ASN American Society of Nephrology

Kidney Week Edition

KidneyNews

October/November 2019 | Vol. 11, Number 10 & 11

Time on Dialysis, Cause of Kidney Failure Appear to Affect Likelihood of Pregnancy in Women on Dialysis

Analysis examines U.S. pregnancy rates over 9 years

By Tracy Hampton

Fertility diminishes with declining kidney function, and it is challenging for women with kidney failure who are undergoing dialysis to become pregnant. Because there is limited information on current pregnancy rates in women on dialysis, a recent study examined pregnancy data in the United States by age, race, dialysis modality, time on dialysis, socioeconomic status, rurality, and cause of kidney failure, along with factors associated with pregnancy.

"Pregnancy in a woman with end stage kidney disease is not common, and many questions still remain unanswered. I was curious to know the nationwide incidence of conceptions and pregnancies among women undergoing dialysis and whether it was associated with differences in race/ethnicity," said lead author Silvi Shah, MD, of the University of Cincinnati Medical Center.

In the *JASN* analysis conducted by Shah and her colleagues, the team analyzed national registry information from the United States Renal Data System, as well as Medicare Part A institutional claims and Medicare Part B physician/supplier claims.

"Previous research has mostly been conducted on voluntary registries and single center studies and therefore accurate estimation of rate of pregnancy in women with end stage kidney disease was difficult," Shah said. "Our study uses data from the largest retrospective cohort of dialysis patients in the United States."

The analysis included 47,555 women who were aged 15 to 44 years and were on peritoneal or hemodialysis at any time between January 1, 2005, and December 31, 2013.

The investigators identified 2352 pregnancies and showed that for every 1000 women on dialysis each year, pregnancies occurred in 18 women. Rates were highest in women aged 20 to 24 years.

In adjusted analyses, white women had a lower likelihood of becoming pregnant than other groups. Compared with white women, the likelihood of becoming pregnant was 77% higher in Native American women, 51% higher in Hispanic women, and 33% higher in black women.

Kidney failure as a result of diabetes appeared to lessen the likelihood of pregnancy. The likelihood of becoming pregnant was 64%, 38%, 32%, and 18% higher when women's kidney failure was due to cancer, glomerulonephritis, hypertension, or vasculitis, respectively, compared with diabetes.

Women on peritoneal dialysis had a 53% lower likeli-

Continued on page 3 >

Kidney Week Scientific Sessions

THURSDAY

Rewriting the Code of Life: The Future of Genome Editing
State-of-the-Art Lecture: Jennifer A. Doudna

FGF23 and Risks of Cardiovascular and Noncardiovascular Diseases
Jack W. Coburn Endowed Lectureship: Sharon M. Moe

Diabetic Kidney Disease: Structural–Functional Relationships and the Possibilities of Cure
Barry M. Brenner Endowed Lectureship: Michael Mauer

FRIDAY

Genes Controlling Sleep and Circadian Rhythms
State-of-the-Art Lecture: Michael Young

The Future of Value-Based Care and Nephrology
Christopher R. Blagg Lectureship in Kidney Diseases and Public Policy: Adam Boehler

Genome-Wide Association Study (GWAS)–Derived Targets for Glomerular Diseases
Michelle P. Winn Endowed Lectureship: Rasheed A. Gbadegesin

Educating Patients and Practitioners About the Benefits of Transplantation
Burton D. Rose Endowed Lectureship: Bertram L. Kasiske

Diagnostic Exome Sequencing in Chronic Kidney Disease
Robert W. Schrier Endowed Lectureship: Ali G. Gharavi

Prospects for NAD+ Based Therapies in Acute Kidney Injury
Donald W. Seldin Young Investigator Award: Samir M. Parikh

SATURDAY

Perspectives on Innovation and Transformation in Kidney Care
State-of-the-Art Lecture: Dean Kamen
State-of-the-Art Lecture: Bruce Culleton

Person-Centered Dialysis Care: A Patient's Perspective
Celeste Castillo Lee Memorial Lectureship: Derek L. Forfrang

SUNDAY

What Patients Say; What Doctors Hear
State-of-the-Art Lecture: Danielle Ofri

Presentation of Inaugural ASN Midcareer Award Winners

Inside

Baxter

PrisMax

ACUTE CARE SYSTEM

WHAT IF

you could experience the next generation in CRRT?

Experience the innovation behind the new **PRISMAX** System, including:

- Intelligent fluid management with an auto-effluent drain option
- Integrated THERMAX blood warmer
- Powerful data tracking with TRUEVUE Analytics

FOR MORE INFORMATION

renalacute.com/prismax | **800-525-2623**

DESIGNED FOR ACCURACY AND SIMPLICITY.

CRRT BUILT FOR **YOUR** ICU.

The PRISMAX control unit is intended for:
Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.
Therapeutic Plasma Exchange Therapy (TPE) for patients with diseases where removal of plasma components is indicated.

Rx Only. For the safe and proper use of the devices mentioned herein, please refer to the appropriate Operator's Manual.

USMP/MG207/18-0015 02/19

THE KIDNEY MOONSHOT

By Ryan Murray and Molly O'Neill

The United States was built on bold, audacious plans in which the public and private sectors collaborate to solve complex problems. Our healthcare system is no exception, and the cancer community wrote the book on how to advance the field on behalf of patients.

When President Richard M. Nixon signed the National Cancer Act of 1971, he shared "that a total national commitment means more than government." Nearly 45 years later, Vice President Joseph R. Biden, Jr., described a Cancer Moonshot to cure cancer through a collaborative, multidisciplinary coalition of public and private resources. Following the former vice president's call to action, Congress passed the 21st Century Cures Act in 2016 and allocated $1.8 billion to the National Institutes of Health (NIH) over seven years dedicated to cancer research in what is referred to as the Beau Biden Cancer Moonshot.

As a direct result of the Obama administration making cancer research a priority, the National Cancer Institute received an additional $300 million in appropriations for fiscal year (FY) 2017 designated specifically for the Cancer Moonshot, an additional $300 million for FY 2018, and an additional $400 million for FY 2019. This three-year $1 billion was on top of the average annual appropriation for the National Cancer Institute, which during the time was $5.9 billion.

Kidney disease, often ignored and underfunded in terms of research when compared to other diseases, affects approximately 37 million Americans. More than 700,000 Americans face kidney failure and require dialysis or a transplant to live. Kidney disease was the ninth leading cause of death in 2017. Each year more than 100,000 Americans begin hemodialysis treatment, but tragically there is nearly a 60% mortality rate within five years of treatment—a rate worse than nearly all forms of cancer, which receives 11 times more funding for NIH-supported research than kidney disease.

In addition to poor patient outcomes, there is a tremendous financial cost associated with kidney care. In 2016, the Medicare Program spent approximately $114 billion to care for people with kidney disease or kidney failure. That represents more than one in five dollars spent by the program. By comparison, the FY 2019 budget for the entire NIH is $39.1 billion.

For the 37 million Americans with kidney disease, these figures highlight a poor quality of life that is unjustifiable given the financial costs of treatment. Therefore, the current administration has prioritized improving kidney care by creating a version of a kidney moonshot and demanding that the nation support kidney health instead of paying for kidney sickness. The status quo is no longer tolerable, and the kidney community was thrilled to witness President Donald J. Trump sign the Executive Order (EO) on Advancing American Kidney Health (AAKH) on Wednesday, July 10, 2019. The EO calls for a fundamental shift toward a system of value-based care by incentivizing earlier clinical interventions to delay the progression, or prevent, kidney disease and kidney failure.

For decades, the American Society of Nephrology (ASN) has advocated tirelessly for the priorities highlighted in AAKH, which has three overarching goals:

- Reduce the risk of kidney failure
- Improve access to and quality of person-centered treatment options
- Increase access to kidney transplants

As with the Cancer Moonshot, the kidney community can leverage AAKH to create a variety of opportunities benefiting both patients and kidney health professionals. While at press time Congress was finalizing its appropriations for FY 2020, the House bill provided a substantial increase in funding for the NIH at $41.1 billion and for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at $2.1 billion. Appropriations increases will support NIDDK initiatives including the pioneering work that is being conducted by the APOL1 Long-term Kidney Transplantation Outcomes Network (APOLLO) and Kidney Precision Medicine Project (KPMP).

By better educating patients on all treatment options and encouraging home dialysis and preemptive transplant when appropriate, patient outcomes will improve. An increase in the use of telemedicine, new technology that empowers the patient, and the development of an artificial kidney will attract the next generation of clinicians and innovators, helping the specialty reverse its course and ensure a robust workforce pipeline.

AAKH is galvanizing the community behind a singular goal and sparking renewed optimism and hope among kidney health professionals and patients:

> *For the entire government and president to show this much interest in kidney disease and kidney failure is unprecedented. Having the president sign an Executive Order that increases the recognition of the value, diagnosis, development and use of alternative dialysis therapies, and increasing the number of transplants, signals to the kidney community that they are serious about changing the care of kidney patients." – Mark E. Rosenberg, MD, FASN, ASN President*

> *The American Association of Kidney Patients (AAKP) "enthusiastically endorses President Donald Trump and his health policy team in their bold and bipartisan efforts to fully empower kidney patient consumers and save kidney patient lives through greater care choice and innovations aimed at preventing and better managing kidney disease." – Richard A. Knight, MBA, AAKP President*

> *The Executive Order on Advancing American Kidney Health is "a major win in the battle against kidney disease. They have thought about the entire spectrum of kidney disease from better detection to better dialysis therapies and better access to transplantation." – Holly Kramer, MD, MPH, President of the National Kidney Foundation.*

Advancing innovation and reenergizing the nephrology field is a core component of the EO. This is also the overarching mission behind KidneyX, a public-private partnership between ASN and the Department of Health and Human Services. KidneyX is taking a cutting-edge approach to address the lack of funding and ingenuity, and the stagnation in kidney care by accelerating innovation in the development of drugs, devices, biologics, and other therapies. It is also specifically highlighted in the EO as an opportunity to develop an artificial kidney and is actively working on this goal through a series of staged prize competitions.

The initial prize competition sponsored by KidneyX, Redesign Dialysis Phase I, encouraged innovators to conceptualize next-generation dialysis products. Participants were asked to design possible solutions that can replicate normal kidney function and improve patient quality of life. Phase I ignited enthusiasm throughout the nephrology community and received more than double the number of expected submissions. The winning submissions included companies developing advanced nanofiltration for toxin removal, miniaturized wearable dialyzers, real-time infection and clotting sensors, cell-based implantable dialyzers, and regenerative kidneys.

The excitement for Phase I spurred the launch of Redesign Dialysis Phase II, which challenges participants to build prototype solutions, or solution components, that replicate normal kidney functions or improve dialysis access. KidneyX will award up to three winners $500,000 each in Phase II. Submissions are due by Friday, January 31, 2020, and innovators are encouraged to visit KidneyX.org.

Having experienced stagnation in innovation in kidney care for decades, the kidney community must recognize that this battle cannot be fought alone. AAKH is shining a spotlight on kidney disease. There has been an increase in news coverage on the plight of kidney care, and a public awareness campaign (called for in the EO) will also raise the profile of kidney health. The current focus on kidney disease, failure, and health provides an opportunity to attract creative minds in the fight against kidney disease, not just the next generation of clinicians and researchers but innovators from diverse disciplines.

With the kidney community uniting, and the full support of the federal government, ASN is optimistic about the innovation on the horizon for patients and about the future of the specialty. ■

Ryan Murray is ASN research advocacy specialist and Molly O'Neill is ASN KidneyX coordinator.

Time on Dialysis

Continued from page 1

hood of becoming pregnant than those on hemodialysis. The duration of dialysis appeared to play a role as well: compared with women on dialysis for less than 1 year, women on dialysis for 1 to 3 years had a 21% lower likelihood of pregnancy, and women on dialysis for more than 3 years had a 33% lower likelihood of pregnancy.

"For patients undergoing dialysis, the study findings increase the awareness regarding incidence of pregnancy and factors associated with it," Shah said. "This information will help them in shared decision-making regarding management of their reproductive health."

Shah noted that the racial/ethnic differences uncovered in the analysis should be a focus of future research. "The real reasons for these differences remain unknown," she said. "We were also not able to determine the differences in unintentional and intentional pregnancies and whether level of education was associated with likelihood of pregnancy."

An unknown pregnancy outcome in 31% of the women is an important limitation of the study, said Giorgina Piccoli, MD, of the University of Torino, Italy.

"The study basically says that pregnancies are much more frequent on dialysis than previously thought, and this, from my optimistic point of view, may be a good message; however, when we dissect the paper, we find that pregnancies more often occur in poor and Hispanic or black women, and we may suppose that these pregnancies are not the positive result of improved care, but the current disaster of lack of attention," Piccoli said. "In this line, I have been almost shocked . . . to see that, according to the data only about one-third of the babies survived. This paper conveys a fundamental message: pay more attention to women on dialysis and pay more attention to their pregnancies." ■

ASN American Society of Nephrology

KidneyNews

ASN Kidney News is published by the American Society of Nephrology
1401 H Street, NW, Suite 900, Washington, DC 20005. Phone: 202-640-4660

www.asn-online.org

Postmaster: Please send address changes to *ASN Kidney News*, c/o Customer Service, American Society of Nephrology 1401 H Street, NW, Suite 900, Washington, DC 20005.

Publications mail agreement No. 40624074. Return undeliverable Canadian addresses to PO Box 503, RPO West Beaver Creek, Richmond Hill ON L4B 4R6

ASN Kidney News (ISSN print 1943-8044 and online 1943-8052) is an official publication of the American Society of Nephrology, 1401 H Street, NW, Suite 900, Washington DC 20005, and is published monthly 11 times a year except November. Periodicals postage paid at Washington, DC and at additional mailing offices. Subscription rates: $12 per year. To order, please email bhenkel@asn-online.org. Subscription prices subject to change. Annual ASN membership dues include $12 for *ASN Kidney News* subscription.

★ WINNER OF 2 DESIGN AWARDS ★

WINNER 2019 APEX AWARDS FOR PUBLICATION EXCELLENCE

GD USA 2018 WINNER

ASN Kidney Week—New in 2019

Bringing Discovery to People with Kidney Diseases

Early Programs

ASN offers 10 Early Programs on November 5–6, preceding the Annual Meeting (November 7–10). New offerings are:

- ★ Advances in Research Conference: Machine Learning and Kidney Diseases
- ★ Diabetic Kidney Disease: Translating Pathogenic Mechanisms into Therapies
- ★ Evolving Concepts in Hypertension: Mechanisms, Management, and Future Directions
- ★ Onco-Nephrology: Cancer, Chemotherapy, and the Kidneys

Burton D. Rose, MD, Endowed Lectureship

This lectureship is named for Dr. Rose, the esteemed clinician, educator, and scientist who is internationally famous for his innovative teaching and textbooks on management of kidney diseases, and for creating and cofounding UpToDate, a leading resource for clinicians to access current, expert medical information online. Dr. Rose has inspired generations of nephrologists and other health professionals, enhancing the care of patients across wide areas of medicine. This lectureship in his honor recognizes innovative advances in the approach to clinical decision-making and leading-edge educational techniques.

This inaugural lecture will be presented by **Bertram L. Kasiske, MD**, on the topic of "Educating Patients and Practitioners About the Benefits of Transplantation, in the session "Let's Get You that Kidney Transplant" on November 8, 10:30 a.m.–12:30 p.m.

ASN gratefully acknowledges Wolters Kluwer (publisher of UpToDate), the Beth Israel Deaconess Medical Center Department of Medicine Foundation, the Rose Family, and several of Dr. Rose's colleagues for supporting this lectureship.

Abstract Categories

Check out the oral presentations and posters in these new categories: Onco-Nephrology; Women's Health and Kidney Diseases.

Medical Educators Workshop

The workshop "Leveraging the Science of Learning to Elevate Your Teaching" on November 6 showcases high-yield strategies participants can use to optimize their teaching and to translate teaching innovations into education scholarship for dissemination and academic credit. Topics include an overview of the science of learning, maximizing learning while teaching physiology, utilization of technology in medical education, the power of metacognition, and mindfulness of factors influencing the clinical learning environment. Please note that separate registration is required.

In addition to the new items above, don't forget:

- ★ Welcome Reception in the Exhibit Hall on November 7, 6:30–7:30 p.m.
- ★ Daily state-of-the-art lectures during the plenary sessions (November 7–10, 8:00–9:30 a.m.)
- ★ Daily poster presentations with more than 3500 posters (November 7–9, 9:30 a.m.–2:30 p.m.)
- ★ ASN Communities Lounge in the Exhibit Hall (November 7–9, 9:30 a.m.–2:30 p.m.)

2008T
BlueStar

Get a faster start. Take fewer steps.

Auto Prime with Auto Start on the new 2008T BlueStar hemodialysis machine simplifies priming and testing processes.

- Requires fewer steps and user touches than current priming methods
- Provides on-screen graphics to guide setup
- Completes most "Self Tests" before priming
- Automates remaining tests after priming bloodline

Discover how fewer steps can help you gain more time.
1-800-662-1237 / www.2008TBlueStar.com

Indications for Use: 2008T Hemodialysis Machine: The 2008T hemodialysis machine is indicated for acute and chronic dialysis therapy in a healthcare facility.

Additional therapy options for patients receiving hemodialysis include: Isolated Ultrafiltration, Sustained Low Efficiency Dialysis (SLED), and low volume hemodialysis (patients weighing ≥ 20kg and ≤ 40 kg). This machine accommodates the use of both low flux and high flux dialyzers. The SLED therapy option is not to be used for patients weighing ≤ 40 kg. The 2008T Hemodialysis Machine is not to be used for plasma replacement therapies, for patients weighing less than 20 kg, or for renal therapies using substitution fluid.

FRESENIUS MEDICAL CARE
RENAL TECHNOLOGIES

ASN in the Year of Advancing KIDNEY HEALTH

The year 2019 has seen unprecedented developments in kidney care, research, and education for both patients and professionals. ASN and partner organizations have been at the forefront of these developments.

In July 2019, the ASN Council finalized the ASN Alliance for Kidney Health: Proposed Vision in 2030. Through several areas of focus, the ASN Alliance for Kidney Health will aim to fulfill its mission to improve care, drive innovation, educate and inform, and generate policies that result in meaningful change. Also, ASN rolled out its new brand identity, featuring a new logo signifying the patient as the center of focus, interconnected with researchers, clinicians, educators, and kidney health professionals, as well as new logos for the other entities in the ASN Alliance.

Here, we present ASN's accomplishments since Kidney Week 2018, grouped according to five of the Alliance for Kidney Health's areas of focus.

Excellence in Patient Care

Transforming Dialysis Safety

ASN's partnership with the Centers for Disease Control and Prevention (CDC) completed its third contract year in July 2019. During this time, the initiative reached over 1 million members of the kidney community and engaged with over 31,000 meeting attendees, encouraging them to take the lead in the cultural change necessary to transform infection prevention in dialysis facilities. NTDS is led by a Project Committee chaired by Alan S. Kliger, MD.

Key accomplishments include presentation of "Targeting Zero Infections: Hepatitis C Detection, Prevention, and Treatment"; the fifth webinar in the Targeting Zero Infections series; issuance of hepatitis C testing recommendations; publication of a NephSAP special edition on infection prevention; and development of recommendations for standardization of blood culture collection for patients receiving in-center hemodialysis.

In 2018, the contract with CDC was expanded to include the use of human factors engineering assessments to identify barriers and facility adherence to CDC-recommended infection prevention practices. This work included six site visits nationwide. A final report will be presented to the community soon.

Future work will include two additional webinars, an infection-prevention curriculum for fellows, presentation of research on methods of preventing *C. difficile* transmission in outpatient dialysis, four additional human factors observations, a Kidney Leadership Academy for the physician-nursing dyad, an online educational module for infection prevention and safety, a pilot study of vascular access electronic checklists, and continued presence at Kidney Week.

Putting Diabetic Kidney Disease in the Spotlight

In response to the recent development of new therapies for diabetic kidney diseases, ASN launched the Diabetic Kidney Disease Collaborative (DKD-C) in March 2019. With the recently reported results of CREDENCE, which demonstrated substantial kidney and cardiovascular benefits in patients with type 2 diabetes and DKD on top of standard of care, ASN has prioritized efforts to educate the nephrology community and increase collaboration across specialties about the use of these life-changing therapies.

The DKD-C Task Force, which is led by ASN Councilor Susan E. Quaggin, MD, FASN, has already produced a call-to-action editorial and a policy-related editorial. The former strongly encourages SGLT2 inhibitor therapy in patients with type 2 diabetes using the inclusion criteria of CREDENCE. The latter recommends that public policy is needed to support a change in focus from kidney failure to kidney preservation.

The Task Force is currently working to develop a series of meetings that will include representatives from industry and stakeholders from other specialties to address key considerations and major questions about DKD as well as increase awareness, engagement, and excitement about new therapies. These discussions are intended to result in concrete recommendations for ensuring that people with diabetic kidney disease benefit from the new therapies.

Improving AKI Care through AKI!Now

ASN has partnered with Baxter Healthcare to build a foundational program to transform how AKI care is delivered, reduce its morbidity and mortality, and improve long-term outcomes, thus promoting recovery and reducing the incidence of kidney disease and failure.

To achieve these goals, the AKI!Now Steering Committee, chaired by Jorge Cerda, MD, FASN, will study other AKI initiatives to determine knowledge gaps and potential areas of collaboration. The Steering Committee will also conduct a needs assessment among the medical community where AKI is first encountered: nurses, physicians, primary care providers, advance practice providers, and emergency room personnel. Educational tools will be developed to assist this broad group of healthcare providers in identifying and managing high-risk populations using evidence-driven practices.

Early deliverables include a white paper addressing "Identification and Management of AKI in High-Risk Populations" and a web-based compendium of the most up-to-date content on AKI available through ASN education and publications. Ideally, the web-based compendium will serve as a model for similar efforts in other areas, such as diabetic kidney disease.

Creating the Emergency Partnership Initiative

Natural disasters require wide-ranging and well-organized responses from medical organizations and volunteers. Post-emergency care of people with kidney disease, notably those on dialysis, as well as people who suffer kidney injuries during disasters, requires special expertise.

In recognition of the need for an organized approach to the provision of this specialized care and services, ASN launched the Emergency Partnership Initiative (EPI). Nicole Lurie, MD, chairs the Advisory Committee and Zaheeb Choudhry, MD, will lead the EPI Caribbean Steering Committee. Initiative partners include dialysis organizations, local leaders, emergency preparedness experts, and disaster relief entities.

Under the direction of Drs. Lurie and Choudhry, this initiative will address gaps in coordination and support of kidney-specific disaster care in the Caribbean and work with United States policymakers to review current processes.

Research, Discovery, and Innovation

Launching KidneyX

KidneyX, the public-private partnership established between ASN and the U.S. Department of Health and Human Services (HHS), was created to accelerate the development of drugs, devices, biologics, and other therapies across the spectrum of kidney care. The KidneyX Steering Committee is chaired by ASN Secretary-Treasurer John R. Sedor, MD, FASN.

In 2019, KidneyX received an overwhelming response of 165 submissions to its first prize, *Redesign Dialysis Phase I*. Fifteen outstanding recipients were chosen to receive a prize of $75,000 each. These recipients were highlighted at the first KidneyX Summit held in April 2019. Two additional prizes were launched in the third quarter of 2019: *Patient Innovator Challenge* and *Redesign Dialysis Phase II*. Recipients of these prizes will be announced in spring 2020. Learn more at kidneyx.org.

Expanding the Kidney Health Initiative's Footprint

On January 1, 2019, Raymond C. Harris, MD, FASN, began his three-year term as ASN co-chair of the Kidney Health Initiative (KHI). Founded in September 2012, KHI continues to be the largest consortium in the kidney arena with more than 100 member organizations. As a public-private partnership with the U.S. Food and Drug Administration, KHI strives to catalyze innovation and the development of safe and effective patient-centered therapies for people with kidney disease. KHI's Seventh Annual Stakeholders Meeting focused on "Collaborating for Innovation to Improve Patient Care and Outcomes."

Two supplements to the *Technology Roadmap for Innovative Approaches to Renal Replacement Therapy* were published in 2019: a Patient Edition to the Technology Roadmap and *Fostering Innovations in Fluid Management*. Both the roadmap and the supplements are valuable to the entire community, including the winners of KidneyX's *Redesign Dialysis* contest.

KHI also published *Proteinuria Reduction as a Surrogate End Point in Trials of IgA Nephropathy*, bringing the total number of publications to 17. The Kidney Pediatric Accelerator Trial Clearing House (Kidney-PATCH) was launched, in partnership with pediatric trial networks and organizations, to optimize planning for pediatric kidney disease clinical trials. KHI continues to support the community with nine project teams, the newest titled "Patient Reported Outcomes for Muscle Cramping in Patients on Dialysis" and "Patient Reported Outcomes for Dialysis Vascular Access." To learn more, visit www.kidneyhealthinitiative.org.

Renaming the ASN Foundation for Kidney Research as KidneyCure

In July 2019, the ASN Foundation for Kidney Research launched a major rebrand. The new name, KidneyCure, focuses all foundation efforts toward improving treatments and finding cures for the approximately 37 million Americans living with kidney disease.

The foundation granted nearly $3 million in support of 46 leading kidney researchers in 2019, including 27 new projects and 19 projects continuing from 2018. Established in 2012 by ASN, the foundation, now KidneyCure, will continue funding current grant programs, while exploring new avenues to support.

Cosponsoring APS Summer Kidney Research Conference

In June 2019, ASN cosponsored the American Physiological Society (APS)/ASN Conference: Control of Renal Function in Health and Disease (formerly the APS Renal Hemodynamics Summer Research Conference). The triennial conference "focuses on cutting-edge research presented by top investigators in the field of renal research."

In addition to co-presenting the conference, ASN provided travel support for 28 participants to attend the conference, underscoring the society's continued commitment to expand opportunities for ASN members interested in basic, or fundamental, science. The next APS/ASN Conference will take place in summer 2022.

Education and Information

Tapping *Kidney360* Editorial Team, Selecting NephSAP 3.0 Editorial Director

The open access, online-only journal *Kidney360* hired Michael Allon, MD, as editor-in-chief, with Luis Juncos, MD, and Mark Perazella, MD, FASN, serving as deputy editors. The peer-reviewed, general kidney journal will begin taking submissions in fall 2019 and will begin publishing in January 2020.

In April 2019, ASN announced the appointment of Alice M. Sheridan, MD, as the Editorial Director for NephSAP 3.0. Dr. Sheridan will oversee the production of NephSAP beginning in January 2020. NephSAP is one of the most widely used educational programs in nephrology.

Maintaining High Rankings for *JASN*, *CJASN*

JASN remains the most cited nephrology journal publishing original research about the kidney and kidney disease. Under the leadership of Editor-in-Chief Josephine P. Briggs, MD, and a distinguished board of editors, *JASN* has continued its role as the flagship of nephrology with original articles, provocative perspectives, and important reviews. New this year is an Editorial Fellowship program that engages nine early career kidney researchers in the work of the journal.

