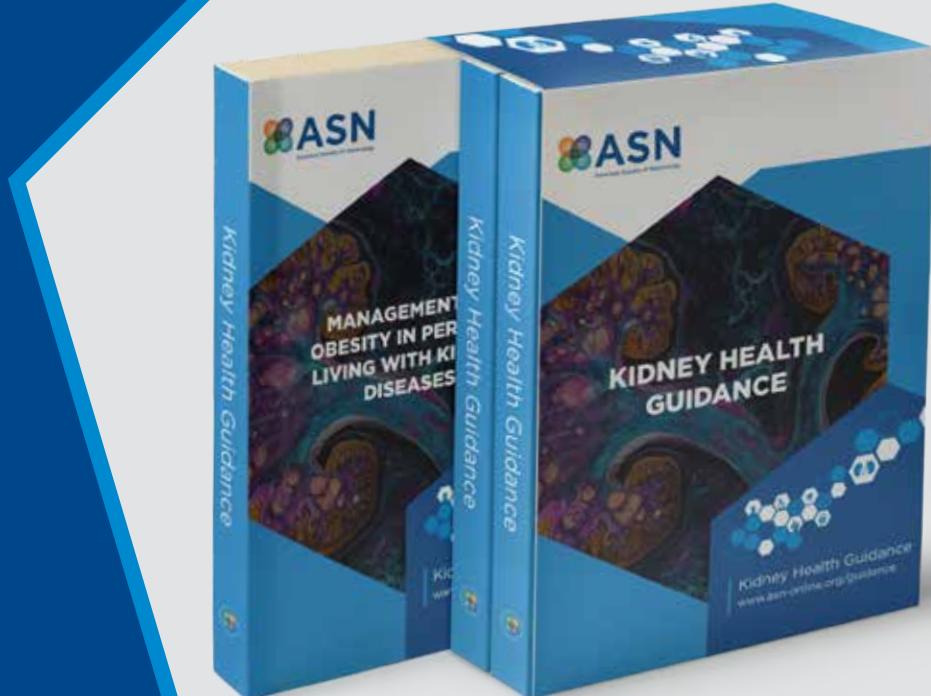
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Correction and Clarification

Correction to “Shaping Kidney Science and Scientists: The Work of Kurt Amsler” (December 2025)

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The article “Shaping Kidney Science and Scientists: The Work of Kurt Amsler” by Zach Cahill, published in the December 2025 issue of *Kidney News* (1), mischaracterized Dr. Kurt Amsler’s predoctoral research and has since been corrected. The original article was published online on December 8, 2025, and updated on January 12, 2026. ■

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