CJASN continues to expand its offerings to the kidney community and will launch a series on genetics in winter 2020 under the leadership of Raj Mehrotra, MD, FASN. Recent initiatives for trainees include the annual *CJASN* Trainee of the Year manuscript competition and the *CJASN* Trainee Reviewer Program, which educates early career researchers in mastering peer review. The first-ever "Best of ASN Journals" session at Kidney Week 2018 had great turnout, and both *JASN* and *CJASN* look forward to another successful session at Kidney Week 2019.

Partnering with Renal Fellow Network

ASN recently established a partnership with Renal Fellow Network (RFN), an online forum where trainees can share posts that are open to the community to read and comment on. Currently led by Samira S. Farouk, MD, FASN, Sam Kant, MD, and Matthew A. Sparks, MD, FASN, RFN was one of the first nephrology blogs and was created by the late Nate Hellman in 2008.

RFN has grown over the past decade from a personal blog to a rich source of easily accessible information for current and future nephrology trainees around the world. The RFN–ASN collaboration marks the beginning of an exciting new chapter for the website that has allowed RFN to continue to have a positive effect in nephrology education, with over 40,000 page views in July 2019. Recurring series on the blog address high-yield topics for trainees including urine microscopy, kidney biopsy, landmark nephrology studies, interventional nephrology, kidney transplant, home hemodialysis, peritoneal dialysis, basic science, and pediatric nephrology. Published content also includes submissions from trainees and graduates.

Broadening ASN Communities, Social Media

ASN Communities' outreach and impact continues to grow. Since Kidney Week 2018, there have been over 100,000 logins to Communities from 10,500 members from 115 countries, with 1500 members using the free ASN Communities mobile app released in January 2019.

In the Loop now publishes weekly "Community Minded" summaries highlighting recent "hot topics" from Communities. In mid-2019, the AKI Community was relaunched with one of the most popular discussions of the year: CRRT in the ICU. Popular discussions from the Open Forum included Calcium Channel Blockers, Uncontrolled Blood Pressure in an HD Patient, and Proteinuria/Nephrotic Syndrome in Pregnancy.

At Kidney Week, stop by Poster PO0800-1, *ASN Communities: A Growing Thriving Online Educational Asset,* at 10 a.m., on Saturday, November 9, to learn more about how you can leverage the collective knowledge of ASN Communities.

ASN's social media presence continues its strong pattern of yearly growth. ASN's main Twitter page, @ASNkidney, experienced a 28% growth in followers since 2018; @ASNAdvocacy, @KidneyNews, @JASN_News, @CJASN and @Kidney_X experienced steady growth as well. In December 2018, the society launched a Twitter page for ASN's newest online, open access journal, Kidney360 (@ASNkidney360), set to debut in January 2020. ASN's social media users are mostly from the United States, the United Kingdom, Mexico, Canada, Spain, and India.

Leadership Development and Culture Change

Welcoming All

ASN membership shows continued growth. More than 21,000 kidney professionals in more than 130 countries now contribute to ASN as members. Since 2015, membership has grown 32%.

The first ever lesbian, gay, bisexual, transgender, and queer and questioning (LGBTQ) and ally member reception, launched at Kidney Week 2018, will continue at this year's Kidney Week. The reception offers a venue for networking and gathering to discuss ways of serving LGBTQ patients and members of the kidney community.

Establishing ASN Midcareer Awards, Continuing to Support Grants

ASN successfully launched the ASN Midcareer Awards Program, recognizing healthcare providers between 10 and 20 years from completion of their professional training who have demonstrated impact in nephrology in the areas of clinical service, research, education, mentorship, and leadership. The inaugural group of 10 recipients will be honored at

Continued on page 8 >

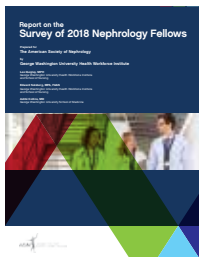
Continued from page 7

ASN Kidney Week 2019 during the plenary session on Sunday, November 10.

ASN partners with the Robert Wood Johnson Foundation to administer the ASN-Amos Medical Faculty Development Program (ASN-AMFDP) award. The second scholar, Rasheeda K. Hall, MD, MS, started her grant this year. Interviews were held in July 2019 to fund a new candidate for 2020. ASN expanded Kidney TREKS (Tutored Research and Education for Kidney Scholars) to include PhD students.

KidneyCure, the newly renamed ASN foundation, funds the Career Development Grants Program (to be renamed Transition to Independence Grants in 2020), the Ben J. Lipps Research Fellowship Program, the William and Sandra Bennett Clinical Scholars Program, the American Society of Nephrology-Harold Amos Medical Faculty Development Program, and the ASN Pre-Doctoral Fellowship Program.

Setting New Directions for ASN's Nephrology Fellow Survey, Data Subcommittee



The annual ASN Nephrology Fellow Survey successfully transitioned to a new principal investigator, Stephen M. Sozio, MD, FASN (Johns Hopkins University School of Medicine), who also chairs the ASN Data Subcommittee. The subcommittee retooled the 2019 survey to include more pediatric nephrology–specific questions and mechanisms to more accurately assess a wider array of nephrologist practice patterns, including starting salaries and educational debt levels for new nephrologists.

The retooling also streamlined the process for participants, resulting in the survey's best response rate (50%) since its inception in 2014. An analysis of survey results, to be released before ASN Kidney Week 2019, found the overall proportion of fellows recommending nephrology to medical students and residents has risen to 80%, an all-time high.

The recently expanded ASN Data Subcommittee comprises the chair, as well as eight physician volunteers and nephrology fellows. The subcommittee has identified knowledge gaps and mechanisms for the ASN Alliance's Data Science Program to quantify, such as assessing protected efforts for program directors' educational activities. Future initiatives include assessments of the nephrology employment market and journey analyses to determine how programs can affect career trajectories.

Communicating New Understandings of Medical Career Choices

Insights from ongoing research collaborations with internal and external stakeholders were disseminated in several peer-reviewed articles. Results from the first phase of the ASN *Best Practices Project*—studying institutions graduating large numbers of future nephrologists and led by ASN Data Subcommittee Chair Dr. Sozio—underscored the importance of exposure to clinical nephrology experiences and nephrology faculty contact to instilling interest in the specialty (*American Journal of Nephrology*, https://doi.org/10.1159/000501058).

Another paper examined influencing factors for specialty choice among late-stage medical students and residents. Across both cohorts, lack of interest in and exposure to nephrology, as well as perceptions about earning potential and work-life balance, were key in their choice to not pursue a nephrology career (*BMC Nephrology*, https://doi.org/10.1186/s12882-019-1289-y).

Policy and Advocacy

Shaping the Advancing American Kidney Health Initiative

ASN worked with the White House and the Department of Health and Human Services (HHS) to shape the components of the Advancing American Kidney Health (AAKH) initiative. The initiative, created in July 2019 by Executive Order of President Donald Trump, will bring sweeping changes to care for people with kidney disease, including more focus on upstream treatment to slow the progression of kidney disease, choices for dialysis modalities, greater access to transplantation, and concerted support for development of innovative therapies, including artificial kidneys.

The executive order established three objectives as official U.S. policy: 1) reduce the risk of kidney failure, 2) improve access to and quality of person-centered treatment options, and 3) increase access to kidney transplants.

To accomplish these goals, efforts are underway to launch a nationwide kidney disease awareness campaign, streamline kidney transplantation and increase the supply of organs, provide consideration for "requests for premarket approval of wearable or implantable artificial kidneys," produce a strategy for encouraging innovation in new therapies through KidneyX, and develop payment models both to identify and treat at-risk populations earlier in kidney disease development and to increase home dialysis and kidney transplantation.

Demanding Increased NIH Research Funding and Innovation through KidneyX

ASN's advocacy efforts contributed to the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) experiencing a trend of significant increases after more than a decade of flat budgets. At press time, the House version of the appropriations bill that will fund NIH and NIDDK provided a substantial increase: $41.1 billion for NIH and $2.1 billion for NIDDK. The House also included $10 million for KidneyX in its FY2020 funding bill. The Senate had not released its funding bill for FY2020.

Advocating for Changes in Transplant Policy

ASN's longtime policy priorities in transplantation saw significant movement. HHS released a report confirming the cost savings to Medicare that would result from extending coverage and an actuary appraisal of a proposal to extend Medicare Part B and Part D coverage of immunosuppressive drugs for ESRD beneficiaries indefinitely.

Following these developments, the White House announced it would act on two of ASN's policy priorities: improving the data used to evaluate Organ Procurement Organizations and removing financial barriers to living donation. ASN also supported efforts by Representative Jaime Herrera Beutler (R-WA) requesting that the Health Resources and Services Administration (HRSA) change its policy to allow the National Living Donor Assistance Center to reimburse lost wages and other non-travel expenses of living donors as currently permitted under the National Organ Transplant Act of 1984.

Convening Kidney Health Advocacy and Kidney Community Advocacy Days

ASN convened the Seventh Annual Kidney Health Advocacy Day (KHAD) in Washington, DC, to urge Congress to fund and support legislation to improve care for kidney patients and accelerate innovation in kidney medicine. In partnership with the American Association of Kidney Patients, 49 patient and physician advocates met during KHAD with nearly 100 congressional delegations about the urgent need to provide funding for KidneyX.

During Kidney Week 2019, patients and health professional organizations will gather for the Fifth Kidney Community Advocacy Day to raise the profile of kidney health on Capitol Hill. On the heels of the historic executive order on Advancing American Kidney Health, advocates will unify under a call for Congress to support the goals of the executive order and pass priority legislation of the kidney community, such as the Living Donor Protection Act and Immunosuppressive Drug Coverage Extension for Kidney Patients Act.

In addition to these accomplishments, ASN hosted an invitational conference for Nephrology Division Chiefs in Dallas, Texas, in June 2019. More than 35 adult and pediatric nephrology division chiefs from around the nation attended to discuss asserting the value of nephrology; physician productivity and compensation; financial support of educational efforts; recruitment, retention, diversity, and inclusion; and rightsizing training programs. A white paper on the discussions and recommendations from the conference is being drafted.

Kidney health has become a national priority in the United States, and the ASN Alliance for Kidney Health looks forward to working with every member of the kidney community to create a world without kidney diseases. That work starts now.

Repositioning the ASN Brand Identity for the Next Decade

By Steve Doran

They say a brand should be revisited every 10 years. ASN last rebranded in 2008 and since then, the society has gone through drastic changes. Membership has increased by 138%. ASN added two publications (ASN *Kidney News* and e-newsletter In the Loop) as well as launched a new self-assessment program (KSAP). But most important, ASN not only established a foundation during that time, but also created three public-private partnerships with different government agencies. These include:

- Kidney Health Initiative (KHI) with the U.S. Food and Drug Administration.
- Nephrologists Transforming Dialysis Safety (NTDS) with the Centers for Disease Control and Prevention.
- Kidney Innovation Accelerator (KidneyX) with the U.S. Department of Health and Human Services.

None of these five entities (ASN, ASN Foundation, KHI, NTDS, and KidneyX) were connected visually, creating difficulty with relationship and brand awareness. Informally, the collective was referred to as the ASN Enterprise, but the average ASN member wasn't always aware of that term or the connection. Other members of the kidney community were equally confused.

The goal of the rebranding effort was to resolve several issues:

- Create a visual cohesiveness among the organizations.
- Formalize a name for the collective (ASN, ASN Foundation, KHI, NTDS, and KidneyX).
- Revisit and potentially revise the current ASN tagline ("leading the fight against kidney disease").
- Establish guidelines for any future logo creation.

ASN assembled an 11-person team to draft a request for proposal, interview and select a creative agency, and participate in several brainstorming and discovery sessions. This process helped outline what was important for the creative agency to understand about ASN and the ASN Enterprise as they constructed these new brands and fashioned an overarching brand identity.

The creative agency and staff team agreed to tackle ASN and the ASN Enterprise in the first round, keeping in mind that decisions made at this stage would serve as the building blocks for the subsequent entities. Ideas were generated and recommendations were fine-tuned with participation from the ASN Council.

Together, the council, creative agency, and staff team agreed that the ASN Enterprise would formally be called the ASN Alliance for Kidney Health. This name reflects the five entities working in unison but allows for growth with future partnerships, relationships, and collaboratives. With the tagline, the group thought it was important to shoot for the loftiest of goals, "**A World Without Kidney Diseases**."

For the visual aspect of the logo, the initial concepts began with strong colors and a subtle reference to kidneys. The creative agency presented numerous ideas, but the one that kept being revisited was based on a Venn diagram. This design emphasized valuing relationships, identifying similarities, and embracing differences among entities. Venn diagrams originate from mathematics and are used to easily present complex ideas. Such an approach also indicates infinite possibilities, while still hinting at the shape of kidneys.

The quadrants allowed for four colors instead of the two-color limitation from the previous logo. Blue was kept as a callback to the former logo with three new colors being added. In graphic design, contrast is important, so one soft hue is always needed to enhance the three remaining strong colors.

The group agreed that both the American Society of Nephrology and the ASN Alliance for Kidney Health would share the same logo. Subsequent logos for the remaining entities would then incorporate three out of four of the colors in their respective brands.

Once the brands for the American Society of Nephrology and the ASN Alliance for Kidney Health were in place, brainstorming sessions were held with each of the remaining groups. KHI, NTDS, KidneyX, and the ASN Foundation each refreshed their individual brands to create a unified look and feel. This transformation resulted in a new focus for the ASN Foundation, which is now called KidneyCure.

Created with input from all of ASN's constituencies (as well as the leaders of KidneyCure, KHI, NTDS, and KidneyX), the new brand allows the society to continue its growth and work that began more than 50 years ago. Today, ASN represents more than 20,000 kidney health professionals in nearly 130 countries working toward—and most of all, looking forward to—a world without kidney diseases. The ASN Alliance for Kidney Health is well positioned to start a new 10-year run in 2020. ■

Steve Doran is director of marketing at ASN.

ASN ALLIANCE FOR KIDNEY HEALTH
A world without kidney diseases

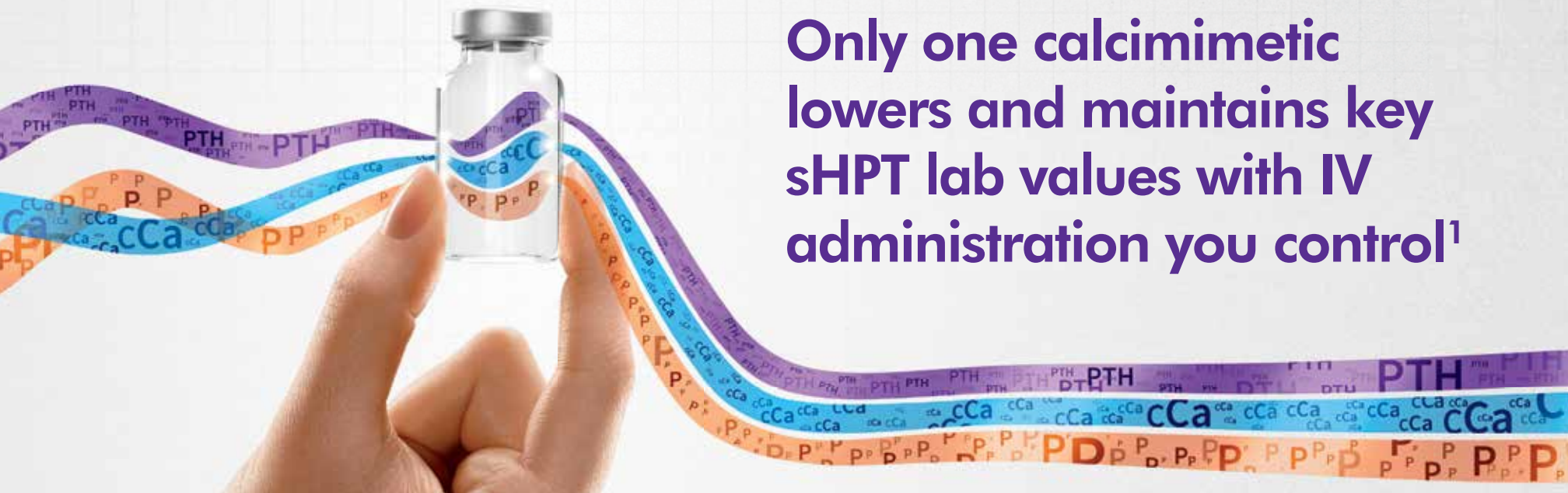
ASN American Society of Nephrology

KidneyCure
The ASN Foundation CureKidneyDiseases.org
Fund it. Find it.

KIDNEY X INNOVATION ACCELERATOR

NTDS Transforming Dialysis Safety

KHI KIDNEY HEALTH INITIATIVE



Only one calcimimetic lowers and maintains key sHPT lab values with IV administration you control[1]

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

Indication

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

Limitations of Use:

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

Important Safety Information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Visit **ParsabivHCP.com** for more information.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

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

Please see package insert for full Prescribing Information.

INDICATIONS AND USAGE

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

Limitations of Use:

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

CONTRAINDICATIONS

Hypersensitivity

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

WARNINGS AND PRECAUTIONS

Hypocalcemia

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

QT Interval Prolongation and Ventricular Arrhythmia

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

Seizures

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

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

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

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

Worsening Heart Failure

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

Upper Gastrointestinal Bleeding

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

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

Adynamic Bone

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

ADVERSE REACTIONS

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

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

Clinical Trials Experience

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

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

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

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

Adverse Reaction*	Placebo (N = 513)	PARSABIV (N = 503)
Blood calcium decreased[a]	10%	64%
Muscle spasms	7%	12%
Diarrhea	9%	11%
Nausea	6%	11%
Vomiting	5%	9%
Headache	6%	8%
Hypocalcemia[b]	0.2%	7%
Paresthesia[c]	1%	6%

*Included adverse reactions reported with at least 1% greater incidence in the PARSABIV group compared to the placebo group

[a] Asymptomatic reductions in calcium below 7.5 mg/dL or clinically significant asymptomatic reductions in corrected serum calcium between 7.5 and < 8.3 mg/dL (that required medical management)

[b] Symptomatic reductions in corrected serum calcium < 8.3 mg/dL

[c] Paresthesia includes preferred terms of paresthesia and hypoesthesia

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

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

Description of Selected Adverse Reactions

Hypocalcemia

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

Hypophosphatemia

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

QTc Interval Prolongation Secondary to Hypocalcemia

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

Hypersensitivity

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

Immunogenicity

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

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

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

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

Data

Animal Data

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

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

Lactation

Risk Summary

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

Data

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

Pediatric Use

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

Geriatric Use

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

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

OVERDOSAGE

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

AMGEN®

PARSABIV™ (etelcalcetide)

Manufactured for:
KAI Pharmaceuticals, Inc., a wholly owned subsidiary of Amgen, Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

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

ABIM Announces Plans for New Longitudinal Assessment Option for MOC

A self-paced pathway that could replace Knowledge Check-In

By Eric Seaborg

The American Board of Internal Medicine (ABIM) has announced plans to develop a new self-paced longitudinal assessment for maintenance of certification (MOC) as an alternative option to the traditional every-10-years exam.

"With this new option, physicians will be able to answer a question and receive immediate feedback as to whether it was correct or not, along with the rationale, and links to educational material," according to a statement from ABIM Board of Directors Chair Marianne M. Green, MD, and President and CEO Richard J. Baron, MD.

ABIM is currently seeking comments on the proposal at its website and has no timeline for its implementation. The new option could possibly replace the every-two-years Knowledge Check-In (KCI) exam rolled out just last year.

"We see the development of the longitudinal assessment option as an ongoing collaboration with the internal medicine community, with many opportunities for feedback throughout the process. We've already had a strong initial response to the announcement, and will spend a lot of time reviewing what physicians have told us," Baron told *Kidney News*.

The longitudinal assessment format would allow physicians to log on from anywhere and answer as few or as many questions as desired or as time permits, using whatever information resources they use when treating patients.

Addressing physician concerns

The new format would address some of the major concerns physicians have expressed about MOC, according to Jeffrey S. Berns, MD, FASN, chair of the ABIM nephrology board and a nephrologist at the Hospital of the University of Pennsylvania.

"A lot of physicians have been asking for something you can do at your own pace, you could do it on nights and weekends and without all the high security," Berns said. "They want robust, formative feedback, with the questions linked to educational material, and a discussion as to why the right answer is right, and the wrong answers are wrong. That makes it a vehicle for ongoing learning, for self-assessment as well as assessment for maintenance of certification."

The American Board of Anesthesiology has successfully pioneered this formative process by dropping its 10-year recertification test and replacing it with regular online tests and learning modules called the MOCA (Maintenance of Certification in Anesthesiology) Minute. Participants are required to answer 30 questions each quarter of the year at their own pace. The board reports that diplomates have been enthusiastic about the new approach.

Checking in with the Knowledge Check-In

ABIM said it hopes to announce more details about the development timeline later this fall. That leaves the KCI as the alternative to the 10-year exam for the foreseeable future. Nephrology and internal medicine were the first two ABIM specialties given the option last year, and it was rolled out in eight more specialties in 2019.

In addition to the two-year frequency, the KCI differs from the traditional 10-year test in other ways. Physicians can take the KCI either at a test center (in similar circumstances to the 10-year exam) or online from their home or workplace. The KCI is much shorter, with a time cutoff of three hours rather than all day. Failing the exam does not lead to loss of certification; physicians can try again two years later. Both tests are now open book, with UpToDate as the only reference permitted.

In the first year the KCI was offered, about twice as many nephrologists chose it over the 10-year exam. "Seven of eight people who took the KCI in nephrology said it was a fair assessment of knowledge in the discipline, and most of them were satisfied with the testing experience," Baron said, adding that the KCI received the most positive ratings any ABIM test ever has.

New blueprint

He said the test benefited from the recent review of the "blueprint" used to map out which questions were the most relevant for inclusion on the test. "We set up an online tool and invited everybody who is board-certified in the discipline to rate the relevance of the questions, identify which conditions they treat and which they rarely see, and discuss what is important to know about a condition. The relevance ratings of test questions went up substantially after we did that review," Baron said. More than 400 nephrologists participated.

One aim of the KCI was to lessen the pressure of the 10-year exam, but many test takers still view it as a high-stakes situation. And although it is a shorter exam, the two-year frequency actually adds up to more time-taking tests.

One test taker with a positive impression despite low expectations was Paul M. Palevsky, MD, FASN, chief of the renal section at the VA Pittsburgh Healthcare System and professor of medicine at the University of Pittsburgh School of Medicine.

"I have spoken to colleagues who have taken the 10-year recertification exams, and [without exception] they said that the questions were on minutiae that were clinically irrelevant. They said, 'We don't see the rare diseases that they are asking questions about.' One of my colleagues texted me immediately after finishing the exam, asking if he still had a job if he didn't pass because there was so much ridiculous material on the exam," Palevsky said. "That is the sort of negative feedback that anyone who has followed discussions about the recertification process is well aware of."

But Palevsky said that he found the KCI covered the "bread and butter topic areas in nephrology" in a reasonable way.

Open book

"Having the opportunity to use UpToDate was beneficial and reflects a reality of how people take care of patients," Palevsky said. "If you are unsure of something, you can quickly look it up and see what the experts say. I would love to see ABIM allow a broader open book approach. It is quick to look things up if you are acquainted with UpToDate, [but] someone who doesn't routinely use it might be at a bit of a disadvantage."

Specialty societies offer resources such as self-assessment programs that they would like to see included among the approved sources, according to Jin Soo Kim, ASN senior director of education.

Kim said another potential test option ASN has been discussing with ABIM is the development of what ABIM calls "practice profiles," or tests that are customized based on the focus of a physician's practice, such as dialysis or transplantation.

ASN and ABIM surveyed nephrologists on their practice patterns earlier this year and are in the process of analyzing the results. The analysis will include Medicare data about practice patterns. "Creating practice profiles is a data-driven, expert-informed activity," Baron said.

Berns said: "There could be two or three or four practice profiles so that every nephrologist can take a version of the assessment that reflects their practice more closely than a single-blueprint–based exam might. So it is modifying the blueprint—not changing the questions, but changing the fraction of the exam that is associated with different blueprint topics."

Palevsky said of the KCI: "I would have preferred getting more granular feedback about the questions that were answered incorrectly. To turn the exam into a valuable learning experience, it would be nice to have feedback with information about the questions, and why the ABIM question-writers thought that their answers were the correct ones."

ABIM has heard this request from enough physicians that the longitudinal assessment is designed to take this approach as part of an ongoing evolution.

"I think as an organization we have done a better job of listening to a very broad community," Baron said. "We didn't used to focus very much on connecting with those folks, but I think we have gotten better at hearing what they have to say and using it to change the program. The people who hold our certificates are expert clinicians, and we are getting better at using their expertise to make our program better."

Diplomates can comment on the proposal at www.abim.org.

Diabetic Kidney Disease at a Tipping Point: **Kidney Week Offerings**

By Katherine R. Tuttle and Meaghan Allain

For nearly 20 years, the field of diabetic kidney disease (DKD) was essentially stalled without impactful therapeutic advances. However, that landscape has dramatically changed with the recent discovery of kidney and cardiovascular benefits from SGLT2 inhibitors and GLP-1 receptor agonists. In response to these recent advancements, the American Society of Nephrology (ASN) has launched the Diabetic Kidney Disease Collaborative (DKD-C), which is working to raise awareness and to promote dissemination and implementation of optimal treatment to patients with, and at risk for, DKD.

Because a central goal of the DKD-C is to provide education and tools to help nephrologists and other healthcare professionals provide high-quality care for DKD, this year's Kidney Week is filled with a number of robust sessions squarely focused on diabetes, metabolism, and the kidney.

The DKD-specific educational opportunities available during this year's Kidney Week include a two-day early program, as well as basic, clinical, and translational science sessions with state-of-the-art lectures. These sessions cover evidence from the recent blockbuster clinical trials of new therapies and also emphasize implementation of current standards of care and lifestyle approaches to manage DKD. What an exciting time, truly a tipping point, in the field of DKD!

A complete listing of Kidney Week opportunities for diabetic kidney disease can be found here:

Session	Title	Date	Time
Early Program	Diabetic Kidney Disease: Translating Pathogenic Mechanisms into Therapies	November 5 and 6, 2019	7:00 a.m.
Basic and Clinical Science Sessions	Mitochondrial Dynamics and Dysfunction in Metabolic Disease	November 7, 2019	2:00 p.m.
	Functional Proteomics: Unraveling Molecular Machines to Protein Networks in Metabolic Disease	November 8, 2019	10:30 a.m.
	Nutrient Metabolism in Diabetic Complications	November 9, 2019	2:00 p.m.
	Move Over and Make Room for SGLT2 Inhibitors in CKD	November 9, 2019	12:45 p.m.
	Beating the Law of Averages: Predicting Diabetic Kidney Disease Outcomes Through Integrative Biology	November 10, 2019	10:00 a.m.
Translational Science Sessions	The Revolution Is Here: New Treatments for Diabetes and Kidney Diseases, Including the Barry M. Brenner, MD, Endowed Lectureship	November 7, 2019	10:30 a.m.
	Unraveling Connections Between Obesity and Kidney Diseases	November 7, 2019	2:00 p.m.
	Major Clinical Trials for Diabetic Kidney Disease: CREDENCE and SONAR	November 8, 2019	10:30 a.m.
Clinical Practice Session	Can Lifestyle and Diet Make a Difference for Patients with Diabetes and Kidney Diseases?	November 9, 2019	2:00 p.m.

Be sure to attend the late-breaking clinical trials sessions for cutting-edge data on DKD (and other therapeutic areas).

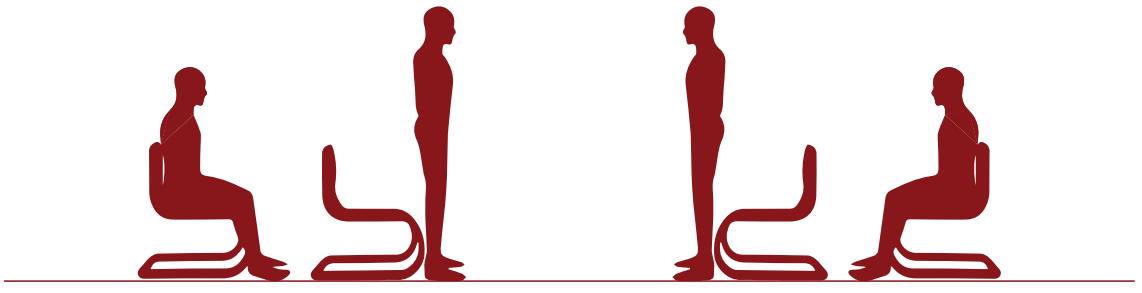
In addition to the breakthrough therapies announced in 2019, there are numerous clinical trials in the pipeline that are sure to have an impact on the way DKD is managed, further expanding the menu of treatment options available. Stay tuned.

Katherine R. Tuttle, MD, is a member of the ASN Diabetes Kidney Disease Collaborative and is affiliated withProvidence Health Care, the Kidney Research Institute, the Institute of Translational Health Sciences, and the University of Washington School of Medicine. Meaghan Allain is a senior project associate at ASN.

DO YOU ACCEPT THE CHALLENGE?

See how you score to raise money for the

National Kidney Foundation®



TAKE THE CHALLENGE AT BOOTH 805

TRICIDA

KIDNEY WEEK 2019

Supporters

Abstracts USB Drive

OPKO Renal

Column Wraps

AstraZeneca

TRICIDA

Complimentary Wi-Fi

TRICIDA

Convention Center Banners

Akebia Therapeutics

AstraZeneca

FRESENIUS MEDICAL CARE

relypsa — A Vifor Pharma Group Company

TRICIDA

Convention Center Clings

Akebia Therapeutics

Alnylam Pharmaceuticals

AstraZeneca

FRESENIUS MEDICAL CARE

relypsa — A Vifor Pharma Group Company

ROCKWELL MEDICAL

Exhibit Hall Refreshment Breaks

FRESENIUS MEDICAL CARE

Exhibitor Spotlights

ALEXION

AMGEN

Baxter

Daiichi-Sankyo

gsk

janssen — Pharmaceutical Companies of Johnson & Johnson

Mallinckrodt Pharmaceuticals

Otsuka

relypsa — A Vifor Pharma Group Company

ROCKWELL MEDICAL

SANOFI GENZYME

TRICIDA

ASN gratefully acknowledges the following companies, institutions, and organizations for their support of Kidney Week 2019.

FIT Bowl 2019

AstraZeneca

Hotel Key Cards

relypsa
A Vifor Pharma Group Company

Hotel Room Drops

Akebia THERAPEUTICS

AstraZeneca

Mallinckrodt Pharmaceuticals

TRICIDA

Kidney Week Podcasts

Kidney360

Kidney Week *On-Demand*

Akebia THERAPEUTICS

ALEXION

Mallinckrodt Pharmaceuticals

relypsa
A Vifor Pharma Group Company

TRICIDA

Lanyards

UNC HEALTH CARE KIDNEY CENTER

Light Boxes

AstraZeneca

Retrophin

TRICIDA

Meeting Bags

University of Virginia Health System

Mobile App

REATA PHARMACEUTICALS

Onsite Guide

TRICIDA

Power Stations

REATA PHARMACEUTICALS

President's Dinner

relypsa
A Vifor Pharma Group Company

Shuttle Buses

FRESENIUS MEDICAL CARE

Water Stations

REATA PHARMACEUTICALS

Welcome Reception

ASN
American Society of Nephrology

As of August 21, 2019

Policy Update

ASN Submits Comments about ETC Model to CMS

By David White

Creation of payment models is a critical component of the Executive Order on the Advancing American Kidney Health (AAKH) initiative issued by President Donald J. Trump on July 10, 2019. At the time this article was written, the Innovation Center of the Centers for Medicare and Medicaid Services (CMS) had only released the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, a mandatory model that tests using payment policy to drive higher rates of home dialysis and kidney transplantation. The proposed payment policies will affect the managing clinicians and dialysis facilities assigned to the model. The four voluntary models to accompany the ETC model were still to be released.

With a clear perspective of the breadth of what CMS proposed in the ETC model—and the overall AAKH initiative—American Society of Nephrology (ASN) President Mark E. Rosenberg, MD, FASN, submitted comments and recommendations developed by the ASN Quality Committee to CMS on September 16, 2019. The recommendations were developed with guidance from the ASN Council and input from numerous ASN members and in collaboration with other kidney community members. While ASN provided its own specific recommendations, ASN, the National Kidney Foundation, and the Renal Physicians Association also submitted a high-level overview outlining five areas for improvement in the model (See Table 1).

Essentials for ensuring success

ASN maintained its support for the objectives of the proposed ETC model to expand patient access to a variety of dialysis modalities and to kidney transplantation. ASN has emphatically maintained—in meetings with the agency and in this comment letter—that the agency needs to focus the model on "access" to modality choices, not on requiring every program to offer home dialysis, and that the evaluation methods and payment adjustments in the model need to be aligned with more investment in building capacity and significantly reducing the penalties.

ASN maintains there needs to be more safety guardrails for patients in the model to incent patient-centered choice. As such, the society identified several key essential elements that "must be addressed to maximize the likelihood of optimal outcomes for patients and ensure the success of the model":

- Establishing appropriate targets and benchmarks with a top combined home dialysis and transplant rate of 50% as opposed to 80%
- Using shared decision-making tools and incorporating additional risk adjustment to mitigate the risk of non-patient–centered decision-making
- Aggregating home dialysis rates at a geographic level such as a hospital referral region—not the facility level
- Incentivizing and investing wisely by reducing the performance payment adjustment (PPA) to a level comparable with the ESRD Quality Incentive Program (QIP), investing in the home dialysis payment adjustment (HDPA) at 3-5% annually for the life of the model, and making the model an advanced alternative payment model (AAPM)
- Increasing access to transplantation by incorporating adjusted transplantation rates as an outcome
- Delaying both the start date of the model until April 2020 and implementation of downside adjustments until measurement year three
- Using the rulemaking process for the model annually

Establishing appropriate targets and benchmarks

Dr. Rosenberg shared the concern of ASN members and other kidney community organizations that critical guardrails for patients need to be strengthened in the model by emphasizing throughout the letter that the optimal kidney replacement therapy differs from patient to patient.

"Establishing appropriate thresholds and benchmarks provides those important guardrails for patients with contraindications—absolute or relative—or insurmountable barriers for home dialysis or transplant," he wrote. "We recommend lowering the target goal of 80% combined home dialysis and transplant rate in the final years of the ETC model to 50%—a still audacious, but achievable, target."

CMS was also encouraged to review the risk adjustment of the patient population that is to be placed in the denominator for evaluating ETC participants—clinicians and dialysis facilities—to support their ability to make truly shared, patient-centered choices. The recommendations specifically asked the agency to add to its risk adjustment neighborhood census socioeconomic data linked at the zip code level as has been done for the Agency for Healthcare Research and Quality.

In detail, ASN demonstrated the math needed to reach an 80% rate and declared it to not be achievable in the timeframe allotted. Also, the society cautioned CMS to avoid unfairly penalizing programs that have already been successful at increasing rates of home dialysis and transplant and are therefore "topped out." Similarly, ASN urged the agency "to not implement a forced bell curve approach that could apply penalties to as much as 30% of participants regardless of their improvement and achievement scores." The letter pointed out that a forced bell curve was not essential to achieving the program's goals of increased patient choice among in-center, home, and transplant—goals ASN has previously endorsed and did so again in these comments.

Empowering patients and care teams to evaluate the range of treatment options

ASN's comment letter recognized that current reimbursement and delivery systems for kidney care often do not emphasize patient choice, tending to default to in-center hemodialysis (HD). To achieve balance in the new payment model, the society encouraged the use of shared decision-making tools. ASN also urged CMS to reconsider its position on self-care. In the proposed rule, the agency wrote, "We considered including beneficiaries whose dialysis modality is self-dialysis or temporary peritoneal dialysis (PD) furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC model, to increase beneficiary choice regarding ESRD treatment modality. However, these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same codes as in-center HD, making it impossible for CMS to identify the relevant claims."

ASN responded by recommending the agency include in-center, self-care patients in the numerator of home patients for a given clinic/program/geographic area for a defined period of time, maintaining "these activities can serve as a bridge to home dialysis, a period of adjustment and confidence building, and a mechanism for support for patients who need an alternative to their normal home dialysis." To accomplish this, ASN proposed a definition of self-care for CMS consideration and proposed using the existing condition code for "self-care in unit" (code 72) as defined in

Table 1. Five principles in ASN, NKF, and RPA joint letter to CMS

Establishing patient-centered targets, benchmarks, and risk adjustments that ensure there are guardrails in the model for patients with contraindications or insurmountable barriers for home dialysis or transplant. In addition, correctly risk adjusting the patient population that is to be placed in the denominator for evaluating ETC participants—clinicians and dialysis facilities—would empower them to make truly shared, patient-centered choices.
Empowering patients and care teams when evaluating treatment choices. The model should encourage the use of shared decision-making tools by patients and their care team when educating and evaluating kidney replacement therapies.
Guaranteeing access to home dialysis programs. Enhancing patient access to kidney failure treatment choices and the education needed to properly evaluate those choices) is a key goal of the ETC model that we support. However, ensuring reasonable patient access to a home dialysis program does not require that every dialysis facility offer a home dialysis program.
Incentivizing and investing wisely in the proposed model. We believe the model must balance appropriate adjustments that are not overly punitive while providing more up-front investment to make possible the desired achievements in increased home dialysis and transplantation rates. The truly significant savings to Medicare under the proposed model derive directly from improved outcomes, less hospitalization, more transplantation, and fewer years of dialysis—results that will require investment in order to achieve.
Providing ETC participants the time to properly prepare for the model and the opportunity to comment as the model progresses. We believe the success of all participants in the model would be enhanced by providing more time before commencing the ETC Model date for stakeholders to prepare starting April 1, 2020. We also believe the success of the model would be enhanced by using the rulemaking process throughout the life of the model."

Abbreviations: NKF, National Kidney Foundation; RPA, Renal Physicians Association; CMS, Centers for Medicare and Medicaid Services

section 50.3 of Chapter 8 of the Medicare Claims Processing Manual to track self-care patients.

Guaranteeing access to home dialysis programs

The proposed model allowed managing clinicians to aggregate their home dialysis rate to the taxpayer identification number (TIN) of their practice, or to the national provider identifier (NPI) for solo practitioners, but required facilities to be graded at the facility level. ASN expressed concern that incenting every facility to offer a home option will not actually result in better outcomes for patients. ASN recommended aggregating all facilities regardless of corporate ownership or affiliation to a geographic level such as the hospital referral region when assessing access to home dialysis.

ASN also asked the agency to examine the option of excluding companies or institutions that do not provide in-center care in their clinics in the geographic region from participating in the model unless they are contractually aligned with providers that offer in-center dialysis to prevent unintended consequences. To support this recommendation, the letter provides several examples of how home dialysis programs work in reality and how a facility-based evaluation could actually prevent the model from achieving its goals.

Incentivizing and investing wisely in the ETC model

In response to the model being weighted negatively, ASN clearly stated it did not believe the patient benefits and cost savings to Medicare could be realized by cutting costs alone. The society maintains that truly significant savings to Medicare under the proposed model derive directly from improved outcomes, less hospitalization, more transplantation, and fewer years of dialysis—results that will require investment in order to achieve.

ASN requested the agency do the following:

- Reduce the PPA and align it with penalties in the ESRD QIP
- Invest in the HDPA at 3-5% annually for the life of the model
- Make the model an AAPM

ASN urged the agency to reduce the magnitude of the PPA to lower penalty levels below the proposed up to 11% for managing clinicians and replicate the penalties in the ESRD QIP with a maximum 2% penalty and sufficiently fund the HDPA throughout the model's life to cover the investments that will need to be made. ASN also raised its concern about the availability of home dialysis nurses and other healthcare professionals who will be essential for the model's success.

ASN encouraged CMS to more transparently detail how it believes relative contraindications and other barriers to home dialysis will be factored into the model. Targets for PD utilization may be difficult to achieve because many older patients have relative contraindications to PD or barriers to self-care leading to the need for home-assist efforts or the removal of such patients from the denominator.

Increasing access to transplantation

The AAKH initiative has a stated goal of doubling the number of kidneys available by 2030. ASN offered its assistance to HHS in reaching this goal and indicated its strong support for the use of an actual transplant rate as a metric in the ETC model. Dr. Rosenberg wrote, "This approach also constitutes a fundamental shift and will necessitate greater cooperation with patients, their families and loved ones, transplant centers, Organ Procurement Organizations, and other stakeholders." ■

Human Factors Engineering Helps Identify Threats to Infection Control in Dialysis

By Bridget M. Kuehn

Central venous catheter care takes a great deal of dexterity, so much so that some clinicians at Westchester Medical Center's dialysis clinic say it "takes three hands," said Renee Garrick, MD, a nephrologist and executive medical director at the center. Yet interruptions during this critical procedure are common—raising the risk of an infection control breach.

Garrick spoke during a webinar hosted by Nephrologists Transforming Dialysis Safety (NTDS), ASN's partnership with the Centers for Disease Control and Prevention (CDC).

Understanding how such disruptions in critical procedures affect infection control in dialysis settings is one important part of NTDS, which is working with the CDC to target a goal of zero dialysis-related infections. To help achieve this goal, NTDS engaged human factors engineering researchers to assess infection control practices at six outpatient dialysis facilities across the United States to find ways to improve them.

"We can't necessarily change the human condition, but what we can do is change the conditions in which humans work," said Sarah Henrickson Parker, PhD, senior director of the Center for Simulation, Research, and Patient Safety at the Carilion Clinic in Roanoke, Virginia, which is conducting the research. The clinic is part of the Virginia Tech Carilion School of Medicine.

"Human factors and system safety [engineering] is really focused on trying to understand all those aspects of the system that are influencing how people do their job and take that human capability and limitation into account to actually redesign work so that it is safer," Parker said.

Systems design

Parker and her team were tasked with assessing four key infection control practices at the dialysis facilities, including hand hygiene, injection safety, environmental disinfection, and central venous catheter care. To do this, they observed nearly 8000 infection control tasks during 484 patient encounters over 157.5 hours at the facilities. They also discussed the procedures and systems involved with both frontline staff and leadership from each facility.

In the process, they identified several key challenges including patient factors like access and clotting delays; environmental factors like noise, lighting, machine design, and access to hand hygiene; the complexity of center policies and procedures; and things like interruptions during care, alarms, multitasking, and difficulties delineating clean versus dirty. The researchers' sketches of staff movements during workflows often looked like a "bowl of spaghetti," revealing the importance of facility layout, noted Garrick, who chairs the NTDS Human Factors Workgroup.

"It's easy to see that the environment in which our staff work influences the care that we provide," Garrick said. "All of these environmental interactions can affect how easily our staff can follow infection control steps no matter how good our policy and no matter how well trained and well intentioned our staff might be."

Interruptions during care were also identified as a major concern. About 1 in 5 patient encounters were interrupted, noted

Garrick. Only 18% of these interruptions were clinically relevant, and many occurred during critical procedures. For example, 62% of interruptions occurred during fistula or graft care and 18% occurred during central venous catheter care.

One common type of interruption was alarms. Alarms went off during about half of the patient encounters even though 70% of them were not clinically actionable. Garrick noted that staff often have to stop what they are doing and touch the machines to turn off the alarms, which "dramatically" increased the need for hand hygiene and introduced opportunities for breaches in hand hygiene. The noise from alarms and other sounds in the unit can also affect both patients and staff.

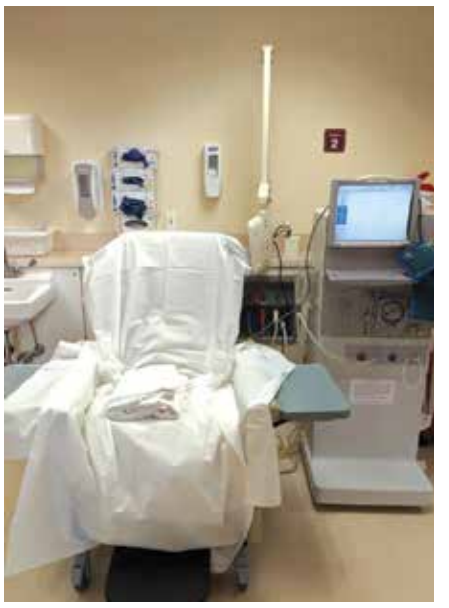
"Noise levels can influence the perception of the staff and the perception of our patients regarding the kind of care that they're receiving and the quality of that care," Garrick said.

Task-stacking or multi-tasking was another concern identified by the researchers. Garrick noted that such multitasking may feel essential in a busy dialysis center, but it may increase the likelihood of interruptions and errors.

"We're switching back and forth quickly from one task to another and when we do it, we're actually using the same cognitive function [to accomplish multiple tasks]," Garrick said. "The reality is that that can actually kind of overwhelm human capabilities."

Other challenges identified were complex procedures and policies regarding items designated as "clean" or "dirty." Often, items may switch from clean to dirty during the course of a patient's care, Parker noted.

Absence of readily available hand sanitizer and remote location of sink could be a barrier to infection control in this dialysis unit



Facilitating better care

The researchers also identified factors that can support infection control practices, including interoperability of machines and computer systems, teamwork and staffing support, and leadership.

"The facilities that worked well together tended to support each other in times of stress where patients needed extra help," Garrick said.

The NTDS program doesn't yet have any new recommendations on how to improve infection control in dialysis units based on the human factors data, said Alan Kliger, MD, nephrologist and clinical professor at Yale School of Medicine in New Haven, Connecticut. But the preliminary insights shared during the webinar, which will be freely available on the NTDS website, may help dialysis centers better implement existing CDC infection control guidelines.

"We hope that by presenting these initial findings we've provoked some thoughts about what we can do in our clinical practice to alleviate some of the problems that we've addressed," he said. For example, he suggested that dialysis centers may want to implement a policy that bars nonessential interruptions during critical procedures, an approach similar to what airlines use to prevent nonessential pilot interruptions during takeoff.

Kliger also emphasized the importance of engaging staff and soliciting their ideas about configuring workflows and tasks to improve the efficiency and safety of care. He highlighted strategies such as creating a staff input bulletin board or encouraging group staff interactions.

Often, small changes in workflows and practices can make a big difference in how well highly trained staff are able to do their jobs, Parker said. Human systems engineering analyses can help identify those changes.

"By identifying these systems issues or these systems contributors, we can improve care for patients as well as make life easier for providers, let them do what they are good at, what they are trained to do."

COMMUNITY LOUNGE EVENTS

Make the most of your time at ASN Kidney Week with quick, informal sessions.

Community Events
Quick, informal presentations by a variety of experts.

Hear from:

- Past winners of the Innovations in Kidney Education Contest
- Leading nephrologists and educators discussing a variety of topics like social media in nephrology
- Experts like Dr. Rodby and Dr. Lerma as they lead you on an exciting poster tour

Join an intimate group of your peers as you listen and partake in conversations.

ASN Communities

Thursday

10:00 – 10:30 a.m.	**Continuous Renal Replacement Therapy Simulator** *Kamalanathan K. Sambandam, MD**
10:30 – 11:00 a.m.	**General & Clinical Nephrology Poster Tour** *Meet in the Lounge; Roger Rodby, MD, FASN and Edgar Lerma, MD, FASN*
11:00 – 11:30 a.m.	**Renal Pathology Web Episodes** *Timothy Yau, MD**
12:00 – 12:30 p.m.	**Glomcom Trivia and Case Conferences** *Pravir V. Baxi, MD*
1:00 – 1:30 p.m.	**Leveraging Social Media for Your Career in Nephrology** *Joel Topf, MD*

Friday

10:00 – 10:30 a.m.	**CRRT Virtual Patient Simulator Mobile App** *Benjamin Griffin, MD**
11:00 – 11:30 a.m.	**Navigating a Career in Medicine for Women in Nephrology** *Silvi Shah, MD, MS, FASN*
12:00 – 12:30 p.m.	**Hemodialysis Access 101** *Namrata Krishnan, MD**
1:00 – 1:30 p.m.	**Nephro360: Virtual Reality and Gaming** *Aleksandr Vasilyev, MD, PhD**

Saturday

10:00 – 10:30 a.m.	**Why you should be reading Renal Fellow Network** *Matt Sparks, MD, FASN*
11:00 – 11:30 a.m.	**Q&A with the new Kidney360 Editor-in-Chief** *Michael Allon, MD, EIC*
12:00 – 12:30 p.m.	**NephSIM** *Samira Farouk, MD, MS, FASN**
1:00 – 1:30 p.m.	**ASN Communities Mobile App** *Susan Willner, Manager, ASN Communities*

**Innovations in Kidney Education Contest Winners (2015-2018)*

STATE-OF-THE-ART LECTURE

CRISPR Inventor to Speak on Gene-Editing Future

Jennifer A. Doudna, PhD

The discoverer of a revolutionary gene-editing technique will give a state-of-the-art lecture on "Rewriting the Code of Life: The Future of Genome Editing" at a plenary session on Thursday, Nov. 7.

Jennifer A. Doudna, PhD, is an internationally renowned professor of chemistry and molecular and cell biology at the University of California Berkeley. She and her colleagues rocked the research world in 2012 by describing a simple way of editing the DNA of any organism using an RNA-guided protein found in bacteria.

Her investigations into clustered regularly interspersed short palindromic repeats (CRISPRs) and the CRISPR-associated (Cas) enzyme Cas9 led to the transformative discovery of DNA cleavage by Cas9. Cas9 is an RNA-guided enzyme whose ability to cut double-stranded DNA can be programmed by changing the guide RNA sequence. Recognizing that this enzyme–RNA complex could be employed for precision genome engineering, Dr. Doudna's team created a simple-to-use system that triggered a revolution in the fields of molecular genetics and genomics.

The CRISPR-Cas9 technology opened the floodgates of possibility for human and non-human applications of gene editing. It is being used in laboratories around the world to advance biological research by engineering cells and organisms in precise ways. This genome editing in animals and plants is revolutionizing the fields of medicine, genetics, and molecular biology in ways that will almost certainly lead to the development of new therapeutics, biofuels, and agricultural products. It is assisting researchers in the fight against HIV, sickle cell disease, and muscular dystrophy.

Dr. Doudna is the Li Ka Shing Chancellor's Chair in Biomedical and Health Sciences at Berkeley and an investigator at the Howard Hughes Medical Institute.

She is a member of the National Academy of Sciences, National Academy of Medicine, National Academy of Inventors, and American Academy of Arts and Sciences. She is also a Foreign Member of the Royal Society, and has received many other honors, including the Breakthrough Prize in Life Sciences, Princess of Asturias Award (Spain), Gruber Prize in Genetics, Heineken Prize (Netherlands), Gairdner Award (Canada), Tang Prize (Taiwan), Japan Prize (Japan), and L'Oreal-UNESCO International Prize for Women in Science.

She is the co-author with Sam Sternberg of *A Crack in Creation*, a personal account of her research and the societal and ethical implications of gene editing.

Dr. Doudna received her doctorate in biological chemistry and molecular pharmacology from Harvard Medical School and completed postdoctoral fellowships in molecular biology at Massachusetts General Hospital, genetics at Harvard Medical School, and biomedical science at the University of Colorado. She was on the faculty of Yale University prior to joining Berkeley.

Coburn Lecture Will Cover Fibroblast Growth Factor-23 Risks

Sharon M. Moe, MD

Patients with kidney disease have disordered bone and mineral metabolism, including elevated serum concentrations of fibroblast growth factor-23 (FGF23). These elevated concentrations are associated with cardiovascular and all-cause mortality, which will be the subject of the Jack W. Coburn, MD, Endowed Lectureship, on Thursday, Nov. 7.

Sharon M. Moe, MD, will speak on "FGF23 and Risks of Cardiovascular and Noncardiovascular Diseases." Dr. Moe is director of the division of nephrology and Stuart A. Kleit Professor of Medicine at the Indiana University School of Medicine. She has been a faculty member at Indiana University since 1992 and was recently named distinguished professor. She has also served as the associate dean for research support in the school of medicine and vice chair for research in the department of medicine.

Dr. Moe's research is translational and involves the study of all aspects of chronic kidney disease–mineral bone disorder. She is the principal investigator for several basic and clinical research studies in the field, including studies on vascular calcification, mineral metabolism, and bone metabolism in kidney disease. She has studied the pathogenesis of vascular calcification in animal models and human studies, evaluated the role of abnormal bone in the pathogenesis of vascular calcification, examined treatments to reduce fractures, and examined the role of nutrition.

She has also been involved in the design and conduct of clinical trials for multiple drugs to treat hyperphosphatemia and secondary hyperparathyroidism.

Her research has been funded by the National Institutes of Health and Department of Veterans Affairs for more than 20 years. She has authored over 200 scientific manuscripts, teaching manuscripts, and textbook chapters.

Dr. Moe served on the National Kidney Foundation's bone and mineral metabolism clinical practice guidelines committee in 2003, co-chaired the international Kidney Disease: Improving Global Outcomes mineral and bone guidelines committee in 2009, and was a member of the 2017 update committee.

Dr. Moe served as president of the American Society of Nephrology in 2013–2014 and has served ASN in many other capacities as well.

She has served on the executive committee of the Kidney Disease Outcomes Quality Initiative, on the American Heart Association kidney council, and as councilor to the International Society of Nephrology. Her service on editorial boards includes *JASN, American Journal of Kidney Diseases, and American Journal of Nephrology*.

Key honors she has received include election to the American Society for Clinical Research and the National Kidney Foundation Garabed Eknoyan Award for exceptional contributions.

She attended the University of Illinois College of Medicine at Chicago, was an intern and resident at Loyola University Medical Center in Maywood, Ill., and completed a nephrology fellowship at the University of Chicago.

Diabetic Nephropathy Expert to Give Brenner Lectureship

Michael Mauer, MD

Michael Mauer, MD, will speak on "Diabetic Kidney Disease: Structural–Functional Relationships and the Possibilities of Cure" in the Barry M. Brenner, MD, Endowed Lectureship on Thursday, Nov. 7.

Dr. Mauer is professor of medicine at the University of Minnesota in Minneapolis, where he is a faculty member in both the division of pediatric nephrology and the division of renal diseases and hypertension.

His early clinical research involved the development of hemodialysis methods and kidney transplant strategies and protocols for infants and small children, an interest that continued for years. He began his basic research with studies of mesangial cell function in rats. He then performed structural and functional studies of diabetic nephropathy models in rats and mice.

His lab developed quantitative morphometric electron microscopic methods to quantify diabetic nephropathy lesions in rats that were subsequently applied to research renal biopsies, primarily in type 1 diabetes patients. Over the next four decades, he conducted studies elucidating the structural and functional relationships in diabetic nephropathy, diabetic nephropathy natural history studies, and clinical trials with diabetic nephropathy structural primary endpoints. His recent studies have also included Pima Indian, Japanese, and Caucasian patients with type 2 diabetes. He also performed a series of in vitro molecular studies using cultured skin fibroblasts from patients with type 1 diabetes that elucidated potential pathophysiological pathways of interest.

For the past 12 years, he has pursued quantitative structural studies of renal biopsies in Fabry disease. These studies have helped to define an important role for the podocyte in the kidney complications in this disorder.

Dr. Mauer has had continuous National Institutes of Health funding for more than four decades. He has published more than 350 peer-reviewed articles and 90 book chapters. He serves on many editorial boards, including those of *Diabetes Care, International Journal of Pediatric Nephrology, Journal of Pediatric Nephrology, Kidney International, and Pediatrics*.

Dr. Mauer graduated from McGill Medical School in Montreal, Canada. He completed his residency in pediatrics at McGill and the University of Colorado. After his fellowship in pediatric nephrology at the University of Minnesota, he joined the faculty there. He was co-director of the division of pediatric nephrology from 1992 to 2009.

PROVEN RESULTS THROUGH CKD PATIENT EDUCATION

Improve your practice with our physician-directed patient education program created by physicians for physicians in an easy-to-deliver format.

BENEFITS:

+ Increase in-home dialysis (both home hemodialysis and peritoneal dialysis)
+ Decrease catheter rate at dialysis initiation
+ Empower patients to make informed decisions
+ Improve patients' overall health and quality of life
+ Improve patient satisfaction
+ Increase practice revenue (meets CMS guidelines)

> *This program has been a great benefit for our patients. Many more patients choose home therapy and are more interested and compliant with their medical care.*
>
> — G. Walker, MD, FRCP, FACP, FASN
> President, North Texas Renal Management

What Patients Have To Say

93.4% said the workshop provided information they needed

98.0% said they would recommend program to other patients

raenali PUBLICATIONS
physicians educating patients

Visit Raenali Publications during the American Society of Nephrology Kidney Week November 7-9, 2019 at **Booth #1534**

For more information on how you can implement this unique program for your patients visit **raenali.com.**

Trump Administration Officials to Receive President's Medals

In July 2019, President Donald Trump signed an executive order to launch the Advancing American Kidney Health (AAKH) initiative, creating an unprecedented focus on kidney disease, while also shifting the focus to kidney health. The executive order articulates a unified strategy that will guide the efforts of ASN and the kidney community to improve every aspect of kidney care, research, and education.

For more than a decade, ASN has worked to build bipartisan support throughout all parts of the U.S. government—including the White House, all relevant agencies, and both chambers of Congress—for people with kidney disease, their caregivers, and researchers aiming to eradicate it. As part of this effort, ASN has worked closely with countless professionals at the U.S. Department of Health and Human Services (HHS), which demonstrated a commitment to ASN's mission and sense of responsibility to the 37 million Americans living with kidney diseases. Together, we partnered to establish the Kidney Health Initiative in 2012, Nephrologists Transforming Dialysis Safety in 2016, and KidneyX in 2018. With the president's Executive Order, our work continues.

The ASN President's Medal recognizes individuals who are not ASN members but who nonetheless have helped to advance ASN's mission.

In recognition of their work in advancing the AAKH initiative, ASN is presenting the President's Medal to the administration officials listed here for their roles in providing "unprecedented attention and action related to kidney care, research, and innovation within the administration." Ultimately, without their vision and leadership, the executive order and the national prioritization of kidney health would not have happened.

Alex M. Azar II

Alex M. Azar II was sworn in as Secretary of Health and Human Services on Jan. 29, 2018. Mr. Azar has spent his career working in both the public and private sectors, as an attorney and in senior leadership roles focused on advancing healthcare reform, research, and innovation.

From 2001 to 2007, Mr. Azar served at the U.S. Department of Health and Human Services—first as its General Counsel (2001–2005) and then as Deputy Secretary. During his time as Deputy Secretary, Mr. Azar was involved in improving the department's operations, advancing its emergency preparedness and response capabilities as well as its global health affairs activities, and helping oversee the rollout of the Medicare Part D prescription drug program.

In 2007, Mr. Azar rejoined the private sector as senior vice president for corporate affairs and communications at Eli Lilly and Co. From 2012 to 2017, he served as president of Lilly USA LLC, the company's largest affiliate.

Mr. Azar clerked for U.S. Supreme Court Justice Antonin Scalia prior to practicing law for several years. He graduated summa cum laude with a bachelor's degree in economics and government from Dartmouth College and earned his law degree from Yale University.

Eric D. Hargan

Eric D. Hargan is Deputy Secretary of the Department of Health and Human Services (HHS). HHS is dedicated to promoting and enhancing the health and well-being of the American people, and as the largest department in the federal government has an annual budget in excess of $1.3 trillion and over 80,000 employees across 26 divisions. As Deputy Secretary, he is the Chief Operating Officer and is responsible for overseeing the day-to-day operations and management of the department in addition to leading policy and strategy development.

Mr. Hargan was sworn into office as Deputy Secretary on October 6, 2017. He immediately served as Acting Secretary of HHS from October 2017 to January 2018.

From 2003 to 2007, Mr. Hargan served at HHS in a variety of capacities, including Acting Deputy Secretary. During his tenure at HHS, Mr. Hargan also served as the department's Regulatory Policy Officer, where he oversaw the development and approval of all HHS, CMS, and FDA regulations and guidances.

He received his B.A. cum laude from Harvard University, and his J.D. from Columbia University Law School, where he was senior editor of the *Columbia Law Review*. Between his tours of duty at HHS, Mr. Hargan taught at Loyola Law School in Chicago, focusing on administrative law and healthcare regulations.

Adam Boehler

Adam Boehler is Senior Advisor, HHS Secretary; Deputy Administrator, Centers for Medicare & Medicaid Services; and Director, Center for Medicare and Medicaid Innovation.

Widely regarded as an innovative leader in the private sector, Mr. Boehler founded and was CEO of several successful large businesses and was a leader at two international investment firms.

Mr. Boehler was the founder and CEO of Landmark Health. Landmark is the largest home-based medical group in the country, with over 1000 employees across 20 locations in the United States and India and 80,000 chronic patients under management. He co-founded Imagine Health, Landmark's wholly owned subsidiary in India.

Mr. Boehler was an Operating Partner at Francisco Partners, a $14 billion global investment firm with offices in San Francisco and London. He focused on new and existing investments both domestically and abroad.

He was a Principal at Accretive, LLC, a private equity firm based in New York. Prior to joining Accretive, Mr. Boehler was Executive Vice President and General Manager at MedeAnalytics, a leading global provider of SaaS analytics. He started and managed Mede's European operations, headquartered in London, and led product innovation with over 200 engineers in Ukraine and Hungary.

Mr. Boehler worked at Battery Ventures, a global technology–focused venture capital firm with over $2 billion under management and offices in Boston, Silicon Valley, London, and Israel. He focused on investments in software and emerging technologies in the United States and Israel.

Mr. Boehler graduated magna cum laude from the Wharton School of the University of Pennsylvania.

Admiral Brett P. Giroir, MD

Admiral Brett P. Giroir, MD, was sworn in as Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS) on February 15, 2018. He leads development of HHS-wide public health policy recommendations and oversees 11 core public health offices—including the Office of the Surgeon General and the U.S. Public Health Service Commissioned Corps.

Dr. Giroir is a physician, scientist, and innovator. He serves as Senior Advisor to the Secretary for Opioid Policy. In this capacity, he is responsible for coordinating HHS's efforts across the administration to fight America's opioid crisis.

From 2014 to 2015, Dr. Giroir chaired the Veteran's Choice Act Blue Ribbon Panel to reform the U.S. Veterans Health Administration. During the Ebola emergency, he directed the Texas Task Force on Infectious and Disease Preparedness Response.

He was executive vice president and CEO of Texas A&M's Health Science Center from 2013 to 2015, having earlier served as vice chancellor of strategic initiatives (2011–2013) and vice chancellor for research (2008–2011) for the entire Texas A&M University system. A pediatric critical care physician and a former member of the American Board of Pediatrics, Dr. Giroir cared for critically ill children for 14 years and was the first chief medical officer of Children's Medical Center of Dallas (now Children's Health).

Dr. Giroir has authored or co-authored almost 100 peer-reviewed scientific publications and holds patents on a number of biomedical inventions. He is the recipient of numerous honors and awards, including the U.S. Secretary of Defense Medal for Outstanding Public Service and the American Heart Association's President Lyndon Baines Johnson Research Award.

He received a bachelor's degree in biology from Harvard University in 1982 and a medical degree from the University of Texas Southwestern Medical Center (Dallas) in 1986.

Sandeep Patel

Sandeep Patel currently serves as the Open Innovation Manager in the Immediate Office of the Secretary for the U.S. Department of Health and Human Services, where he co-founded and led the public-private partnership Kidney Innovation Accelerator (KidneyX) to advance innovation and diagnostic and therapeutic tools for kidney disease, and helped craft the administration's Advancing American Kidney Health initiative.

He has also built a $50 million program to spur innovation through use of prizes and challenges to catalyze new product development in health. Mr. Patel is singularly focused on ensuring that advances in science and technology are utilized for public benefit, leveraging his experience in research, policy, and product development, including his time at the National Academy of Sciences, Thomson Reuters, and several startup companies. He holds a PhD in physical chemistry from the Georgia Institute of Technology and a BA in chemistry from Washington University in St. Louis.

Murray Sheldon, MD

Murray Sheldon, MD, received his medical degree from the University of Michigan Medical School in 1975. He completed his general surgical residency with Kaiser Permanente Medical Center and his cardiovascular fellowships at the University of California, Davis, and the Montefiore Hospital and Medical Center in New York. In 1983, he entered private practice as a staff surgeon in several medical centers in northern California. His career led him to the medical device industry, where he led device development projects and provided expertise to numerous device development firms.

From 2003 to 2009, Dr. Sheldon was medical director for Arbor Surgical Technologies, which developed a unique two-piece, sutureless aortic valve for clinical aortic valve replacement that was sold to Medtronic. Prior to joining FDA, he was the medical director for the minimally invasive surgical program at BioVentrix, Inc., and developed a catheter-based procedure for surgical ventricular reconstruction for heart failure patients. That device recently received two 510(k) clearances.

Dr. Sheldon joined the Food and Drug Administration (FDA) in 2013 as the Associate Director for Technology and Innovation. He oversees the center's initiatives to proactively facilitate medical device innovation to address unmet public health needs. His primary focus is working with staff, the medical device industry, the clinical community, and other stakeholders on ways to facilitate bringing innovative medical devices to patients. Dr. Sheldon currently leads the Center for Devices and Radiologic Health Payer Communication Task Force, identifying methods to streamline the path from FDA approval to coverage and reimbursement.

Ed Simcox

Ed Simcox is the Chief Technology Officer (CTO) at the U.S. Department of Health and Human Services (HHS). As CTO, Mr. Simcox provides leadership and direction to ensure that HHS effectively leverages data, technology, and innovation to improve the lives of the American people and the performance of the operating divisions across the department. Mr. Simcox has been working at the intersection of healthcare and technology for 18 years.

Prior to joining HHS, Mr. Simcox served as the Healthcare Practice Leader at Logicalis, an international IT service provider and consultancy with over 300 healthcare clients in the United States. In this role, he led the strategy, solution development, and consulting for the U.S. healthcare sector.

Prior to joining Logicalis, Mr. Simcox was director of U.S. healthcare strategy, partnerships, and product development for AT&T. Before joining AT&T, he held multiple leadership roles at Indiana University Health, a large U.S. healthcare system with 19 hospitals, 50 physician groups, and annual revenue of over $6 billion. Mr. Simcox served as the CTO at Indiana University, and prior to that, as Director of Business Innovations, an internal innovation incubator and design lab. He was awarded ComputerWorld's Laureate medal for leading a project that achieved $5 million in savings through the design and implementation of innovative IT solutions in the inpatient healthcare setting. During Mr. Simcox's time as CTO, Indiana University Health received Hospitals and Health Networks' "Most Wired Hospital" award based in part on his team's work with emerging technologies.

Seema Verma

As the Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma oversees a $1 trillion budget, representing 26% of the total federal budget, and administers health coverage programs for more than 130 million Americans. She was nominated by President Trump on November 29, 2016—the seventh nomination by the President-elect—and confirmed by the U.S. Senate on March 13, 2017.

The Administrator has set a bold agenda to empower patients and transform the healthcare system to deliver better value and results for patients through competition and innovation. CMS will focus all of its efforts on 16 strategic initiatives across Medicare, Medicaid, and the Exchanges to move the healthcare delivery system toward value.

Administrator Verma is a graduate of the University of Maryland and holds a master's degree in Public Health with a concentration in health policy and management from Johns Hopkins University. Her editorial commentaries have appeared in the *Wall Street Journal, Washington Post, Washington Times*, and *Health Affairs*, and she also previously served as Vice President of Planning for the Health & Hospital Corporation of Marion County, Indiana. Most recently before heading CMS, she was President and CEO of SVC, Inc.

James T. Parker

James T. Parker is Senior Advisor to the Secretary of Health and Human Services (HHS) for Health Reform, a role he accepted in May 2018. In this capacity, Parker works with Secretary Alex M. Azar II to guide the development and implementation of health policies that will improve America's health system.

Mr. Parker brings to this role over 30 years of executive-level experience in healthcare and healthcare policy. He spent much of his professional career with Anthem, where he held several senior executive P&L and staff leadership roles. Immediately prior to joining HHS, Mr. Parker led the turnaround of MDwise, an Indiana-based Medicaid managed care organization, and served as President of IU Health Plans, an affiliate of Indianapolis-based IU Health, a top 20 health system headquartered in Indianapolis.

Abe Sutton

Abe Sutton is currently a student at Harvard Law School. He previously focused on health policy at the White House and served as Secretary Azar's Advisor for Value-Based Reform at the U.S. Department of Health and Human Services. Mr. Sutton was a consultant with McKinsey & Company, where he worked with clients in the healthcare sector, and holds a degree in healthcare management and policy from the Wharton School at the University of Pennsylvania. He has been named to Forbes 30 under 30 for Law and Policy.

Nicholas Uehlecke

Nicholas Uehlecke is currently an Advisor in the Immediate Office of the Secretary at the Department of Health and Human Services. In this role, he works on issues including Medicare, Medicaid, general insurance issues, and healthcare reform. Prior to this work, he was on the professional staff at the House of Representatives Committee on Ways and Means for 8 years, working on issues ranging from Medicare Parts A and B, Medicare Advantage and Part D, and commercial insurance and Affordable Care Act reforms. Before his work on Capitol Hill, Mr. Uehlecke spent nearly three years as an analyst for the Marwood group, working on healthcare as well as other market-related issues. He is a graduate of the University of Richmond.

STATE-OF-THE-ART LECTURE

Nobel Laureate to Speak on Circadian Rhythms

Michael Young, PhD

A winner of the Nobel Prize in Physiology or Medicine will give a state-of-the-art lecture titled "Genes Controlling Sleep and Circadian Rhythms" at the plenary session on Friday, Nov. 8.

The speaker, Michael Young, PhD, is Richard and Jeanne Fisher Professor and head of the genetics laboratory at The Rockefeller University in New York City. He is also the university's vice president for academic affairs.

In the late 1970s, Dr. Young began to use the fruit fly, *Drosophila*, to explore the molecular bases of circadian rhythms. His laboratory used molecular and genetic screens to identify six genes involved in the formation of a biochemical oscillator with a periodicity close to 24 hours. Interactions among these genes and their proteins contribute to a network of molecular oscillations within most tissues at the level of single cells.

Most of the "clock genes" Dr. Young and his colleagues discovered in *Drosophila* are also central to the circadian pathways in vertebrates. Mutations in any of these "clock" genes can lengthen or shorten the period of behavioral, physiological, and molecular circadian rhythms, or abolish the rhythms altogether.

Recently, Dr. Young's laboratory showed that a prevalent human sleep disorder is caused by dysfunction of such a well-conserved circadian clock gene. The researchers identified a gene variant associated with the most commonly diagnosed type of circadian rhythm disorder—delayed sleep phase disorder—which is characterized by a persistent and intractable delay of sleep onset and offset times relative to the societal norm.

Dr. Young has served on many study sections and advisory panels for the National Institutes of Health and National Science Foundation. He is associate editor of the *Journal of Biological Rhythms*, was associate editor of *Neuron*, and served on the editorial board of *Molecular and Cellular Biology*.

Dr. Young's elected memberships include the National Academy of Sciences, American Philosophical Society, President's Council of the New York Academy of Sciences, American Academy of Microbiology, and Physiological Society, London (Honorary).

Along with colleagues Jeffrey Hall and Michael Rosbash, he received the 2017 Nobel Prize in Physiology or Medicine for discoveries of molecular mechanisms that control circadian rhythms. He has also received the Neuroscience Prize of the Gruber Foundation, Horwitz Prize from Columbia University, Canada Gairdner International Award, Massry Prize from the University of Southern California, Wiley Prize in Biomedical Sciences, Shaw Prize in Life Science and Medicine, and Hayaishi Prize from the University of Tokyo.

Dr. Young received a PhD in genetics from the University of Texas, Austin. His graduate work examined gene sizes and distributions in the chromosomes of *Drosophila*. After postdoctoral work on transposable elements at the Stanford University School of Medicine, he joined Rockefeller in 1978.

John Peters Award to Honor Vicente E. Torres

Vicente E. Torres, MD, PhD

ASN will recognize the wide-ranging contributions of Vicente E. Torres, MD, PhD, with the presentation of the John P. Peters Award on Friday, Nov. 8.

The John P. Peters Award is given for outstanding contributions to improving the lives of patients and to furthering the understanding of the kidney in health and disease.

Dr. Torres is director of the Mayo Translational Polycystic Kidney Disease Center at the Mayo Clinic in Rochester, Minn.

His research has focused on polycystic kidney disease (PKD) and related diseases for three decades. He has published on wide-ranging topics related to these diseases, including their epidemiology, phenotypic characterization, natural history, and clinical management. He has also worked to identify responsible genes as well as the expression and function of their encoded proteins. He has led preclinical and clinical therapeutic trials as well as translational studies aimed at improving treatment for autosomal dominant PKD.

He has been the principal investigator for the National Institutes of Health (NIH)-funded CRISP imaging study, the recently completed HALT-PKD clinical trial, and industry-funded clinical trials of vasopressin V2 receptor antagonists. His research has led to publication of 350 articles, three books or monographs, 50 book chapters, and 400 abstracts.

He has been active on NIH study sections and advisory panels in his research area and on the scientific advisory board of the PKD Foundation. He has organized many meetings on PKD, including the first Kidney Disease: Improving Global Outcomes (KDIGO) controversies conference dedicated to PKD and the 2017 Federation of American Societies for Experimental Biology science research conference on PKD.

Dr. Torres has served on the editorial boards of *Kidney, Kidney International, American Journal of Kidney Diseases, NephSAP, CJASN*, and *JASN*.

His contributions to PKD research have been recognized by the Lillian Jean Kaplan International Prize for Advancement in the Understanding of PKD and by Mayo naming him to the Robert M. and Billie J. Pirnie Professorship in Kidney Research.

Dr. Torres received medical and doctoral degrees from the University of Barcelona in Spain and moved to the Mayo Clinic in 1972 for research fellowships and residencies in internal medicine and nephrology. He joined the faculty there in 1979 and became professor of medicine in 1991. He served for five years as chair of the division of nephrology and hypertension and for eight years as director of the kidney disease research training grant program at the Mayo Clinic.

Young Investigator Recognized for Insights into Acute Kidney Injury

Samir M. Parikh, MD

The Donald W. Seldin Young Investigator Award will be presented to Samir M. Parikh, MD, who will speak on "Prospects for NAD+ Based Therapies in Acute Kidney Injury" on Friday, Nov. 8.

Dr. Parikh is associate professor of medicine and associate vice chair for research at Harvard Medical School. He is also director of the Center for Vascular Biology Research at Beth Israel Deaconess Medical Center.

His research is focused on molecular mechanisms underlying acute kidney injury and sepsis. In recent studies, the Parikh laboratory has implicated mitochondrial maintenance via PGC1α and NAD+ as a novel pathway for resilience against acute kidney injury. Ongoing studies are examining mechanistic links between acute kidney injury, chronic kidney disease, and aging and how NAD+ metabolism impacts injury in other organs.

Dr. Parikh has served as the principal investigator on research grants from the National Institutes of Health, ASN, American Heart Association, and American Diabetes Association.

He has served ASN as a member of the ASN Highlights faculty, a member of the Kidney Self-Assessment Program committee, reviewer of abstracts for Kidney Week, chair of AKI abstracts review for Kidney Week, member of the Kidney Week program committee, member of the "Securing the Future" capital campaign committee, member of the *JASN* editorial board, and associate editor for ASN's newest journal, *Kidney360*.

He served on the committee on acute kidney injury of the International Society of Nephrology and on the editorial boards of the *Public Library of Science* and *JASN*.

An elected member of the American Society of Clinical Investigation, Dr. Parikh has received the outstanding investigator award from the National Heart, Lung, and Blood Institute; the Sir William Osler Young Investigator Award from the Interurban Clinical Club; and the Carl Gottschalk Award from ASN.

He received the founder's medal for highest academic standing from Vanderbilt University School of Medicine and completed postgraduate medical training and a fellowship in nephrology at Beth Israel Deaconess Medical Center and Harvard Medical School.

CORPORATE SUPPORTERS

The ASN Corporate Support Program recognizes supporters year round for their generous contributions to the Society. Through this program, supporters help ASN lead the fight against kidney diseases. ASN gratefully acknowledges the following companies and organizations for their contributions in 2019.

DIAMOND LEVEL

AstraZeneca

Baxter

FRESENIUS MEDICAL CARE

relypsa
A Vifor Pharma Group Company

TRICIDA

PLATINUM LEVEL

ALEXION

Mallinckrodt Pharmaceuticals

Otsuka

REATA PHARMACEUTICALS

GOLD LEVEL

Akebia Therapeutics
Amgen
Janssen Pharmaceuticals, Inc.
OPKO Pharmaceuticals, LLC
Retrophin, Inc.

BRONZE LEVEL

Amicus Therapeutics
Cara Therapeutics
Daiichi Sankyo, Inc.
GSK
KDIGO
Rockwell Medical
Sanofi Genzyme

As of August 19, 2019

Administration Official to Speak on Value-Based Care

Adam Boehler

A senior official in the Trump administration will speak on "The Future of Value-Based Care and Nephrology" in the Christopher R. Blagg, MD, Lectureship in Kidney Diseases and Public Policy on Friday, Nov. 8.

The speaker, Adam Boehler, is senior advisor to the secretary of Health and Human Services (HHS), deputy administrator of the Centers for Medicare & Medicaid Services (CMS), and director of the Center for Medicare and Medicaid Innovation (CMMI).

As an advisor on value-based care, Mr. Boehler is co-leading the development of the HHS-wide kidney strategy. He cites as motivation to improve kidney patients' lives his personal experience of seeing his aunt undergo dialysis before she passed away. He has a broad assignment to identify opportunities for policy improvement throughout the department by exploring every possible avenue to advance kidney health, including research and innovation efforts, payment and care delivery models, transplantation-related activity, data integrity and availability, and other activities under HHS' purview.

In his role as CMMI director, Mr. Boehler has identified kidney care as a top priority for innovation and has worked extensively with ASN and other members of the kidney community to understand opportunities for improvement. He often speaks at healthcare conferences about the burden of kidney diseases and the need to transform patient care.

At the request of ASN, he recently met with committee staff of the U.S. House Appropriations Committee to underscore that KidneyX is a central tenet of the administration's kidney strategy, a statement of commitment he hoped would increase the likelihood of KidneyX receiving congressional funding.

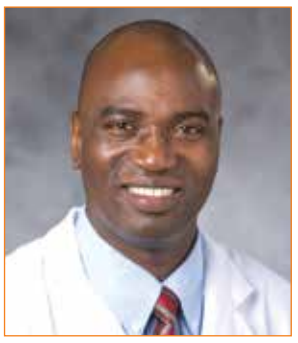
Mr. Boehler founded and was CEO of several successful large businesses and was a leader at two international investment firms. He was the founder and CEO of Landmark Health, the largest home-based medical group in the country, with more than 1000 employees in the U.S. and India and 80,000 chronic patients under management.

He was an operating partner at Francisco Partners, a $14 billion global investment firm with offices in San Francisco and London. He partnered with Francisco Partners to found Avalon, the leading provider of laboratory benefit management services.

He was a principal at Accretive, a private equity firm based in New York. Prior to joining Accretive, Mr. Boehler was executive vice president at MedeAnalytics, a leading global provider of software-as-a-service (SaaS) analytics. He started MedeAnalytics' European operation headquartered in London and led product innovation with over 200 engineers in Ukraine and Hungary. He also worked at Battery Ventures, a global technology-focused venture capital firm managing over $2 billion.

Mr. Boehler graduated magna cum laude from the Wharton School of the University of Pennsylvania.

Study Targets Identified in Genome Study Will Be Lecture Subject



Rasheed A. Gbadegesin, MD, MBBS

Rasheed A. Gbadegesin, MD, MBBS, will discuss "Genome-Wide Association Study (GWAS)–Derived Targets for Glomerular Diseases" in the Michelle P. Winn, MD, Endowed Lectureship on Friday, Nov. 8.

Dr. Gbadegesin is a professor of pediatrics in the division of nephrology at Duke University and an investigator at the Duke Molecular Physiology Institute in Durham, N.C. The lectureship's namesake, Dr. Michelle Winn, recruited Dr. Gbadegesin to Duke University and played a vital role as his main mentor until her death in 2014.

Dr. Gbadegesin's research is aimed at understanding the genetic basis, pathogenesis, and determinants of variable responses to therapy in hereditary and idiopathic nephrotic syndrome. In the past 10 years, his team has identified at least five novel genetic causes of steroid-resistant focal segmental glomerulosclerosis and other kidney diseases. Recently, using the strategy of extreme phenotyping, his group identified the first exome-wide locus for childhood onset steroid-sensitive nephrotic syndrome. In collaboration with other investigators around the world, he has since validated this locus in other populations and identified additional loci.

He has established a large biorepository of phenotype data and biosamples from children with nephrotic syndrome. He is collaborating with other investigators to determine the biologic basis for ethnic disparities in the incidence and severity of nephrotic syndrome with the goal of developing strategies for personalized treatment.

Dr. Gbadegesin has presented his research at both international and national meetings and published almost 100 peer-reviewed journal articles, five textbook chapters, and 60 abstracts. He is the principal investigator on multiple National Institutes of Health, foundation, and industry grants. He was elected into the American Society for Clinical Investigation in 2016.

He served on the ASN glomerular disease subcommittee and is a council member of the American Society of Pediatric Nephrology. He is on the editorial board of *JASN* and associate editor of *Frontiers in Pediatrics (Nephrology)*.

Dr. Gbadegesin received his MBBS degree from the University of Ibadan in Nigeria followed by a residency in pediatrics at the University College Hospital in Ibadan. He received his MD from the University of Manchester and Royal Manchester Children's Hospital in the U.K. He completed another residency in pediatrics at Brooklyn Hospital in New York City and became board certified in pediatric nephrology while at the University of Michigan in Ann Arbor.

He joined the faculty at Duke in 2007, where he also serves as co-director of the clinical and translational science awards KL2 program, program director of the pediatric research scholar program, and associate program director of the pediatric nephrology fellowship program.

Transplant Education Can Be a Key for Both Patients and Clinicians

Bertram L. Kasiske, MD

Patients face a variety of barriers to transplantation, and a specialist will talk about the challenges of "Educating Patients and Practitioners About the Benefits of Transplantation" in the Burton D. Rose, MD, Endowed Lectureship on Friday, Nov. 8.

The speaker will be Bertram L. Kasiske, MD, professor of medicine at the University of Minnesota in Minneapolis and director of the Scientific Registry of Transplant Recipients (SRTR), the federal registry of solid organ transplants in the U.S.

He is former deputy director of the U.S. Renal Data System, former co-chair of Kidney Disease: Improving Global Outcomes, and former director of nephrology at Hennepin County Medical Center in Minnesota.

Dr. Kasiske has served on many elected boards and volunteered on many committees, including serving as medical representative to the board of directors of the United Network for Organ Sharing (UNOS) and chairing the Kidney Disease Outcomes Quality Initiative working group for clinical practice guidelines for the management of dyslipidemia.

He has been a council member of the International Society of Nephrology, on the scientific advisory board of the National Kidney Foundation (NKF), a member of the Renal Physicians Association and ASN working group on guidelines on shared decision-making, on the ASN clinical sciences committee, secretary/treasurer of the American Society of Transplantation, and a member of the NKF task force on cardiovascular disease.

He is the former editor-in-chief of the *American Journal of Kidney Diseases* and the former associate editor of the *Journal of Nephrology*.

Among his research interests, he was U.S. principal investigator in the Study of Heart and Renal Protection (SHARP) and has been the principal investigator for many National Institutes of Health grants to study long-term effects of kidney donation and cardiovascular disease in kidney transplant recipients. His research has resulted in almost 350 peer-reviewed articles and more than 200 editorials, reviews, and book chapters.

Among his honors, he received the NKF Garabed Eknoyan Award and an outstanding research award from his university.

Dr. Kasiske received his medical degree from the University of Iowa. He completed his internal medicine residency and fellowship training in nephrology at Hennepin County Medical Center, an affiliate hospital of the University of Minnesota in Minneapolis. He then joined the staffs of these institutions and spent his career there.

Talk Will Focus on Exome Sequencing in Chronic Kidney Disease

Ali G. Gharavi, MD

A leading researcher in applying DNA sequencing to diagnostics will present the Robert W. Schrier, MD, Endowed Lectureship on Friday, Nov. 8. Ali G. Gharavi, MD, will speak on "Diagnostic Exome Sequencing in Chronic Kidney Disease (CKD)."

Dr. Gharavi is the Jay Meltzer Professor of Nephrology and Hypertension and chief of the division of nephrology at the Columbia University Irving Medical Center in New York City. He is also director of the Center for Medical Genetics and Genomics at Columbia University.

Dr. Gharavi's research is focused on the molecular genetics of kidney diseases. His work has led to the discovery of genes and loci for glomerulonephritis, hypertension, polycystic liver disease, and congenital defects of the kidney and urinary tract. His recent research has demonstrated the utility of sequencing in the diagnosis and management of patients with nephropathy. His ultimate goal is to bring personalized genomic nephrology from the laboratory into patient care.

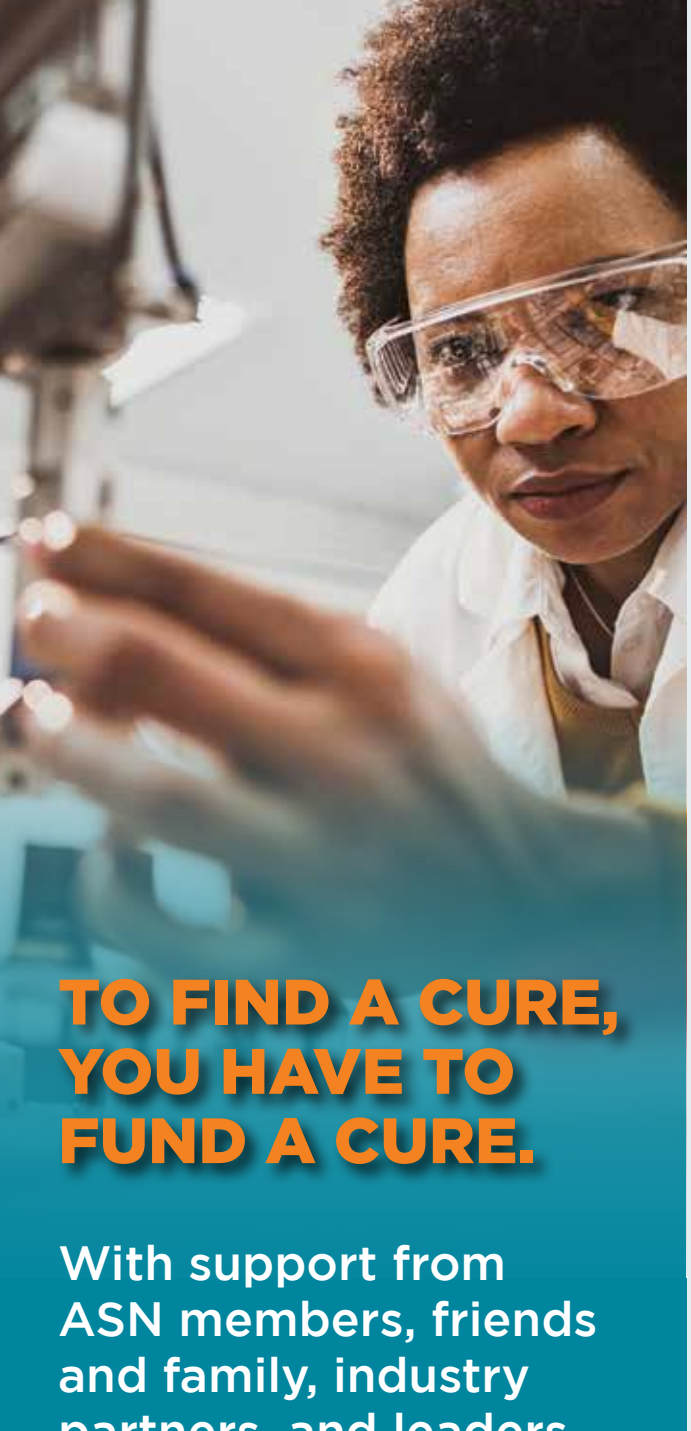
Dr. Gharavi is the principal investigator of multiple scientific projects funded by the National Institutes of Health. His research has led to the publication of 85 peer-reviewed articles, 25 reviews and editorials, and four book chapters.

He has served ASN in many capacities, including chairing abstract reviews for genetics, molecular genetics, and basic and experimental immunology; co-chairing several oral communications sessions; co-chairing a symposium on genetic tools to study renal function; co-chairing a conference on genome engineering; and serving on the program committee of an annual meeting. He served on the board of directors of the eastern chapter of the American Society of Hypertension.

Dr. Gharavi has served on the editorial boards of the *American Journal of Physiology—Renal Physiology, Kidney International,* and *JASN*. He is currently on the boards of the *Journal of Nephrology* and *Kidney International Reports*.

Among his many honors, he received the Judson Daland Prize for Outstanding Clinical Investigation from the American Philosophical Society, the National Kidney Foundation clinical scientist award, and the Kidney and Urology Foundation innovator award. He was elected to the American Society of Clinical Investigation and the American Association of Physicians.

After receiving his medical degree from George Washington University, Dr. Gharavi completed his residency in internal medicine and fellowships in hypertension and nephrology at Mount Sinai Medical Center in New York City. He then completed a postdoctoral fellowship in human genetics at Yale University School of Medicine. He joined Columbia University in 2003.



TO FIND A CURE, YOU HAVE TO FUND A CURE.

With support from ASN members, friends and family, industry partners, and leaders in the field, KidneyCure funds talented fellows and early-career researchers who are transforming the future of kidney care.

Every dollar gets us one step closer to eradicating kidney diseases.

Make a difference.

Visit CureKidneyDiseases.org

KidneyCure

The ASN Foundation CureKidneyDiseases.org

Fund it. Find it.

A special thank you to the following donors for their generous support of KidneyCure.

Founders Circle

The Founders Circle recognizes companies and nonprofit organizations that have made significant contributions in support of foundation programs.

Career Development Grants Program Donors

ASN American Society of Nephrology — $15,000,000

Akebia THERAPEUTICS — $1,000,000

Ben J. Lipps Research Fellowship Program Donors

FRESENIUS MEDICAL CARE — $10,000,000

ASN American Society of Nephrology — $6,500,000

AMERICANRENAL associates — $1,000,000

AMGEN — $1,000,000

Baxter — $1,000,000

PKD FOUNDATION Polycystic Kidney Disease — $500,000

Visionary Circle

The Visionary Circle recognizes individuals who have donated, pledged, or made a bequest of $75,000 or more to the Foundation or its programs.

Bob Alpern and Pat Preisig
William and Sandra Bennett
Jonathan and Deb Himmelfarb
Paula Messenheimer and Ray Harris
William E. Mitch and Alexandra F. Mitch

Securing the Future Campaign Donors

Donations to the Securing the Future Campaign support efforts to endow the Career Development Grants Program.

Industry

Akebia THERAPEUTICS

AMGEN

Benefactors ($50,000+)

Mark D. Okusa and Diane L. Rosin Okusa
Ambra Pozzi and Roy Zent

Patrons ($25,000+)

Sharon Anderson
Tomas Berl
Joseph V. Bonventre
Linda and Tom DuBose
William and Mary Henrich
Thomas H. Hostetter
Allison and Tod Ibrahim
Sharon and John Moe
Barbara T. Murphy
Prabir Roy-Chaudhury
Paul W. Sanders
John Sedor and Geri Presti
Wanda and Donald E. Wesson

Advocates ($10,000+)

Anupam Agarwal and Lisa M. Curtis
Deidra C. Crews
The Hakim Family Fund
Eleanor D. Lederer
Julie Lin and Frank S. David
Rajnish Mehrotra
Susan E. Quaggin
John R. and Margaret Duffey Raymond
Matthew R. Weir
Jerry Yee

Associates ($5,000+)

Peter S. Aronson
Keisha L. Gibson
Lawrence B. Holzman
Yvonne C. and J. Charles Jennette
Jeffrey H. Miner
Bruce and Karen Molitoris
Uptal Patel
Mark Rosenberg and Monica Overkamp

continuing Associates

Detlef O. Schlondorff
The Virginia and Warren Stone Fund held by Vanguard Charitable
C. Craig and Audrae Tisher

Recurring Donors

Nadja Grobe
Anil K. Karihaloo
Pascale Hammond Lane
Jennifer M. Sasser

Annual Fund Donors*

Annual fund donors have contributed to general foundation activities.

Janet and Arthur Atlas
Daniel Batlle
Jacqueline M. Benson
Susan Brain
Josephine P. Briggs
Frank C. Brosius, III
Marilyn L. Cohen
David H. Ellison
Ron Fox
Miguel Angelo Goes
Robert Hamilton
Sandra Herrmann
Kelly A. Hyndman
Edith Jones
Edgar V. Lerma
Robert G. Luke
Hal Nesbitt
Melanie Robey
Matthew A. Sparks
UConn Nephrology Department

*As of August 1, 2019

Roxadustat for Anemia: New Trials in Dialysis and Nondialysis Patients

Roxadustat, a hypoxia-inducible factor prolyl hydroxylase inhibitor, is an effective treatment for anemia both in nondialysis patients with chronic kidney disease (CKD) and in long-term dialysis patients, according to a pair of industry-sponsored trials recently published in the *New England Journal of Medicine (NEJM)*.

Nondialysis trial

The nondialysis CKD trial included 154 patients who were enrolled at 29 sites in China. All the patients with CKD had baseline hemoglobin levels of 7.0 to less than 10 g/dL. None of the patients had received erythropoiesis-stimulating agents for at least the previous 5 weeks.

The researchers note that in China, patients typically have low hemoglobin levels at the time they initiate dialysis. Only about half of patients achieve a hemoglobin level of 10.0 g/dL or higher with the use of recombinant erythropoietin therapy.

In the *NEJM* study, patients were randomly assigned to 8 weeks of treatment with roxadustat or placebo according to a 2:1 ratio. Roxadustat was started at a dose of 70 or 100 mg and adjusted to maintain a hemoglobin level between 10.0 and 12.0 g/dL. The average change in hemoglobin level from week 7 through week 9 was compared between the two groups of patients. The investigators found that during this period, hemoglobin increased by 1.9 g/dL with roxadustat, compared with a 0.4 g/dL decrease in the placebo group.

Roxadustat was also found to be associated with larger reductions in hepcidin, reflecting greater iron availability in the patients taking the drug. The mean reductions in hepcidin were 56.14 ng/mL in patients assigned to roxadustat, compared with 15.10 ng/mL in the placebo group, amounting to a between-group difference of –49.77 ng/mL. Roxadustat was also associated with a greater reduction in mean total cholesterol level between the two groups of patients, with a between-group difference of –21.2 mg/dL.

With regard to side effects, patients receiving roxadustat were more likely to experience hyperkalemia and metabolic acidosis than were patients in the placebo group. The increase in hemoglobin levels and continued maintenance of those hemoglobin levels persisted during an 18-week, open-label period in which all patients received roxadustat.

Dialysis trial

The dialysis trial included 305 long-term dialysis patients in China. The mean baseline hemoglobin for these patients was 10.4 g/dL, and all patients had been receiving erythropoietin-α for at least 6 weeks. In a 2:1 ratio, patients were randomly assigned to 26 weeks of treatment with roxadustat or with erythropoietin-α.

Roxadustat was associated with a numerically greater increase in hemoglobin: 0.5 versus 0.7 g/dL. The difference of less than 1.0 g/dL demonstrated the noninferiority of roxadustat. Patients receiving roxadustat had an increased transferrin level, continued maintenance of serum iron level, and a lesser decrease in transferrin saturation, compared with the patients not receiving roxadustat. As was the case in the nondialysis CKD trial, the roxadustat group had greater reductions in hepcidin and total cholesterol. Roxadustat was associated with higher rates of hyperkalemia and respiratory infections, and erythropoietin-α was associated with a higher rate of hypertension.

Together, the two studies show that roxadustat is superior to placebo in correcting anemia in nondialysis CKD patients and that roxadustat is noninferior to erythropoietin-α for treatment of anemia in long-term dialysis patients. The authors highlight the need for long-term safety data.

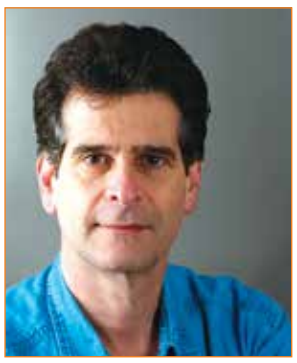
Results from a larger trial are expected soon, with MACE (Major Adverse Cardiovascular Events) data on Roxadustat for CKD-related anemia in 9000+ patients with nondialysis and dialysis CKD. ■

Chen N, et al. Roxadustat for anemia in patients with kidney disease not receiving dialysis. *N Engl J Med* 2019; doi: 10.1056/NEJMoa1813599;

Chen N, et al. Roxadustat treatment for anemia in patients undergoing long-term dialysis. *N Engl J Med* 2019; doi: 10.1056/NEJMoa1901713.

STATE-OF-THE-ART LECTURE

Prolific Inventor Dean Kamen to Co-Present State-of-the-Art Lecture



Dean Kamen

"Perspectives on Innovation and Transformation in Kidney Care" will be the topic of a plenary on Saturday, Nov. 9, that will feature famous inventor Dean Kamen.

Mr. Kamen is an inventor, entrepreneur, and tireless advocate for science and technology. Perhaps best-known for inventing the Segway, he holds more than 440 U.S. and foreign patents, many of them for innovative medical devices that have expanded the frontiers of healthcare worldwide, including the first in-home dialysis device.

While still a college undergraduate, he invented the first wearable infusion pump. In 1976, he founded his first medical device company, AutoSyringe, to manufacture the pumps, which rapidly gained acceptance from such diverse medical specialties as oncology, neonatology, and endocrinology.

Next, working with leading diabetes researchers, Mr. Kamen pioneered the design of the first portable insulin pump. It was quickly demonstrated to be a more effective way of controlling patients' blood glucose levels. At age 30, he sold AutoSyringe to Baxter Healthcare Corporation.

He then founded DEKA Research & Development Corp. to generate inventions as well as provide research and development for corporate clients. DEKA developed the HomeChoice peritoneal dialysis system for Baxter International. By allowing in-home dialysis, it quickly became the worldwide market leader.

Mr. Kamen led the development of technology to improve slide preparation for the CYTYC (now Hologic Inc.) ThinPrep Pap Test. DEKA teams also developed critical components of an extracorporeal photopheresis device T-cell lymphoma treatment marketed by a unit of Johnson & Johnson. An advanced prosthetic arm in development for DARPA could advance the quality of life for returning injured soldiers. Other notable developments include a surgical irrigation pump and an improved stent.

Mr. Kamen also founded FIRST (For Inspiration and Recognition of Science and Technology), an organization dedicated to motivating the next generation to understand and enjoy science and technology. Founded in 1989, this year FIRST will serve more than 1 million young people, ages 6 to 18, in more than 113 countries. Last year, high-school–aged participants were eligible to apply for more than $80 million in scholarships from over 200 leading colleges, universities, and corporations.

Mr. Kamen's most recent nonprofit effort is the Advanced Regenerative Manufacturing Institute (ARMI). ARMI's mission is to develop large-scale manufacturing of engineered tissues and tissue-related technologies. In 2017, ARMI launched BioFabUSA, a public-private partnership with the U.S. Department of Defense to leverage $80 million in federal funding to invest in developing these technologies.

Mr. Kamen has received many awards, including the National Medal of Technology, the Lemelson-MIT Prize, induction into the National Inventors Hall of Fame, and election to the National Academy of Engineering.

CVS Executive to Provide Perspective on Kidney Care

Bruce Culleton, MD

Bruce Culleton, MD, will be one of the co-presenters at a plenary session on "Perspectives on Innovation and Transformation in Kidney Care" on Saturday, Nov. 9.

Dr. Culleton is vice president and chief medical officer of CVS Kidney Care, a subsidiary of CVS Health. In that position, he provides medical oversight and guidance to all strategic initiatives for CVS Kidney Care.

In 2018, CVS Health announced a new initiative focused on CKD and dialysis, built on the company's focus on driving innovation in the management of chronic disease to help improve patient health outcomes while managing costs. The program focuses on early identification of kidney disease and expansion of home dialysis in order to optimize care for patients with CKD. The company plans to introduce innovative home hemodialysis technology.

"While in-center dialysis clinics are currently the most common choice for hemodialysis treatment, published clinical research has shown improved cardiac health, metabolic control, and survival for patients who are treated with longer, more frequent dialysis treatments. This treatment paradigm is best delivered in the convenience of a patient's home," Dr. Culleton said. "CVS Health is uniquely positioned to build a solution that will enable us to identify and intervene earlier with patients to optimize the management of chronic kidney disease, while at the same time making home dialysis therapies a real option for more patients."

Prior to joining CVS Health in 2017, Dr. Culleton spent more than 10 years in the medical device industry. He was vice president of global clinical development at Becton Dickinson for two years and vice president of renal global medical affairs at Baxter Healthcare from 2007 to 2016.

Before joining industry, Dr. Culleton was an academic nephrologist at the University of Calgary in Alberta, Canada, where his research interests included CKD epidemiology and home hemodialysis. During that time, he published more than 100 scientific papers related to CKD, dialysis, and clinical practice guidelines.

Dr. Culleton received his medical degree from Memorial University of Newfoundland, Canada, and completed fellowships in internal medicine and nephrology at the Royal College of Canada as well as in clinical epidemiology at Boston University. He also received an MBA from Northwestern University's Kellogg School of Business in Evanston, Ill.

Mitchell Rosner to Be Given Robert G. Narins Award for Contributions in Education

Mitchell Rosner, MD

Mitchell Rosner, MD, will receive the Robert G. Narins Award on Saturday, Nov. 9, for his many efforts in education and training the next generation of nephrologists.

Dr. Rosner is the Henry B. Mulholland Professor of Medicine in the division of nephrology and chairman of the department of medicine at the University of Virginia (UVA).

His clinical practice focuses on the care of patients with all forms of kidney disease, from acute kidney failure to ESKD. His special interest in patients with polycystic kidney disease led Dr. Rosner to found the first regional clinic to specialize in the management of these patients. He also directs the UVA home dialysis program.

His research interests include the pathogenesis and management of disorders of sodium and water balance, the treatment of polycystic kidney disease, quality improvement in peritoneal dialysis, and the development of novel therapeutics for acute kidney injury. He has participated in more than 10 clinical trials devoted to various aspects of kidney disease.

Dr. Rosner has published more than 170 research articles in peer-reviewed medical journals. He serves on the editorial boards of numerous journals and is the editor-at-large for *CJASN*.

He has received many teaching awards from UVA, including departmental awards from medicine and internal medicine, a dean's award for excellence in teaching, and an all-university award for best teacher. The American College of Physicians presented him with an award for the most influential project to stimulate the interest of medical students in internal medicine as a career.

The U.S. Department of State recognized him with a certificate of appreciation for the development of a collaborative education and research effort between UVA and San Bortolo Hospital in Vicenza, Italy. Dr. Rosner helped develop a UVA course on teaching in academic medicine and organized a yearly symposium where nephrology fellows from regional programs present their original research in a judged competition.

For ASN, he co-developed an in-service examination for nephrology fellows-in-training and served on the training program directors' executive committee, postgraduate education committee, and education committee. He co-directed the ASN Board Review Course and Update. He has co-chaired the program committee and served as co-director for Kidney Week.

He also served on the education committees of the International Society of Peritoneal Dialysis and the Association of Specialty Professors.

Dr. Rosner received his medical degree from the Medical College of Georgia and completed a residency in internal medicine and fellowship in nephrology at UVA. He served as assistant professor of medicine at Mercer University School of Medicine in Macon, Ga., then joined the UVA faculty in 2004.

Dialysis Patient to Share His Experience as a Patient

Derek L. Forfrang

"Person-Centered Dialysis Care: A Patient's Perspective" is the title of the Celeste Castillo Lee Memorial Lectureship, scheduled for Saturday, Nov. 9.

The speaker will be Derek L. Forfrang, a patient advocate who has been a type 1 diabetes patient since age 10. He was diagnosed with CKD in 1990 at age 25, and has been an end stage kidney disease patient since 1998. He has been treated using various modalities including transplantation, peritoneal dialysis, and in-center hemodialysis. He has been a second-time transplant patient since 2013. He received a pancreas transplant in 1998.

Mr. Forfrang chairs the Kidney Patient Advisory Council of the National Forum of ESRD Networks and is a member on the forum's board of directors. He chairs the Patient Advisory Committee of the Health Services Advisory Group (HSAG) ESRD Network #17 and also the Network #17 board of directors. He also chairs the National Kidney Foundation's (NKF) kidney advocacy committee and its public policy committee.

He is an active member of the Making Dialysis Safer for Patients Coalition, which works with the Centers for Disease Control and Prevention. He co-leads the fluid management innovation project of the Kidney Health Initiative and also co-leads the "My Dialysis Care Plan" project of the University of North Carolina Kidney Center.

He has spoken at many meetings and conferences, such as an NKF Symposium on payment models from a patient perspective, Centers for Medicare and Medicaid Services quality conferences, and a Renal Physicians Association annual meeting. He co-chaired the NKF Patient-Centered Outcomes Research Stakeholders' Conference. He has also participated in several technical expert panels for the Centers for Medicare and Medicaid Services.

Mr. Forfrang was the first recipient of NKF's Celeste Castillo Lee Patient Engagement Award.

STATE-OF-THE-ART LECTURE

Doctor-Patient Relationship to Be Highlighted at Plenary

Danielle Ofri, MD, PhD

The author of the bestseller *What Patients Say; What Doctors Hear* will give a talk on that subject at a plenary on Sunday, Nov. 10. The book explores how refocusing the conversations between doctors and patients can lead to improved health outcomes.

Danielle Ofri, MD, PhD, is a practicing internist at New York's Bellevue Hospital, regular contributor to the *New York Times*, and best-selling author of several books. She is one of the foremost speakers about the doctor–patient relationship and how to bring humanity back to healthcare.

In her critically acclaimed book, *What Doctors Feel: How Emotions Affect the Practice of Medicine*, Dr. Ofri explored the hidden emotional world of the doctor and its impact on patient care.

Dr. Ofri has developed a signature style that combines compelling narratives with thoughtful reflection and focused reporting. She uses stories to uncover the mysteries of human life and human nature, to explore the joys and problems of modern medical practice, and to ask questions about society's priorities.

Dr. Ofri is a clinical professor of medicine at New York University, attending physician at Bellevue Hospital, and a columnist in *The New York Times*' Well blog. Her books include *Medicine in Translation: Journeys with my Patients, Singular Intimacies: Becoming a Doctor at Bellevue,* and *Incidental Findings: Lessons from my Patients in the Art of Medicine*.

Her essays have been published in *Slate, New England Journal of Medicine*, *The Lancet*, and *Los Angeles Times*, and she has been heard on NPR. Her writings have been chosen for inclusion in *Best American Essays* twice and *Best American Science Writing 2003*.

She is also the editor-in-chief of *Bellevue Literary Review*, the first literary magazine based at a hospital. It publishes fiction, nonfiction, and poetry that explores the tensions that define our lives in illness and in health.

She was an editor of a textbook, *The Bellevue Guide to Outpatient Medicine: An Evidence-Based Guide to Primary Care*, which won a best medical textbook award from the American Medical Writers Association. She also received the McGovern Award from this association for preeminent contributions to medical communication.

Dr. Oliver Sacks praised her as "a born storyteller and a born physician." She received her MD and PhD in pharmacology from New York University.

Fujita to Receive Smith Award

Toshiro Fujita, MD, PhD

Hypertension researcher Toshiro Fujita, MD, PhD, will be presented the 2019 Homer W. Smith Award on Sunday, Nov. 10. This award recognizes outstanding contributions to understanding how kidneys function in normal and diseased states.

Dr. Fujita will speak on "Salt, Hypertension, and the Kidneys."

He is a senior fellow at the University of Tokyo's Research Center for Advanced Science and Technology and chief of the division of clinical epigenetics. He is also an emeritus professor after serving as chair of the department of nephrology and endocrinology at the university's school of medicine.

Dr. Fujita has a long track record of nephrological research in elucidating mechanisms and clinical challenges of salt-sensitive hypertension.

In 2008, his team reported a seminal discovery of the unique role of the Rho family GTPase Rac1 as a potent regulator of mineralocorticoid receptor nuclear translocation and resultant salt retention, proteinuria, and glomerulosclerosis.

Dr. Fujita had previously contributed to our knowledge of salt-sensitive hypertension when, working with Dr. Fred Bartter's laboratory at the U.S. National Institutes of Health, he reported heightened adrenergic activity as a key factor in salt sensitivity. In 2011, his team defined a lengthy and complex adrenergic pathway leading to sodium retention and resulting hypertension.

Dr. Fujita's group also found that the renin-angiotensin system in the brain plays an important role in prenatal programmed salt-sensitive hypertension.

These discoveries have been invaluable contributions to the understanding of the role of dietary salt in hypertension and kidney diseases and led to publication of more than 600 papers in peer-reviewed journals.

Dr. Fujita has made many other contributions to the profession by serving as president of the Japanese Society of Nephrology, an invited speaker at ASN, a symposium organizer for the International Society of Nephrology, and a work group member of Kidney Disease: Improving Global Outcomes. He chaired the 2018 Gordon research conference on angiotensin.

His contributions have been recognized by the Arthur Corcoran Memorial Lecture award and a hypertension research award from the American Heart Association, an honorary membership from the European Society of Hypertension, and the Franz Volhard Award from the International Society of Hypertension. He also received the medal of the purple ribbon from Japan's emperor for the promotion of science in Japan.

Dr. Fujita received his medical and doctoral degrees from Keio University School of Medicine, where he also did his internship and residency in nephrology. He then completed a fellowship at the U.S. National Institutes of Health. He joined the faculty of the University of Tokyo in 1988.

ASN to Bestow Belding Scribner Award on Paul L. Kimmel

Paul L. Kimmel, MD

The Belding H. Scribner Award will be tendered to Paul L. Kimmel, MD, on Sunday, Nov. 10, for his career-long contributions to the practice of nephrology. Dr. Kimmel is program manager of the Kidney Precision Medicine Project and director of the HIV Kidney Program at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in Bethesda, Md.

Established in 1995, the Belding H. Scribner Award is presented to individuals who have made outstanding contributions to the care of patients with kidney disorders or have substantially influenced the clinical practice of nephrology. Dr. Kimmel has made significant contributions in patient care, research, and service to professional organizations.

He has been a faculty member in the department of medicine at George Washington University in Washington, DC, since 1983. He was director of the division of renal diseases and hypertension at George Washington University Medical Center from 2001 to 2006.

Dr. Kimmel served as the director of education for ASN from 2006 to 2007 and joined the NIDDK in 2008. He currently serves as senior advisor to the director of the Division of Kidney, Urologic, and Hematologic Diseases, where he has managed programs in HIV-associated kidney disease, acute kidney injury, clinical genetics of kidney disease, kidney precision medicine, and opioid use in dialysis patients.

His research interests include sleep disorders, quality of life, and psychosocial issues (including depression, anxiety, and perception of social support) in ESKD and CKD patients. He is also interested in HIV-associated kidney diseases, long-term outcomes of acute kidney injury, perception of pain, and inflammatory and immunologic factors mediating outcomes in patients with kidney failure.

He has published more than 300 papers, edited two monographs, and edited two editions of the textbook *Chronic Renal Disease*.

Dr. Kimmel has served on the editorial boards of *Blood Purification, American Journal of Kidney Diseases, JASN*, and *CJASN*.

He was recently inducted as a fellow of the Royal College of Physicians in London and is a master of the American College of Physicians. He served as a board member and president of the Academy of Medicine of Washington, DC.

Dr. Kimmel received his medical degree from the New York University school of medicine and trained in internal medicine at Bellevue Hospital in New York City. He completed a fellowship in renal and electrolyte disorders at the University of Pennsylvania hospital and stayed there as a faculty member until joining George Washington University.

Educational Symposia SCHEDULE

KIDNEYWEEK 2019
Washington, DC • Nov. 5 – 10

Thursday, November 7 – Saturday, November 9
Marriott Marquis Washington, DC

Breakfast or lunch will be served at each symposium.
Seating is limited and available on a first-come, first-served basis to fully paid Annual Meeting participants.
Doors open approximately 15 minutes prior to each symposium.

Continuing Education Credit

This live activity is eligible for continuing education credit. Please visit *www.asn-online.org/KidneyWeek* for more information.

THURSDAY, NOVEMBER 7

12:45 – 1:45 p.m.

Acute and Chronic Hyperkalemia: An Update on Management*
*Support is provided by an educational grant from **AstraZeneca Pharmaceuticals LP**.*

Contemporary Issues in CKD-MBD*
*Support is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*

Improving Outcomes in Secondary Hyperparathyroidism
*This activity is supported by educational funding provided by **Amgen**.*

Indications and Goals of Treatment in IgA Nephropathy and Focal Segmental Glomerulosclerosis*
*Support is provided by an educational grant from **Retrophin, Inc**.*

Recognizing and Managing Atypical Hemolytic Uremic Syndrome in Complex Clinical Settings*
*Support is provided by an educational grant from **Alexion Pharmaceuticals, Inc**.*

FRIDAY, NOVEMBER 8

6:45 – 7:45 a.m.

Hepatorenal Syndrome Type 1: Pathophysiology and Management*
*Support is provided by an educational grant from **Mallinckrodt LLC**.*

Vascular Access: Breaking the Barriers to Innovation*
*Support is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*

12:45 – 1:45 p.m.

Basic Science Symposium: Organs-on-Chips: Human Kidney Microphysiological Systems
*Sponsored by the **American Society of Nephrology**.*

Autosomal Dominant Polycystic Kidney Disease: Approach to Patient Assessment and Management*
*Support is provided by an educational grant from **Otsuka America Pharmaceutical, Inc**.*

Strategies to Manage Hyperkalemia Risk due to RAAS Blockade*
*Support is provided by an educational grant from **Relypsa, Inc., A Vifor Pharma Group Company**.*

The Vitamin D Debate in CKD and SHPT: How High Should We Aim?*
*Support is provided by an educational grant from **OPKO Pharmaceuticals, LLC**.*

Continued Friday, November 8

When Bone Mineral Disease and Anemia Management Collide*
*Support is provided by an educational grant from **Akebia Therapeutics**.*

SATURDAY, NOVEMBER 9

12:45 – 1:45 p.m.

Anemia, the Hypoxia-Inducible Factor System, and CKD*
*Support is provided by an educational grant from **AstraZeneca Pharmaceuticals LP in collaboration with FibroGen**.*

Move Over and Make Room for SGLT2 Inhibitors in CKD*
*Support is provided by an educational grant from **Janssen Biotech, Inc., administered by Janssen Scientific Affairs, LLC**.*

NRF2 Pathway: Why Is It Important in Kidney Diseases?*
*Support is provided by an educational grant from **Reata Pharmaceuticals**.*

Ultrafiltration Quality Metric Debate: Too Fast or Too Slow?*
*Support is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*

ASN
American Society of Nephrology

**Session will be recorded and available online in the ASN Learning Center in January. Continuing education credits will not be awarded for this online content.*

ASN Announces Inaugural Midcareer Award Winners

ASN has instituted a new set of awards called Midcareer Awards to recognize individuals who have already made substantial and significant contributions in a variety of areas early in their professional lives.

The awards recognize two winners in each of five categories: clinical service, education, leadership, mentorship, and research. The awards will be presented on Sunday, Nov. 10.

Distinguished Clinical Service Award

Award Criteria

- Recognizes individuals who combine the art of medicine with the skills demanded by the scientific body of knowledge in service to patients.
- Exemplifies leadership and excellence in the practice of nephrology and whose time is spent primarily in the delivery of patient care.
- Has initiated or been involved in volunteer programs or has provided volunteer service post-training.

Duvuru Geetha, MD, FASN

Dr. Geetha is associate professor of medicine in the division of nephrology at Johns Hopkins University in Baltimore. She is associate director for the Johns Hopkins Vasculitis Center and does clinical and translational research in vasculitis, with a focus on ANCA-associated vasculitis and kidney disease. Dr. Geetha served as a clinical investigator in multi-center clinical trials in vasculitis, including the RAVE trial, which led to the approval of rituximab for treatment of ANCA vasculitis.

For ASN, Dr. Geetha served on the ASN Postgraduate Education Committee from 2015 to 2018. She is a member of the Nephrology Self-Assessment Program (NephSAP) review panel and a member of the ASN Kidney Health Initiative, focusing on glomerular disease. Dr. Geetha is involved through her work with the Vasculitis Foundation in increasing awareness among patients and physicians about the diagnosis and treatment of vasculitis. She has lectured at national and international vasculitis patient care symposia to educate patients about early detection of renal vasculitis and treatment options.

Dr. Geetha is a peer reviewer for several nephrology and rheumatology journals. She has served as a professional development award grant reviewer for the Vasculitis Foundation and Kidney Research U.K. as well as an abstract reviewer for the American Society of Transplantation and ASN Kidney Week.

A graduate of Madras Medical College, India, she completed postgraduate internal medicine training in the U.K. She completed her internal medicine residency in York, Penn., and her nephrology fellowship at Johns Hopkins University before joining the faculty at Hopkins in 1998.

Jay L. Koyner, MD

Dr. Koyner is associate professor of medicine in the nephrology section at the University of Chicago. He is medical director of the inpatient dialysis unit and director of the nephrology ICU.

Over the past decade, he has served in many roles for ASN, including as a member of the Acute Kidney Injury Advisory Group, co-director of the critical care nephrology Early Program, and co-editor of the Nephrology Self-Assessment Program (NephSAP) for acute kidney injury and critical care nephrology. He is currently a faculty member of ASN Highlights.

He has served on the editorial boards of *CJASN*, *American Journal of Nephrology*, and *Advances in Chronic Kidney Disease*.

Dr. Koyner's critical care nephrology research has focused on the use of plasma and urine biomarkers to improve patient risk stratification and outcomes in the setting of acute kidney injury (AKI). He has contributed to several multicenter studies investigating biomarkers of AKI, including the TRIBE-AKI study, the Furosemide Stress Test study, and several industry-sponsored investigations. He recently began developing an electronic health record–derived AKI risk score, with the goal of improving the care of patients at high risk for developing severe hospital-acquired AKI.

He has published more than 90 peer-reviewed articles and book chapters on AKI and the care of kidney injury patients in the ICU.

Dr. Koyner received his medical degree from the State University of New York at Stony Brook, where he also received a degree with distinction in research following completion of a Howard Hughes Medical Institute research fellowship. He completed his internal medicine and nephrology training at the University of Chicago.

Distinguished Educator Award

Award Criteria

- Honors individuals who have made substantial and meritorious contributions in clinical or research education as it relates to nephrology on both the local and national levels.
- Has made significant contributions to the education and training of trainees and/or junior faculty.
- Has acquired special knowledge and keeps abreast of the latest advances in clinical care or research through participation in lifelong learning.

Kambiz Kalantari, MD, MS

Dr. Kalantari is associate professor of medicine in the division of nephrology at the University of Virginia (UVA).

He began his focus on medical education in 2010. He participated in the UVA school of medicine's overhaul of its teaching curriculum, and since then has served as the course director of the renal system in the pre-clerkship curriculum.

Since 2012, he has served as the UVA nephrology fellowship director. In addition to his teaching and administrative responsibilities in undergraduate and postgraduate medical education, he contributes to training junior faculty across a range of disciplines through faculty development workshops in medical education.

Nationally, he has served as a member of the ASN In-Training Exam Test Materials Development Committee and Career Advancement Committee.

Dr. Kalantari completed his medical training at Shiraz University of Medical Sciences in Iran before traveling to the United States in 1995. He completed his internal medicine residency at Prince George's Hospital Center in Maryland and his nephrology fellowship at UVA, before joining the UVA faculty in 2002. In 2007, he received an NIH career development award in clinical research that permitted him to complete a master's degree in clinical research and also conduct human and animal research in the field of contrast ultrasonography.

Stephen M. Sozio, MD, FASN

Dr. Sozio is associate professor of medicine at Johns Hopkins School of Medicine, and serves in multiple educational roles at his institution, nationally, and internationally.

He is a medical school course director for two courses covering the preclinical. He is also one of the core faculty advisors who guides students from their first day of medical school through graduation; he has advised 68 students and serves as one of the college's faculty leaders.

He is associate director of the Hopkins nephrology fellowship program and teaches an adult learning course in the school of education. He has taught or developed educational programs in eight different countries, including Turkey, Israel, Qatar, China, Singapore, Vietnam, Thailand, and Japan.

Dr. Sozio has made many contributions to ASN in education. He was a member of the workforce committee and is currently on the Workforce and Training Committee. He co-leads the Students and Residents (STARS) program at Kidney Week, chairs the ASN Data Subcommittee, and is Principal Investigator of the ASN Nephrology Fellow Survey. He has been on the planning committee for the Nephrology Training Program Retreat.

Dr. Sozio has received several awards at Johns Hopkins for his contributions to education, including the Lisa J. Heiser Award for Junior Faculty Contribution in Education, Alumni Association Excellence in Teaching Award, and the W. Barry Wood Jr. Award for Excellence in Teaching.

He received his medical degree as well as master's degrees in epidemiology and education from Johns Hopkins University. He completed an internal medicine residency at the University of Pennsylvania and a nephrology fellowship at Johns Hopkins.

Distinguished Leader Award

Award Criteria

- Has sustained achievements in leadership and advanced ASN's mission to "lead the fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality of care for patients."
- Recognizes leadership in any number of areas of medicine, including clinical, educational, research, or administrative efforts.

Deidra C. Crews, MD, MS, FASN

Dr. Crews is associate professor of medicine in the division of nephrology and associate vice chair for diversity and inclusion at the Johns Hopkins University School of Medicine. She holds faculty appointments with the school of nursing; the Welch Center for Prevention, Epidemiology and Clinical Research; the Center on Aging and Health; and the Center for Health Equity, where she is associate director for research development.

Dr. Crews has chaired the Johns Hopkins department of medicine diversity council since 2013. In this capacity she directs efforts to enhance recruitment and retention of under-represented minority faculty and trainees and promotes civility and inclusiveness. She is the founding director of the doctoral diversity program at Johns Hopkins, a research-intensive post-baccalaureate program for students from disadvantaged backgrounds.

She chairs the ASN Diversity and Inclusion Committee and is a member of the nephrology board of the American Board of Internal Medicine.

Dr. Crews has received numerous awards for her research addressing disparities in chronic kidney disease and hypertension, including the Johns Hopkins University President's Frontier Award—a $250,000 award granted to a faculty scholar who is on the cusp of transforming their field. She has examined how the social determinants of health—including poverty and access to healthful foods—contribute to disparities in kidney disease.

She is a member of the National Academy of Medicine's Emerging Leaders in Health and Medicine and was the academy's inaugural Gilbert S. Omenn Anniversary Fellow. Dr. Crews also received the W. Lester Henry Award for Diversity and Access to Care from the American College of Physicians.

Dr. Crews received her medical degree from Saint Louis University. She completed a nephrology fellowship and a master's degree in clinical epidemiology at Johns Hopkins.

Daniel E. Weiner, MD, MS, FASN

Dr. Weiner is a nephrologist at Tufts Medical Center and associate professor of medicine at Tufts University School of Medicine.

His research interests include cardiovascular disease and cerebrovascular disease in people with kidney disease as well as dialysis epidemiology. He was a site principal investigator on the National Institutes of Health-funded systolic blood pressure intervention trial (SPRINT). He is the principal investigator with Dialysis Clinic Inc. of a trial of oral nutritional supplements in more than 11,000 in-center hemodialysis patients. He is collaborating with a team at Boston University to investigate the epidemic of CKD in Nicaragua that disproportionately affects young men of working age.

Dr. Weiner was deputy editor of the *American Journal of Kidney Diseases* and is currently editor-in-chief of both *Kidney Medicine* and the *Primer on Kidney Diseases*.

He has participated in multiple guideline-writing groups, controversies meetings, and technical expert panels. His activities with ASN include serving on the dialysis advisory group, on the public policy board, and as the inaugural chair of the Quality Committee. He is currently ASN's representative to Kidney Care Partners, and is dedicated to improving systems and policies to benefit kidney patients.

Dr. Weiner received his medical degree from Tufts. He completed a residency and chief residency in internal medicine at the University of Maryland. He returned to Tufts for a nephrology fellowship, at which time he also obtained a master's degree in clinical care research with a biostatistics concentration.

Distinguished Mentor Award

Award Criteria

- Recognizes individuals who have made contributions to the kidney community through the mentorship and development of other clinicians or researchers.
- Inspires trainees to pursue nephrology and become leaders in the transformation of healthcare through innovations in research, education, and practice.

Tamara Isakova, MD, MMSc

Dr. Isakova is associate professor of medicine in the division of nephrology and hypertension and director of the Center for Translational Metabolism and Health within the Institute for Public Health and Medicine (IPHAM) at Northwestern University's Feinberg School of Medicine.

Dr. Isakova conducts clinical research in the area of disordered mineral metabolism in chronic kidney disease. She has received research support from the American Kidney Fund, American Heart Association, Patient-Centered Outcomes Research Institute, National Institutes of Health, and ASN.

In addition to her research, she provides clinical care for patients with CKD, bone and mineral metabolism disorders, and kidney stones.

Dr. Isakova is a leader in postdoctoral training and has mentored medical students, residents, fellows, and faculty, many of whom are developing independent research programs focused on improving clinical outcomes for patients with kidney diseases.

Among her honors, she delivered the Jack W. Coburn Endowed Lectureship at ASN Kidney Week in 2017.

Dr. Isakova earned her medical degree from State University of New York Downstate College of Medicine and a master of medical science from Harvard Medical School. She completed internal medicine training at the Massachusetts General Hospital and a nephrology fellowship at the combined Massachusetts General Hospital and Brigham & Women's Hospital program.

Michal L. Melamed, MD, MHS

Dr. Melamed is associate professor of medicine and associate professor of epidemiology and population health at the Albert Einstein College of Medicine/Montefiore Medical Center.

Dr. Melamed has mentored high school students, college students, medical students, residents, fellows, and junior faculty members since joining the faculty at Albert Einstein.

She served as the director of residency research for the internal medicine program and has directed the nephrology fellowship program since 2012.

She has received many teaching and mentorship awards at Einstein-Montefiore. Her mentees have published numerous manuscripts and successfully competed for National Institutes of Health (NIH) and foundation career development and independent investigator grants.

Dr. Melamed's research interests include risk factors for progression of kidney disease, metabolic acidosis, vitamin D, and health services interventions to improve kidney disease outcomes. She has been continuously funded by NIH since 2007 and has authored more than 80 publications, many with associates she has mentored as first author. She is the principal investigator of an NIH grant aimed at training junior investigators for research in kidney disease.

She received her medical degree and completed her internal medicine and nephrology training at Johns Hopkins. During her fellowship, she obtained a master's degree in health sciences from the Johns Hopkins Bloomberg School of Public Health.

Distinguished Researcher Award

Award Criteria

- Recognizes individuals who have made substantial research contributions to the discipline of nephrology.
- Displays innovation and excellence in research to advance the science and/or practice of nephrology.

Laurence H. Beck, Jr., MD, PhD

Dr. Beck is associate professor in the department of medicine at Boston University School of Medicine and a practicing nephrologist at Boston Medical Center.

During his nephrology research fellowship in the laboratory of Dr. David Salant at Boston Medical Center, Dr. Beck investigated membranous nephropathy. The researchers identified the target antigen in adult primary membranous nephropathy as the M-type phospholipase A2 receptor (PLA2R1), as they reported in the *New England Journal* of Medicine in 2009. This report stimulated a new wave of investigations into the pathogenesis of membranous nephropathy as well as the clinical use of anti-PLA2R1 autoantibodies for the diagnosis and monitoring of disease.

In a second *New England Journal of Medicine* report, and in collaboration with the Stahl laboratory in Germany and the Lambeau laboratory in France, Dr. Beck's laboratory described the identification of the second autoantigen in primary membranous nephropathy: thrombospondin type-1 domain-containing 7A (THSD7A).

Dr. Beck continues to collaborate with several research teams nationally and internationally, focusing on the humoral responses to PLA2R1, THSD7A, and other antigens in autoimmune kidney diseases.

He is a reviewer for *CJASN; American Journal of Kidney Diseases; Nephrology, Dialysis, and Transplantation; New England Journal of Medicine; American Journal of Nephrology;* and *International Journal of Nephrology*.

Dr. Beck graduated from Harvard Medical School with a dual medical degree and doctorate in cell and developmental biology. He completed his internal medicine residency and nephrology fellowship at Boston Medical Center.

David Cherney, MD, PhD

Dr. Cherney is associate professor in the department of medicine at the University of Toronto. He is also a clinician scientist and director of the renal physiology laboratory at the University Health Network and Mount Sinai Hospitals.

Dr. Cherney's research focuses on the physiological factors that initiate kidney disease in patients with diabetes, such as renal hyperfiltration and inflammation. His research is closely aligned with his integrated and multidisciplinary cardiac-renal-endocrine clinic at the University Health Network, which maintains a strong emphasis on the prevention of diabetic nephropathy and related cardiovascular disease. He has published more than 150 peer-reviewed manuscripts.

He receives operating funding from the Canadian Institutes of Health Research, Juvenile Diabetes Research Foundation, Heart and Stroke Richard Lewar Centre of Excellence, Heart and Stroke Foundation of Canada, and Banting and Best Diabetes Center. He serves on the editorial boards of *CJASN* and *Cardiorenal Medicine*.

Dr. Cherney studied medicine at McGill University. He completed his clinical training in nephrology and his doctorate in human renal physiology at the Institute of Medical Science at the University of Toronto.

2019 Scientific Exposition

Thurs. Nov. 7 – Sat. Nov. 9

KIDNEY WEEK 2019

Exhibits and Posters

Halls A-B | 9:30 a.m. – 2:30 p.m. daily

Highlights Include

- Over 160 Exhibiting Companies
- ASN Communities Lounge
- Career Fair
- Complimentary Refreshment Breaks
- Exhibitor Spotlights
- FIT Bowl
- Poster Sessions
- Welcome Reception
- Wi-Fi

Welcome Reception

Thursday, November 7 • 6:30 – 7:30 p.m.

ASN welcomes you to Washington, DC with a reception in the exhibit hall the evening of Thursday, November 7.

Supported by ASN American Society of Nephrology

Communities Lounge Aisles 1800 and 1900

A focal point of your exhibit hall experience, visit the lounge to learn more about ASN Communities online forum, meet the leaders, network with your peers, and unwind at the relaxation zone.

ASN FIT BOWL 2019

Support provided by AstraZeneca

Which nephrology training team will reign supreme?

Stop by and watch teams test their knowledge against their peers. The Fellows-In-Training (FIT) Bowl is a two-day, single elimination tournament held in Hall A of the Exhibit Hall. Seating is limited.

Thursday, November 7	10:30 a.m. – 12:30 p.m. *Elimination Rounds*
Friday, November 8	10:30 a.m. – 11:30 a.m. *Semi-Finals*
	11:30 a.m. – 12:30 p.m. *Finals*

Exhibitor Spotlight Schedule

Join your colleagues for the latest advances in nephrology practices, products, services, and technologies presented in two theaters on the exhibit hall floor (no continuing education credit). Seating is limited and available on a first come, first served basis. **All presentations include breakfast or lunch.**

Thursday, November 7	Friday, November 8	Saturday, November 9
10:00 a.m. – 11:00 a.m. Theater 1	**10:00 a.m. – 11:00 a.m. Theater 1**	**10:00 a.m. – 11:00 a.m. Theater 1**
CREDENCE Landmark Trial: Canagliflozin and Renal Endpoints in Diabetes with Established Nephropathy Clinical Evaluation Clinical Trial *Presented by* Janssen Pharmaceutical Companies of Johnson & Johnson	Advances in Hemodialysis-Associated Anemia Management: The Benefits of Physiologic Iron Replacement Therapy *Presented by* ROCKWELL MEDICAL	Expanded Hemodialysis: When Innovation Meets the Need *Presented by* Baxter
11:00 a.m. – 12:00 p.m. Theater 2	**11:00 a.m. – 12:00 p.m. Theater 2**	**11:00 a.m. – 12:00 p.m. Theater 2**
ADPKD: Shattering the Mystery of Stability Looking Beyond eGFR to Assess Disease Progression *Presented by* Otsuka	New Data for the Role of the Melanocortin Pathway in Nephrotic Syndrome *Presented by* Mallinckrodt Pharmaceuticals	Evolving Treatment Considerations for Patients with atypical-HUS *Presented by* ALEXION
12:00 p.m. – 1:00 p.m. Theater 1	**12:00 p.m. – 1:00 p.m. Theater 1**	**12:00 p.m. – 1:00 p.m. Theater 1**
Exhibitor Spotlight *Presented by* AMGEN	Launching the ULTIMA-CKD Patient Registry - Understanding the Long-Term Impact of Metabolic Acidosis in CKD *Presented by* TRICIDA	Iron Deficiency Anemia (IDA) in Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD) *Presented by* Daiichi-Sankyo
1:00 p.m. – 2:00 p.m. Theater 2	**1:00 p.m. – 2:00 p.m. Theater 2**	**1:00 p.m. – 2:00 p.m. Theater 2**
Unexplained Renal Complications: A Case for Fabry Disease *Presented by* SANOFI GENZYME	Made to Measure? Critical Assessment of Anemia and Patient Reported Outcomes in CKD *Presented by* gsk	Potassium Rising – Addressing a Recurring Threat in Patients *Presented by* relypsa A Vifor Pharma Group Company

The following op-ed was published on September 13, 2019, in The Hill, *which is distributed to all congressional offices.*

The 'Advancing American Kidney Health' Initiative Lives Up to Its Name

By Kevin Longino and Tod Ibrahim, Opinion Contributors

Let's start with a simple, sobering fact: an estimated 37 million Americans live with the burden of kidney disease. Worse, 90 percent of those affected by kidney disease don't even know they have it. Approximately 700,000 Americans have kidney failure and require dialysis or a transplant to survive.

Each patient navigating the difficult path of kidney disease or kidney failure has a name and, behind every name, a story. For us at the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN), these are our friends, our family members, our colleagues, our patients and, in some cases, ourselves.

We know that more attention and resources must be devoted to this underreported public health crisis. Nephrologists and grassroots advocates across the country are dedicated to creating a brighter future for those with kidney disease and kidney failure. For years, we have urged Washington to do its part by fundamentally reimagining kidney care to better align incentives for earlier clinical interventions that delay the progression of, or even prevent, kidney disease and failure.

This July, President Donald Trump and his administration issued an executive order to launch "Advancing American Kidney Health." It represents a bold, comprehensive, and long overdue overhaul of the way we treat kidney disease.

The executive order signifies a rejection of the status quo under which hundreds of thousands of our most vulnerable Americans are shuttled back and forth to dialysis centers to receive treatment. Instead, it strives to double the number of kidneys available for transplant while also accelerating the race toward creation of the first artificial kidney and boosting the use of home dialysis when a preemptive transplant is not possible. This is the kind of aspirational change our patients deserve.

To accomplish this vision, Advancing American Kidney Health launches a set of five payment models that will spur improved management of kidney disease with an eye toward incentivizing the prevention of kidney failure, increasing the uptake of kidney transplants and, when this is not doable, encouraging the use of home dialysis—where patients often enjoy better quality of life—as opposed to in-center treatment. NKF and ASN vigorously support this goal, which is based in part on our organizations' years of collective efforts, and we are

committed to working together with the administration to perfect the finer points of this directive.

For example, our organizations are making recommendations for improvement to the administration's proposed mandatory payment model—the ESRD Treatment Choice model—such as ensuring patients are empowered in evaluating the range of treatment options and providing enough capital for fundamental practice transformation. We appreciate the administration's ongoing engagement as we seek to ensure that the incentives in this proposal make good on our shared aim of increasing patient choice and transforming kidney care.

HHS Secretary Alex Azar and his team are doing yeoman's work to bring relief to the millions afflicted by kidney disease and kidney failure nationwide, but they need willing partners in Washington. Congress should complement the administration's efforts by appropriating robust increases in kidney disease research funding at the National Institutes of Health, investing in innovation through KidneyX—a public-private partnership dedicated to advancing new and cutting-edge solutions to kidney disease, removing barriers for living kidney donors by passing the "Living Donor Protection Act," and extending coverage for immunosuppressant drugs for patients who received a transplant through the Medicare End-Stage Renal Disease (ESRD) program. With lawmakers having just reconvened from the annual August recess, the stage is set for them to do exactly that.

We recognize that, in these times, new investments in public health are a tall order. But consider that Medicare spent a staggering $114 billion trying to manage kidney disease and failure in 2016 alone. The price of inaction is far more expensive—both in terms of taxpayer dollars and, more important, precious human lives—than the cost associated with making smart increases in kidney care funding today. For example, a government report released this summer shows that extending Medicare coverage of lifesaving medications for kidney transplant recipients could save taxpayers $165 million a year.

Washington must send a clear signal to the investment community that, at long last, it is serious about innovating kidney care and is committed to partnering with disruptors in the field to bring new products to market and expedite federal review of the latest treatment options.

According to the Organ Procurement and Transplantation Network, more than 3,900 Americans died while languishing on kidney transplant waitlists in 2018 alone. This is not a time to stay idle. Fighting kidney disease and ending kidney failure deserves an all-hands-on-deck effort: from the highest levels of power in Washington to doctors, care partners, and advocates in all 50 states.

The Advancing American Kidney Health initiative has started us down the right track and—on behalf of the 37 million Americans we are privileged to serve and champion—we will ensure these efforts reach the finish line.

Kevin Longino is the CEO of the National Kidney Foundation and a kidney transplant recipient. Tod Ibrahim is the Executive Vice President of the American Society of Nephrology.

Which Oral Anticoagulant Is Best in CKD?

For patients with early CKD, non–vitamin K oral anticoagulants (NOACs) have a better risk-to-benefit profile than vitamin K antagonists (VKAs), concludes a meta-analysis in *Annals of Internal Medicine*.

In a systematic review of the literature, the researchers identified 45 randomized controlled trials that evaluated the two types of oral anticoagulants for any indication and included data on efficacy or bleeding outcomes. The studies included a total of 34,082 patients with early-stage or advanced CKD or with ESKD.

The most frequent indications were atrial fibrillation (AF) and venous thromboembolism (VTE), 11 trials each. Other indications included cardiovascular disease other than AF, 9 trials; prevention of thrombosis in dialysis access, 8 trials; and thromboprophylaxis, 6 trials. Except for 8 trials enrolling ESKD patients, the studies excluded patients with creatinine clearance less than 20 mL/min or estimated GFR less than 15 mL/min per 1.73 m^2. Most of the data came from subgroups of large trials; there was sparse evidence about patients with advanced CKD or ESKD.

On meta-analysis, NOACs were associated with a reduced risk of stroke or systemic embolism in patients with AF, compared with VKAs: risk ratio (RR) 0.79, based on high-quality evidence. Non–vitamin K oral anticoagulants were also associated with a lower risk of hemorrhagic stroke: RR 0.48, based on moderate-quality evidence.

There was no clear difference between the two types of oral anticoagulants for prevention of recurrent VTE or VTE-related mortality. Across all trials, major bleeding risk appeared lower with NOACs: RR 0.75, based on low-quality evidence.

CKD is a prothrombotic state, associated with several indications for oral anticoagulants. However, there are limited data to guide clinical decisions regarding anticoagulant therapy in CKD.

Available evidence suggests that NOACs are preferable to VKAs for patients with early CKD. The review finds scant evidence to determine the benefits or harms of these oral anticoagulants for patients with advanced CKD or ESKD. The authors emphasize the need for further adequately powered randomized trials [Ha JT, et al. Benefits and harms of oral anticoagulant therapy in chronic kidney disease: A systematic review and meta-analysis. *Ann Intern Med* 2019; 171:181–189].

Veverimer Is Effective for Metabolic Acidosis in CKD

The selective hydrochloric acid binder veverimer is a safe and efficacious treatment for metabolic acidosis in patients with CKD, according to a randomized trial report in the *Lancet*.

The study was a 40-week extension of a previous international industry-sponsored trial comparing veverimer with placebo for patients with CKD (estimated GFR 20–40 mL/min per 1.73 m^2) and metabolic acidosis (serum bicarbonate 10–20 mmol/L). In that study (*Lancet* 2019; 393:1417–1427), 59% of patients in the veverimer group met a composite primary endpoint of increased sodium bicarbonate, compared with 22% of the placebo group.

In the extension phase, 196 patients who completed the parent trial continued to receive their assigned blinded treatment for 40 weeks. Safety was the primary outcome; secondary outcomes addressed the long-term effects of veverimer on serum bicarbonate level and physical functioning.

During the extension, the premature treatment discontinuation rate was 3% in the veverimer group, in no case because of an adverse event, compared with 10% in the placebo group. The rates of serious adverse events were 2% and 5%, respectively. Veverimer was also associated with a lower

rate of renal system adverse events: 8% versus 15%.

At 52 weeks, sodium bicarbonate had normalized or increased by at least 4 mmol/L in 63% of patients assigned to veverimer, compared with 38% of the placebo group. At all times, bicarbonate concentrations were higher in the veverimer group. Veverimer was also associated with a relative 12-point improvement in the Kidney Disease and Quality of Life–Physical Function Domain and also with a 3-second difference in mean time to perform the repeat chair stand test.

Metabolic acidosis is a common and serious complication of CKD, for which there are limited approved therapies. Veverimer is an oral nonabsorbed polymer that selectively binds and eliminates hydrochloric acid from the gastrointestinal tract.

This extension study, including an analysis of 52-week outcomes, supports the safety and efficacy of veverimer in correcting metabolic acidosis in patients with CKD. In addition to lasting increases in sodium bicarbonate, this treatment produces lasting improvements in measures of physical functioning. Further studies are needed to evaluate the effects of veverimer on CKD progression and mortality [Wesson DE, et al. Long-term safety and efficacy of veverimer in patients with metabolic acidosis in chronic kidney disease: A multicentre, randomised, blinded, placebo-controlled, 40-week extension. *Lancet* 2019; 394:396–406]. ■

"Deep Learning" Approach Allows Early Prediction of AKI

An approach using artificial intelligence enables continuous prediction of acute kidney injury (AKI) in hospitalized patients, according to a research letter in *Nature*.

The authors developed a deep learning approach for continuous risk prediction of future AKI, based on individual electronic health records. The model was developed by use of retrospective data on more than 700,000 adult patients from the US Department of Veterans Affairs, including 172 inpatient and 1062 outpatient sites. The researchers write, "At every point throughout an admission, the model provides updated estimates of future AKI risk along with an associated degree of uncertainty." The model can output the probability of AKI of any severity within 48 hours, with the possibility of other time windows or severities.

Within the Veterans Affairs dataset, AKI as defined by Kidney Disease: Improving Global Outcomes occurred in 13.4% of hospitalizations. The model correctly predicted 55.8% of AKI episodes. Sensitivity was highest in patients who experienced lasting complications of AKI: the model correctly predicted 84.2% of episodes requiring dialysis in the hospital or within 30 days, and 90.2% of those requiring regular outpatient dialysis within 90 days. For every true alert, there were two false alerts. The model also listed the most relevant clinical features for each prediction, along with predicted future trajectories for important laboratory test results.

Building on work on modeling adverse events from electronic health records, the new study suggests that a machine learning approach can enable prediction of AKI risk within a clinically actionable window. The researchers write, "[O]ur approach may allow for the delivery of potentially preventative treatment—before the physiological insult itself, in a large number of cases" [Tomašev N, et al. A clinically applicable approach to continuous prediction of future acute kidney injury. *Nature* 2019; 572:116–119]. ■

Extreme Heat Linked to Increased Risks in Patients with Kidney Failure

Extreme heat events (EHE) are associated with increases in hospital admission and death for patients with kidney failure, reports a study in *JAMA Network Open*.

The study included data on 7445 patients with kidney failure treated at dialysis facilities in the Boston, New York City, and Philadelphia areas from 2001 through 2012. Meteorologic records were used to identify EHEs, based on 95th percentile maximum temperature thresholds specific to each calendar day and location. The researchers examined the associations of EHEs with daily all-cause hospital admissions and all-cause mortality.

The analysis included data on 2953 deaths and 44,941 hospital admissions. The annual mean number of EHEs was 37.4 days in Boston, 14.2 days in New York, and 11.9 days in Philadelphia.

EHEs were associated with increased rates of both outcomes of interest: rate ratio (RR) 1.27 for same-day hospital admission and 1.31 for same-day mortality. Cumulative exposure to EHEs was associated with increased risks in Boston—RR 1.15 for hospital admission and 1.45 for mortality—but not in Philadelphia.

The associations were similar for black patients and white patients, although the impact of Hispanic or Asian race/ethnicity was less clear. Cumulative lag exposure to EHEs was associated with increased mortality for kidney failure patients with comorbid congestive heart failure, RR 1.55; chronic obstructive pulmonary disease, RR 1.60; or diabetes, RR 1.83.

Extreme heat events are becoming more frequent owing to the effects of ongoing climate change. It is unclear how EHEs may affect the health of vulnerable populations, such as those with kidney failure.

This analysis of dialysis patients in cities of the northeast United States suggests that EHEs are associated with increased rates of hospital admission and death among patients with kidney failure. The investigators conclude, "[F]uture ESKD management guidelines need to incorporate EHEs as part of the adaptation measures to minimize morbidity and mortality among patients with kidney failure in a changing climate" [Remigio RV, et al. Association of extreme heat events with hospital admission or mortality among patients with end-stage renal disease. *JAMA Netw Open* 2019; 2:e198904]. ■

Infection Outbreak at Dialysis Centers Linked to Wall Boxes

Wall boxes were found to be the source of contamination for an outbreak of gram-negative bloodstream infections (BSIs) at three dialysis facilities, according to a report in *American Journal of Kidney Diseases*.

In August 2016, the Centers for Disease Control and Prevention (CDC) identified a cluster of five BSIs with *Serratia marcescens* among patients at an outpatient hemodialysis center. The outbreak was identified by means of routine surveillance data reported to the National Healthcare Safety Network.

Further analysis identified BSIs caused by *S. marcescens* or similar gram-negative bacteria at two additional dialysis facilities owned by the same company. In October to November 2016, an on-site investigation including CDC participation was performed to assess the scale of the outbreak and to identify the source of the infection.

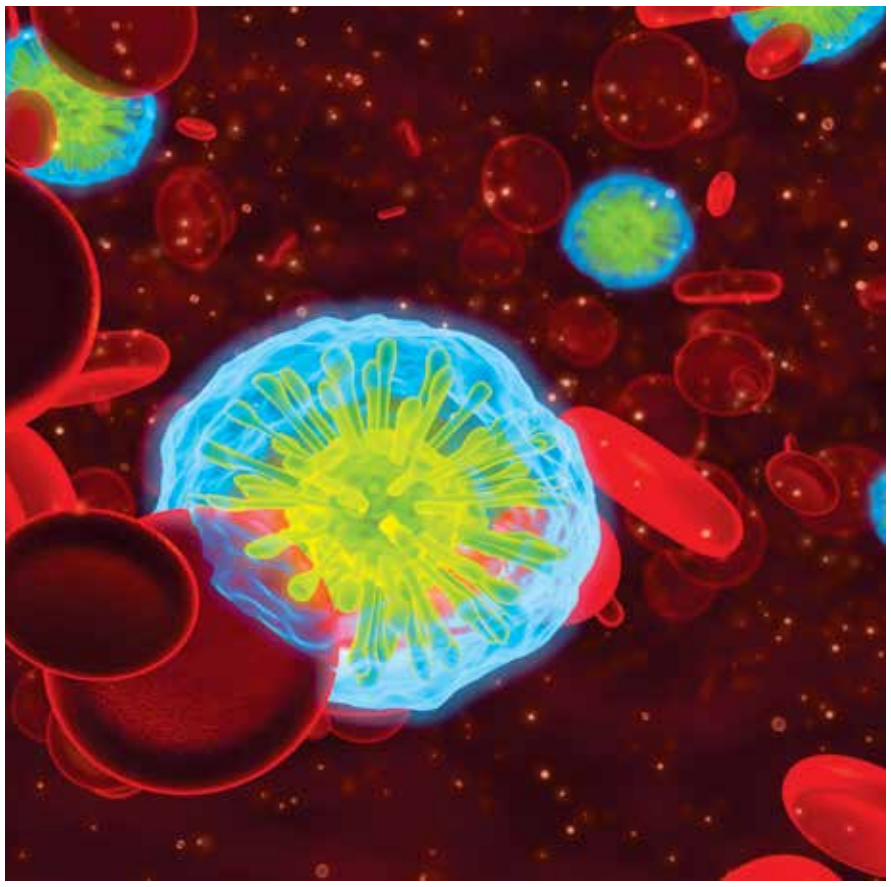
Over a 17-month period, 58 patients who had undergone dialysis at one of the three facilities experienced gram-negative BSIs, defined as a positive blood culture for any gram-negative organism. The causative organism was *S. marcescens* in 36% of the infections, *Pseudomonas aeruginosa* in 21%, and *Enterobacter cloacae* in 19%. All these organisms are commonly found in water-related biofilms. Multiple gram-negative organisms were isolated in 28% of BSI cases. Eighty-three precent of patients were hospitalized, with a median 8-day length of stay.

Most patients with BSIs had a central venous catheter for dialysis access: matched odds ratio (mOR) 54.32. Other session-specific risk factors included dialysis performed after the first treatment shift, mOR 2.83; and involvement of more than three staff members in the patient's care, mOR 3.75. Longer dialysis vintage was associated with a lower risk of infection, mOR 0.19.

The investigation identified problems with infection control practices at all three facilities, including deficient aseptic technique during central venous catheter care, missed opportunities for hand hygiene, and lapses in machine and station cleaning and disinfection practices. Inspection revealed problems with wall boxes at the dialysis facilities, including foaming and fluid regurgitation in wall box basins.

Gram-negative bacteria were found in environmental samples including tap water, sinks, and surfaces. All wall box samples showed at least one of the three most commonly isolated organisms. Pulsed-field gel electrophoresis of 18 patient isolates identified two clusters of *S. marcescens* at one facility and one cluster of *P. aeruginosa* at another. Control measures included a wall box drain care protocol and staff education on the importance of hand hygiene after touching wall boxes.

With wall boxes reported as the source of contaminated fluids and biofilms responsible for a large outbreak of gram-negative BSIs at related dialysis facilities, inadequate hand hygiene appears to have been the major mechanism by which pathogens spread from the wall boxes to patients. The investigators conclude: "Infections with gram-negative organisms commonly found in water-related biofilms should prompt investigation into water and sources of waste fluid serving as potential reservoirs in the health care environment" [Novosad SA, et al. Multicenter outbreak of gram-negative bloodstream infections in hemodialysis patients. *Am J Kidney Dis* 2019; doi: 10.1053/j.ajkd.2019.05.012].



SGLT-2 Inhibitors Don't Increase Risk of Severe UTI

Sodium–glucose cotransporter-2 (SGLT-2) inhibitors are not associated with an increased risk of severe urinary tract infection (UTI) in routine clinical practice, concludes a study in *Annals of Internal Medicine*.

Using two large commercial claims databases based in the United States, the researchers created propensity-matched cohorts of adults with type 2 diabetes who were initiating treatment with SGLT-2 inhibitors versus other antidiabetic drugs. Cohort 1 included matched groups of 61,876 patients starting SGLT-2 inhibitors versus dipeptidyl peptidase-4 inhibitors. Cohort 2 included groups of 55,989 patients starting SGLT-2 inhibitors versus glucagon-like peptide-1 receptor agonists. Severe UTIs were defined as hospitalization for primary UTI, sepsis with UTI, or pyelonephritis. Outpatient UTI treated with antibiotics was evaluated as a secondary outcome.

In cohort 1, the incidence rate of severe UTIs (per 1000 person-years) was 1.77 in patients starting SGLT-2 inhibitors and 1.76 in those starting dipeptidyl peptidase-4 inhibitors. In cohort 2, the incidence rates were 2.15 with SGLT-2 inhibitors and 2.96 with glucagon-like peptide-1 receptor agonists.

There were no significant differences in sensitivity analyses including subgroups defined by age, sex, or frailty, or for canagliflozin versus dapagliflozin. There was also no increase in the risk of outpatient UTIs for patients starting SGLT-2 inhibitors.

Because SGLT-2 inhibitors increase glucose availability in the urinary tract, there is concern that they might increase the risk of genitourinary tract infections. Despite a U.S. Food and Drug Administration label warning, there is limited evidence on the association between these drugs and the risk of severe UTIs.

This large population-based study finds no increase in severe UTI events in patients with type 2 diabetes starting SGLT-2 inhibitor therapy, compared with other antidiabetic drugs. The researchers conclude, "[O]ther factors beyond risk for UTI events should be considered in decisions about whether to prescribe SGLT-2 therapy for patients with diabetes in routine care settings" [Dave CV, et al. Sodium–glucose cotransporter-2 inhibitors and the risk for severe urinary tract infections: A population-based cohort study. *Ann Intern Med* 2019; doi: 10.7326/M18-3136].

Empagliflozin May Reduce CKD Progression in Type 2 Diabetes

The sodium–glucose cotransporter-2 inhibitor empagliflozin may help prevent progression of chronic kidney disease (CKD) in patients with type 2 diabetes, independently of background medications that alter intrarenal hemodynamics, reports a study in *Kidney International*.

The post hoc exploratory analysis used data from the industry-sponsored BI 10773 (Empagliflozin) Cardiovascular Outcome Event Trial in Type 2 Diabetes Mellitus Patients (EMPA-REG OUTCOME) trial.

In that earlier study, 7020 patients with type 2 diabetes and established cardiovascular disease were randomly assigned to empagliflozin 10 mg or 25 mg or placebo, added to standard care. On primary analysis, empagliflozin reduced major cardiovascular events, cardiovascular mortality, and hospitalization for heart failure.

The current study evaluated the effects of empagliflozin on the risk of incident or worsening nephropathy. The analysis included the impact of four classes of background medications known to affect intrarenal hemodynamics: angiotensin-converting enzyme inhibitors/angiotensin receptor blockers (ACEis/ARBs), calcium channel blockers, diuretics, and nonsteroidal anti-inflammatory drugs (NSAIDs). All patients in the study had a baseline estimated GFR of 30 mL/min per 1.73 m^2 or higher.

Patients taking any of the classes of background medications tended to have higher rates of incident or worsening nephropathy. However, in all four subgroups of patients taking background medications known to affect intrarenal hemodynamics, the incidence of kidney events was lower with empagliflozin than with placebo. The protective effect of empagliflozin was consistent with that in the overall trial population, with no clinically relevant heterogeneity.

The use of empagliflozin in combination with other drugs did not increase the risk of serious adverse events or events leading to discontinuation.

The results suggest that the benefits of empagliflozin for patients with type 2 diabetes and established cardiovascular disease are consistent for patient subgroups taking widely used medications that affect intrarenal hemodynamics. The researchers conclude, "[O]ur data suggest that the proposed kidney mechanisms of empagliflozin (i.e., lowering of glomerular pressure) are preserved in patients already taking ACEis/ARBs, diuretics, calcium channel blockers, or NSAIDs."

Mayer GJ, et al. Analysis from the EMPA-REG OUTCOME® trial indicates empagliflozin may assist in preventing the progression of chronic kidney disease in patients with type 2 diabetes irrespective of medications that alter intrarenal hemodynamics. *Kidney Int* 2019; 96:489–504.]

KIDNEY WEEK 2019

Washington, DC | Nov. 5–10

2019 ASN Career Fair

Meet face-to-face with top employers looking to hire!

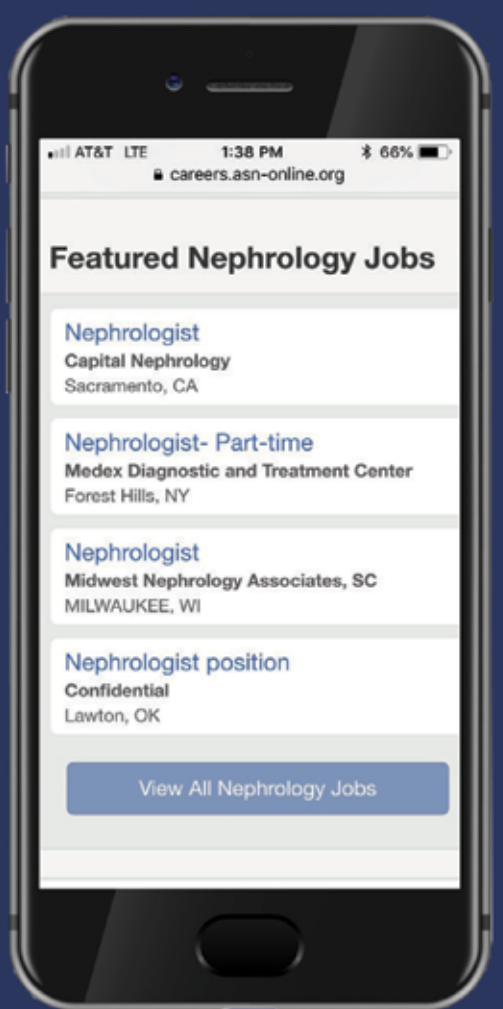
November 7–9, 2019
9:30 a.m. - 2:30 p.m.

Located in the Exhibit Hall

ASN invites you to take part in the 2019 ASN Career Fair Fair. Connect with employers and find your next nephrology opportunity. It's FREE to attend!

Be on the lookout for the ASN Featured Employers Guide which will include open positions from top employers. It will be sent directly to your email after Kidney Week.

Take charge of your career! Upload or update your resume on the ASN Career Center.

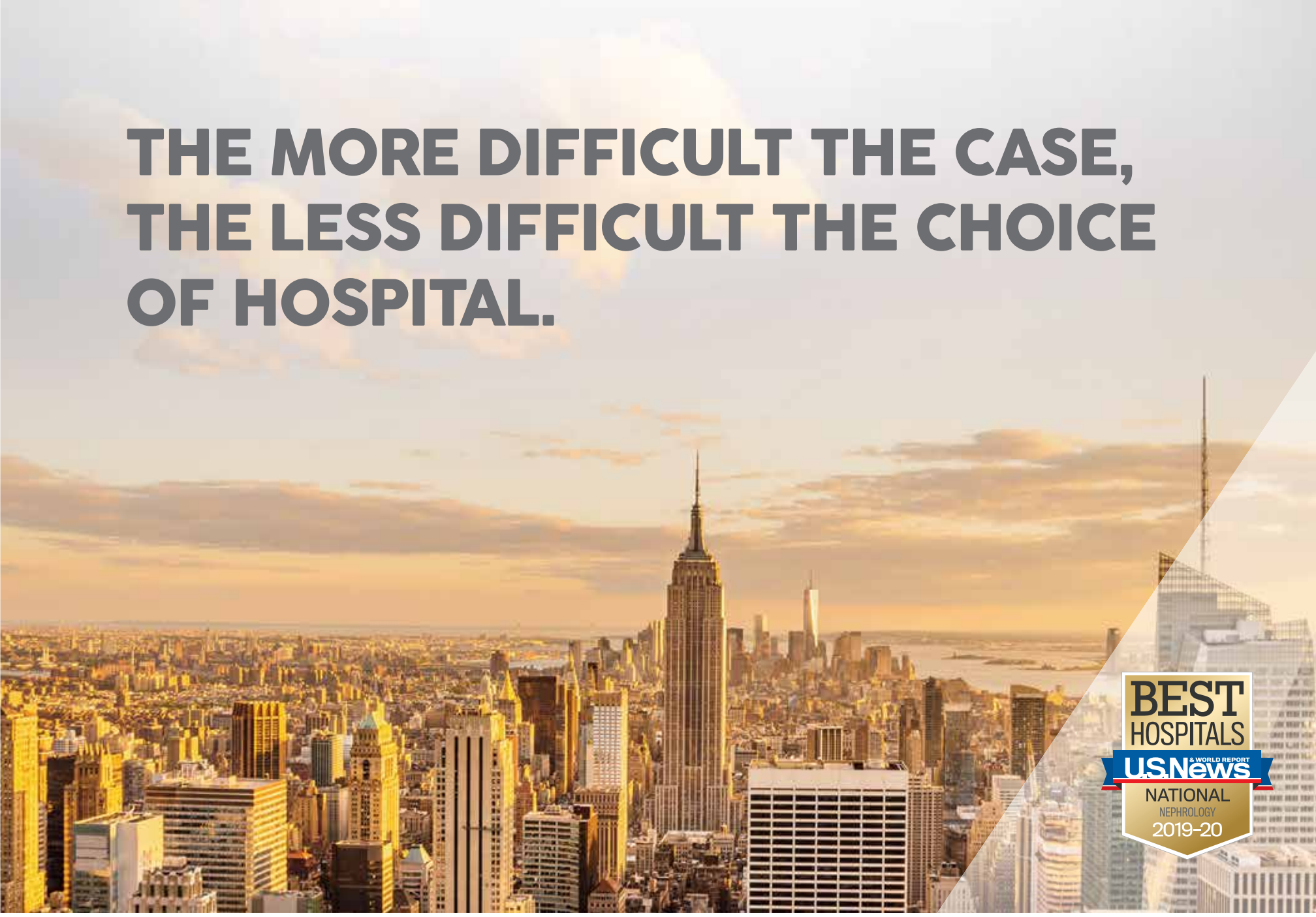


- Get your resume in front of employers hiring nephrology professionals who search the database.
- Search jobs that are posted right from your smartphone or tablet.
- Be the first to get job alerts when a job that meets your criteria is posted.
- Gain resume writing tips and how to prepare for an interview.

Visit **careers.asn-online.org** to get started!

ASN
American Society of Nephrology

THE MORE DIFFICULT THE CASE, THE LESS DIFFICULT THE CHOICE OF HOSPITAL.



Ranked No. 11 in the nation by *U.S. News & World Report, 2019-2020,* our physicians and scientists at The Mount Sinai Hospital's Division of Nephrology are internationally recognized as authorities on the causes and treatments of all forms of adult and pediatric kidney diseases. Our kidney transplant specialists are investigating new ways to detect, prevent, and treat rejection that will have a lasting impact on the field. We also provide outstanding nephrology services at Mount Sinai St. Luke's, Mount Sinai West, and Mount Sinai Beth Israel. Our physicians are all on the faculty at the Icahn School of Medicine at Mount Sinai, which is ranked among the nation's top medical schools by *U.S. News & World Report.*

- Division of Nephrology
- Division of Pediatric Nephrology
- The Recanati/Miller Transplantation Institute
- Hypertension Program
- Geriatric/Palliative Care Nephrology Program
- Glomerular Disease Program
- Mount Sinai Home Dialysis Program
- Mount Sinai Kidney Center (Dialysis)
- Mount Sinai Kidney Stone Center

Mount Sinai
New York

1-800-MD-SINAI

icahn.mssm.edu/nephrology

Detective Nephron

Detective Nephron, world-renowned for his expert analytic skills, trains budding physician-detectives in the diagnosis and treatment of kidney diseases. L. O. Henle, a budding nephrologist, presents a new case to the master consultant.

Nephron What do you have for us today, my dear apprentice?

Henle A 70-year-old woman with acute kidney injury.

Nephron More AKI—good. It had better be a case of some exotic chemotherapy causing thrombotic microangiopathy.

Henle Hmmm…you are reading too much onconephrology these days. Getting back to the case, she was in her usual state of health until a few months ago, when she received a diagnosis of ovarian cancer. Her creatinine was 1.0 mg/dL at baseline. She has occasional heartburn but no other past medical history.

Nephron What was her creatinine 6 months ago?

Henle It was 0.7 mg/dL 1 year ago, and 1.1 mg/dL 6 months ago. Thank you for your interruption.

Nephron (*angry*): OK, now what happened? Let me guess: she got a checkpoint inhibitor?

Henle (*surprised*): There you go again; you are stealing my thunder. Yes, she did get into a trial and got pembrolizumab, which is an immunotherapy. It was started 5 months ago.

Nephron Is there any proteinuria?

Henle No, not at all. The urine is clean…. I mean no red blood cells, no casts, no white blood cells, no proteinuria.

Nephron I am sure they did serologies before they called you.

Henle No, they started steroids instead. But the creatinine is not improving and continues to get worse. No further workup was done.

Nephron Stop right there. Before we go any further, let's think if this is truly a checkpoint inhibitor–mediated renal injury?

Henle (*wondering to himself about quick decision by Nephron*): Well, I wanted first to tell you what the creatinine was. It was 1.9 mg/dL 2 weeks ago, they started prednisone 40 mg per day, and creatinine continues to rise at 2.6 mg/dL now. There are no other electrolyte disorders. They thought it was acute interstitial nephritis (AIN) from the checkpoint inhibitor, and now they are confused.

Nephron Oh no! This is a good one. Glad you brought this one to me. What do you know about checkpoint inhibitor nephrotoxicity?

Henle (*trying to remember*): The immune system is required to attack and fight the cancer. Immunotherapy uses certain negative regulators like CTLA-4 and PD-1 to allow the immune system to attack the cancer. It is an emerging area of cancer care. Because the immune system has been activated, T cell–mediated–injury is not uncommon, and we can start seeing a lot of "itis"—inflammatory side effects. Dermatitis is fairly common, as are colitis and pneumonitis. Nephritis is usually in the form of acute interstitial nephritis (by far), and there have been cases of glomerular diseases such as PLA2R-negative membranous nephropathy, minimal change disease, or vasculitis with these agents. And recently I also read that pembrolizumab can also cause a tubular injury. So not all AKI from checkpoint inhibitors is AIN.

Nephron (*surprised*): That is a quick and succinct summary of the literature on immunotherapy and the kidney. Impressive! What do you think happened to our patient? Does this immune-mediated nephritis just happen to all?

Henle Hmmm. To the best of my knowledge, the incidence quoted is around 2 to 3% but higher if there is combined CTLA4 and PD-1 therapy. But usually they require a "second hit." Most of the literature supports that the injury happens when there are either nonsteroidal anti-inflammatory drugs (NSAIDs) or proton pump inhibitors (PPIs) on board. The checkpoint therapy leads to loss of tolerance of these agents and hence to AKI.

Nephron (*shocked*): What did our patient do? Was she taking any of those? Perhaps PPIs. given her history of heartburn?

Henle (*jumps in*): I asked her. She keeps saying she wasn't taking any PPIs or NSAIDS.

Nephron Of course not. So, what could be the mechanism of injury here?

Henle (*not sure*): It is possible that the T cells are recognizing an off-target kidney antigen after PD-1 receptor blockade, which then leads to AKI. Or, it's possible that the autoantibodies are formed and they lead to kidney injury, or perhaps there is release of certain T cell cytokines such as INF-α or CXCL-10, causing the AKI.

Nephron Hmmm... if those were guesses, they were amazing guesses and well described! Although there are certain urinary biomarkers now potentially for AIN, such as INF-α and IL-9, but they are still in preliminary stages.

Henle (*confused*): But if this was AIN, why did the steroids not work? Shouldn't we have improvement in renal function by now?

Nephron (*interrupting*): Is there anything on her physical examination results?

Henle Nothing specific except some trace edema bilaterally in the lower extremities. There was some concern for potential lymph nodes felt in the axillary regions. No rashes or joint pains, either.

Nephron Remember that in certain checkpoint inhibitors, we do see acute tubular injury as well, which is not going to respond to steroids. Or the patient might need a longer time to respond to steroids.

Henle Could this be prerenal? I don't think it is a prerenal condition, because her urine sodium is high. She is not oliguric. That leaves us with intrarenal causes. A tubular cause is still possible, regardless of the hematuria and proteinuria. This could be garden-variety tubular necrosis, but I can't find any source of low BP or any other toxic medications, and the urinalysis showed no granular casts. An interstitial cause still bothers me.

Nephron Steroids are the cornerstone of treatment of immune therapy–related toxicities, but other agents such as MMF, tacrolimus, and anti–IL-6 have been used in other nonrenal toxicities.

Henle What are we supposed to do now?

Nephron Let's go to her bedside.

Henle and Nephron exit.

Nephron (*to himself*): Here is my new toy, my friend: my portable point-of-care ultrasound. Let's do a point-of-care examination of her kidneys and bladder.

After 3 to 4 minutes:

Henle Her renal sonogram shows massively enlarged hydronephrotic kidneys. How did we miss this? So—this is hydronephrosis from retroperitoneal metastatic disease from her ovarian cancer.

Nephron Please obtain a formal sonogram as well, and a urology consultation.

A few days later:

Henle Bingo! Her serum creatinine is normal now, and she is continuing her immunotherapy!

Nephron (*relieved*): According to American Society of Clinical Oncology guidelines, a rise in serum creatinine in a patient getting immunotherapy prompts steroid treatment because it is assumed that every AKI is AIN… and that's a problem. I think we have to do the same prerenal, postrenal, and intrarenal process thinking on all patients—even if there is a checkpoint inhibitor involved!

Henle (*surprised*): Yes, you are right; the incidence is only 2%, and hence it is likely to be prerenal or postrenal rather than AIN from immunotherapy!

Nephron Yes, and please don't get a kidney biopsy for a down-trending creatinine; and her steroids can be discontinued.

Henle leaves to discuss the case with his oncology colleagues. A few weeks later:

Henle Assumptions are bad in medicine. Systematic process is important for differential diagnosis in every case.

Nephron Well done, apprentice. Keep an open mind. Again, never assume. Make sure you have done all aspects of your differential diagnosis. Just because someone is taking NSAIDS or PPI or is receiving immunotherapy, that doesn't equate that the rise in creatinine is related to that medication. And it is cool that I got to use my point-of-care ultrasound… that is so amazing. Henle, let's get a cup of my favorite coffee. ■

Detective Nephron was developed by Kenar D. Jhaveri, MD, professor of medicine at Zucker School of Medicine at Hofstra/Northwell. Special thanks to Dr Rimda Wanchoo, associate professor of medicine at Zucker School of Medicine at Hofstra/Northwell for her editorial assistance. Send correspondence regarding this section to kjhaveri@northwell.edu or kdj200@gmail.com.

KidneyCure congratulates the talented group of individuals awarded grants in 2019.

With support from ASN members, industry partners, and nephrology leaders, KidneyCure provides approximately $3,000,000 annually to young researchers, fellows, and nephrology educators who are changing the future of kidney care. Their innovative approaches will soon lead to better therapies and someday cures.

Make a difference today.

Support these future kidney leaders and their quest for cures by visiting CureKidneyDiseases.org.

KidneyCure

The ASN Foundation CureKidneyDiseases.org

Fund it. Find it.

Career Development Grants Program

The program invests $100,000 annually for two years to foster independent research careers and ensure a pipeline of innovative research in the field of nephrology. The Career Development Grants Program is supported by contributions provided by ASN, Akebia Therapeutics, Inc., Amgen, and individual donors.

Carl W. Gottschalk Research Scholar Grant Recipients

Subhashini Bolisetty, PhD
Targeting Ferritin in Sepsis-Associated Acute Kidney Injury

Louise Evans, PhD
Pathological Role of T-Cells in Salt-Sensitive Hypertension

Naoka Murakami, MD, PhD
Roles of Immune Checkpoint Signaling in Autoimmune Kidney Diseases

Sagar U. Nigwekar, MD, MMSc*
Novel Determinants of Calcific Uremic Arteriolopathy

Tengis S. Pavlov, PhD
Mechanism and Role of ATP Release in Polycystic Kidney Diseases

Fahad Saeed, MD, FASN*
Pilot Testing of a Communication Intervention to Promote Shared Renal Replacement Therapy Decision Making in Older Patients with Chronic Kidney Disease (RRT-SDM Trial)

Tomokazu Souma, MD, PhD
Harnessing Antioxidative Stress Pathways in Renal Epithelial Progenitors to Prevent AKI-to-CKD Transition

John Merrill Grant in Transplantation

Sarah E. Panzer, MD
Impact of B Cell Survival Cytokines on Transplant Glomerulopathy

Norman Siegel Research Scholar Grant

Brian Becknell, MD, PhD
Therapeutic Urothelial Remodeling: A Novel Strategy to Limit Obstructive Kidney Injury

Oxalosis and Hyperoxaluria Foundation (OHF)-ASN Foundation for Kidney Research Grant

Dylan Dodd, MD, PhD
Gut Microbiota Modulation of Oxalate

Ben J. Lipps Research Fellowship Program

Funding ten new research projects annually, the program distributes $50,000 for two years to conduct original, meritorious research. The Ben J. Lipps Research Fellowship Program is fully endowed by contributions provided by Fresenius Medical Care, ASN, the American Renal Patient Care Foundation, Inc., Amgen, Baxter, and the PKD Foundation.

Ben J. Lipps Research Fellows

Lakshmi Ganesan, MD, MAS
Pediatric Peritoneal Dialysis and Uremic Solutes

Kana N. Miyata, MD*
Novel Role of Heterogeneous Nuclear Ribonucleoprotein F (hnRNP F) in Regulation of Sodium- Glucose Cotransporter 2 (SGLT2) Expression in Diabetes

Nabin Poudel, PhD*
Pannexin1 and Acute Kidney Injury

Katherine Scovner, MD*
Acid-Base Status of Hospitalized Patients on Maintenance Hemodialysis as a Predictor of Hospital Outcomes

Seyedmohammad ebrahim Tahaei, PhD
Illuminating the Mechanisms that Control Salt Balance in the Face of NCC Inhibition

Sharon Anderson Research Fellow

Sri Lekha Tummalapalli, MD, MBA*
Screening Strategies for Chronic Kidney Disease in US Populations

Jared J. Grantham Research Fellow

Ken Sutha, MD, PhD
Patient-Derived Kidney Organoids

Dimitrios G. Oreopoulos Research Fellow

Aneta J. Przepiorski, PhD*
Modeling Kidney Fibrosis and Testing Therapeutic Compounds in Human Kidney Organoids

George B. Rathmann Research Fellow

Michael Holliday, Jr., MD, PhD
From Bedside to Bench: Gramoxone and Mesoamerican Nephropathy

Donald E. Wesson Research Fellow

Xiao-Tong Su, PhD*
Dietary Potassium Causes Chloride-Induced Distal Hypertension

William and Sandra Bennett Clinical Scholars Program

Funded annually, the program provides $50,000 for two years to a nephrology educator to conduct a project to advance all facets of nephrology education and teaching.

Tushar Chopra, MD, FASN
Peritoneal Dialysis (PD) Curriculum Development to Improve PD Prescription Writing Amongst Nephrology Trainees

ASN Pre-Doctoral Fellowship Award Program

The program funds early career-stage PhD students to conduct original research projects and make contributions to the understanding of kidney biology and disease.

Benjamin Bowe, III*
Identification of Inpatient Acute Kidney Injury and Phenotypes Using Large Scale Electronic Medical Records

Yijiang Chen*
Computational Pathology Approach for Characterizing Kidney Biopsies and Predicting APOL1 Risk Variants

Pei-Ju Liu
The Role of Myo1e- and Clathrin-Dependent Endocytic Trafficking in Podocyte Health and Disease

Franco Puleo*
Sympathetic Nervous System Regulation of the NCC in Salt Sensitive Hypertension

Annie Ryan
Elucidating Vascular Signals in Nephron Formation Using Human Organoids

ASN-Harold Amos Medical Faculty Development Program

The program aims to increase diversity among future nephrology leaders by supporting the research and career development of a kidney scholar from a historically disadvantaged background.

Rasheeda Hall, MD, MS*
Establishing Evidence to Manage Geriatric Syndromes in Hemodialysis Patients

** Kidney Week 2019 oral and/or poster abstract presenter*

nephSAP

The next generation of nephSAP is arriving in early 2020.

nephSAP provides a learning vehicle to renew and refresh clinical knowledge, diagnostic, and therapeutic skills. Rigorously assess your strengths and weaknesses in the broad domain of nephrology.

What's new for 2020?

New platform and enhanced mobile-friendly design

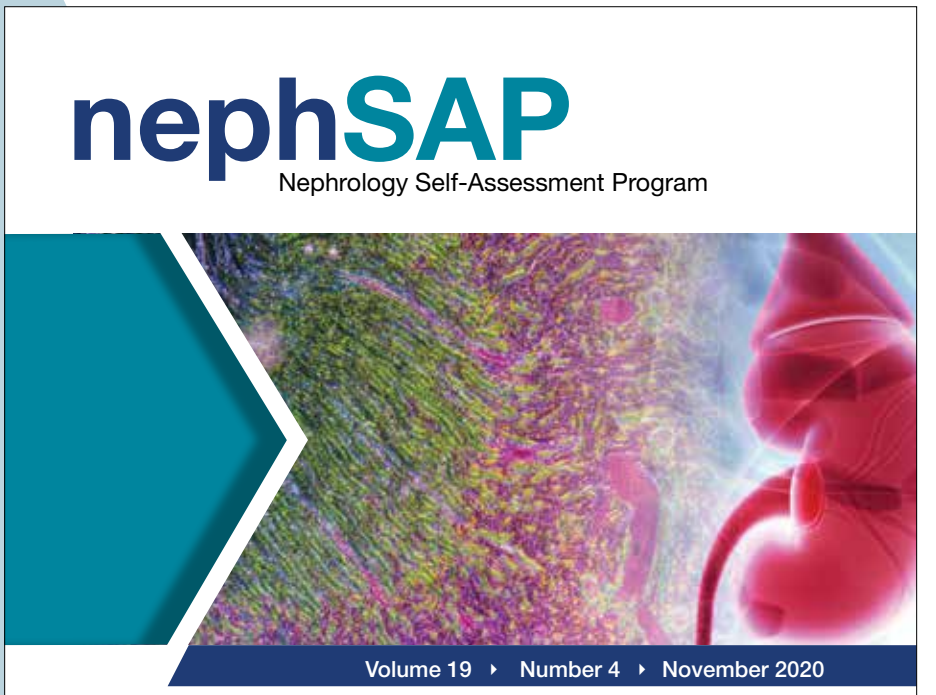
- Access content anywhere, anytime from any device
- Browse content by subject
- Access and print PDFs at the article level
- Download presentation-ready figures

Social networking and collaboration tools

- Annotate and highlight text privately or collaborate in groups
- Share content easily through social media or email
- Download figures instantly with attributions
- Provide your feedback to nephSAP to continue to advance this premier publication

Personalized experience with *My nephSAP*

- Create content collections
- Save search results and bookmark content
- Set search alerts and citation alerts



ASN
American Society of Nephrology

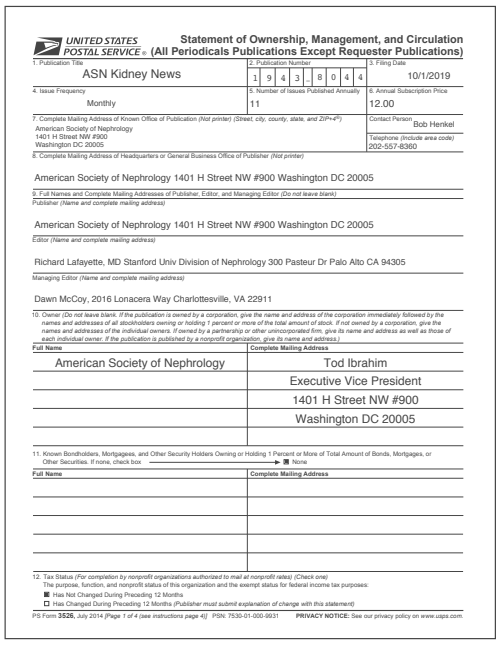
From care to cure… knowledge at the next level

Classified

WASHINGTON, DC SUBURBS

Busy and large, high-quality Nephrology practice in Northern Virginia looking for a motivated and hard-working individual to join our practice. Please email CV to Debbieg@nanvonline.com.

Index to Advertisers



UNITED STATES POSTAL SERVICE® **Statement of Ownership, Management, and Circulation (All Periodicals Publications Except Requester Publications)**

1. Publication Title: ASN Kidney News
2. Publication Number: 1 9 4 3 - 8 0 4 4
3. Filing Date: 10/1/2019
4. Issue Frequency: Monthly
5. Number of Issues Published Annually: 11
6. Annual Subscription Price: 12.00
7. Complete Mailing Address of Known Office of Publication (Not printer) (Street, city, county, state, and ZIP+4®): American Society of Nephrology, 1401 H Street NW #900, Washington DC 20005
Contact Person: Bob Henkel
Telephone (Include area code): 202-557-8360
8. Complete Mailing Address of Headquarters or General Business Office of Publisher (Not printer)
American Society of Nephrology 1401 H Street NW #900 Washington DC 20005
9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor (Do not leave blank)
Publisher (Name and complete mailing address)
American Society of Nephrology 1401 H Street NW #900 Washington DC 20005
Editor (Name and complete mailing address)
Richard Lafayette, MD Stanford Univ Division of Nephrology 300 Pasteur Dr Palo Alto CA 94305
Managing Editor (Name and complete mailing address)
Dawn McCoy, 2016 Lonacera Way Charlottesville, VA 22911
10. Owner (Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual owner. If the publication is published by a nonprofit organization, give its name and address.)

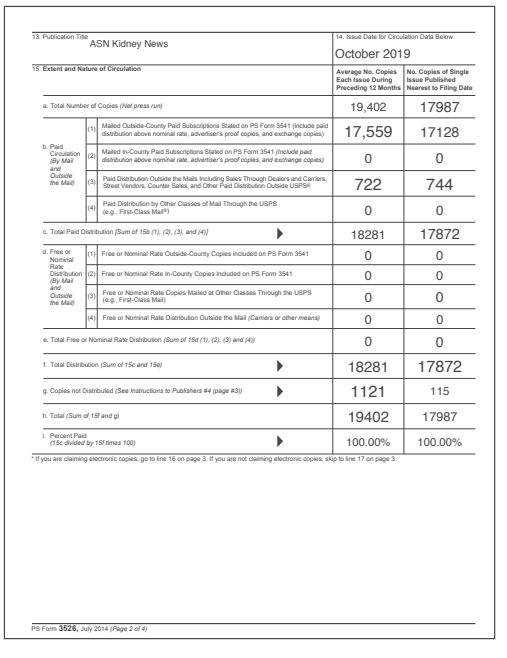
Full Name	Complete Mailing Address
American Society of Nephrology	Tod Ibrahim
	Executive Vice President
	1401 H Street NW #900
	Washington DC 20005

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☒ None

Full Name	Complete Mailing Address

12. Tax Status (For completion by nonprofit organizations authorized to mail at nonprofit rates) (Check one)
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☒ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months (Publisher must submit explanation of change with this statement)

PS Form 3526, July 2014 (Page 1 of 4 (see instructions page 4)) PSN: 7530-01-000-9931 **PRIVACY NOTICE:** See our privacy policy on www.usps.com

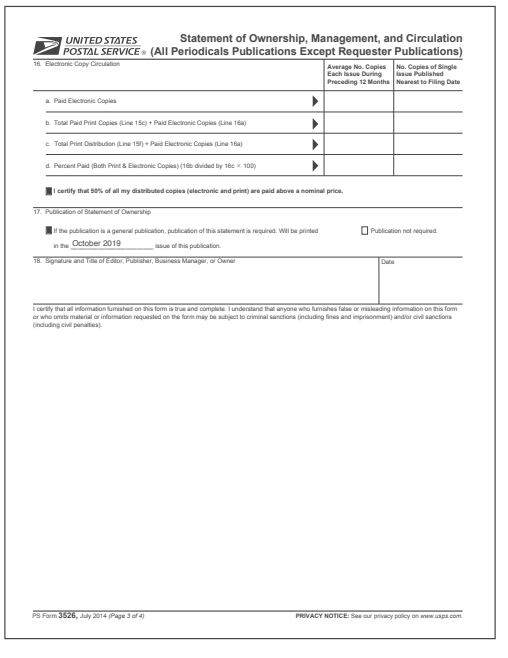


13. Publication Title: ASN Kidney News
14. Issue Date for Circulation Data Below: October 2019

15. Extent and Nature of Circulation			Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Total Number of Copies (Net press run)			19,402	17987
b. Paid Circulation (By Mail and Outside the Mail)	(1)	Mailed Outside-County Paid Subscriptions Stated on PS Form 3541 (Include paid distribution above nominal rate, advertiser's proof copies, and exchange copies)	17,559	17128
	(2)	Mailed In-County Paid Subscriptions Stated on PS Form 3541 (Include paid distribution above nominal rate, advertiser's proof copies, and exchange copies)	0	0
	(3)	Paid Distribution Outside the Mails Including Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid Distribution Outside USPS®	722	744
	(4)	Paid Distribution by Other Classes of Mail Through the USPS (e.g., First-Class Mail®)	0	0
c. Total Paid Distribution (Sum of 15b (1), (2), (3), and (4))			18281	17872
d. Free or Nominal Rate Distribution (By Mail and Outside the Mail)	(1)	Free or Nominal Rate Outside-County Copies included on PS Form 3541	0	0
	(2)	Free or Nominal Rate In-County Copies Included on PS Form 3541	0	0
	(3)	Free or Nominal Rate Copies Mailed at Other Classes Through the USPS (e.g., First-Class Mail)	0	0
	(4)	Free or Nominal Rate Distribution Outside the Mail (Carriers or other means)	0	0
e. Total Free or Nominal Rate Distribution (Sum of 15d (1), (2), (3) and (4))			0	0
f. Total Distribution (Sum of 15c and 15e)			18281	17872
g. Copies not Distributed (See Instructions to Publishers #4 (page #3))			1121	115
h. Total (Sum of 15f and g)			19402	17987
i. Percent Paid (15c divided by 15f times 100)			100.00%	100.00%

* If you are claiming electronic copies, go to line 16 on page 3. If you are not claiming electronic copies, skip to line 17 on page 3.

PS Form 3526, July 2014 (Page 2 of 4)



UNITED STATES POSTAL SERVICE® **Statement of Ownership, Management, and Circulation (All Periodicals Publications Except Requester Publications)**

16. Electronic Copy Circulation	Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Paid Electronic Copies		
b. Total Paid Print Copies (Line 15c) + Paid Electronic Copies (Line 16a)		
c. Total Print Distribution (Line 15f) + Paid Electronic Copies (Line 16a)		
d. Percent Paid (Both Print & Electronic Copies) (16b divided by 16c × 100)		

☒ I certify that 50% of all my distributed copies (electronic and print) are paid above a nominal price.

17. Publication of Statement of Ownership
☒ If the publication is a general publication, publication of this statement is required. Will be printed in the October 2019 issue of this publication. ☐ Publication not required.

18. Signature and Title of Editor, Publisher, Business Manager, or Owner — Date

I certify that all information furnished on this form is true and complete. I understand that anyone who furnishes false or misleading information on this form or who omits material or information requested on the form may be subject to criminal sanctions (including fines and imprisonment) and/or civil sanctions (including civil penalties).

PS Form 3526, July 2014 (Page 3 of 4) **PRIVACY NOTICE:** See our privacy policy on www.usps.com

AlloSure®

Better Surveillance for Better Outcomes

Joyanne F., kidney transplant recipient

It's time for innovation

DETECT ALLOGRAFT INJURY AND REJECTION EARLIER IN YOUR KIDNEY TRANSPLANT PATIENTS

AlloSure is the first and only clinically and analytically validated, non-invasive test that assesses kidney health by directly measuring allograft injury

Put your patients on a clear path forward with AlloSure

FEATURES

+ A non-invasive blood test that measures donor-derived cell-free DNA, an indicator of kidney injury
+ More accurate than serum creatinine in diagnosis of active rejection
+ Results may assist in clinical decision making
+ Covered by Medicare

KIDNEY TRANSPLANT PATIENTS DESERVE A BETTER WAY

DETECTION OF ALLOGRAFT INJURY IS OF THE UTMOST IMPORTANCE

20% Of kidney transplants fail within 5 years[1]

500% A study of over 110,000 patients from the United States Renal Data System (USRDS) showed a 500% increase in cost burden for patients with renal transplant failure[2]

CURRENT TRANSPLANT SURVEILLANCE OPTIONS HAVE LIMITATIONS[3,4]

SERUM CREATININE: non-specific, not sensitive, risk of late signal

BIOPSY: high cost, sampling errors, inconvenient, potential for complications, interpretation challenges

For more information: 1-888-255-6627 | caredxinc.com/ASN-2019 | customercare@caredx.com