Although vascular and soft tissue calcification can be deadly, physicians currently have no reliable tools for determining an individual’s calcification risk. This is particularly pertinent to nephrologists and others who care for patients with compromised kidney function because pathologic vascular calcification has been called “the killer of patients with chronic kidney disease” (Mizobuchi M, et al. J Am Soc Nephrol 2009; 20:1453–1464).

“We currently have quite a good idea about pathomechanisms triggering progressive calcification, and we think we know about a number of clinical factors predicting calcification progression including hyperphosphatemia, high calcium burden, and inflammation,” said Markus Ketteler, MD, head of the division of nephrology at the University Hospital Würzburg, in Germany. “However, none of these factors shows a clear-cut linear relationship with the magnitude or progression of cardiovascular calcification or related events.”

Now a newly developed nanoparticle-based test, which is described in a recent issue of the Journal of the American Medical Association, could change practice and provide an effective way to measure an individual’s overall propensity for calcification in serum (Pasch A, et al. J Am Soc Nephrol doi: 10.1681/ASN.2012030240 [published online ahead of print September 6, 2012]).

“This test may help to identify calcification-prone patients to guide and monitor their treatment. We regard this as an important step ahead in the field of calcification research and of potential importance for the treatment of patients with kidney disease worldwide,” said first author Andreas Pasch, MD, of University Hospital and University of Bern, Inselspital, in Switzerland.

Calculating calcification
Calcifications in the body mainly consist of two components, calcium and phosphate, which combine to form calcium phosphate. Because calcium and phosphate concentrations in the blood are naturally near supersaturation, the balance of inhibitors and promoters of...
Unlike other labs, our kind of number crunching doesn’t compromise patient care. And that’s because we firmly believe that the best way to help you navigate the new CMS Bundle is to maintain the level of expertise, clinical support, and service you’ve come to rely on—including comprehensive laboratory testing with no hidden fees. **And in our eyes, offering everything to you for one fair price isn’t just the right thing to do. It’s the right thing for your patients.**
Calcification-Prone Patients

Continued from page 1

these minerals critically influences the development of calcification. Under physiologic conditions, calcium and phosphate mineralize only in bones and teeth, but pathologic states can lead to soft tissue and vascular calcifications.

Intensive treatment, especially self-medication with calcium-containing antacids and over-the-counter osteoporosis drugs, has led to a resurgence of the "milk alkali syndrome" associated with soft tissue calcifications and kidney damage. Also, patients with chronic kidney disease often have abnormally high blood calcium levels because of their compromised kidney function and metabolic insults of diabetes, dyslipidemia, oxidative stress, uremia, and hyperphosphatemia.

“Despite much progress in our molecular understanding of calcium homeostasis—particularly the role of the calcium-sensing receptor, renal phosphate handling, and epithelial calcium channels that are present in various tissues—the clinical determinants of pathologic calcifications are still incompletely understood,” said Pasch.

"Individual calcification risk cannot be determined, and patients particularly (likely) to develop calcifications cannot be identified.”

Given the major clinical problem of accelerated calcification in many patients with chronic kidney disease, Pasch and his team set out to develop the first potentially widely available blood test that functionally integrates all the procalcification and anticalcification forces inherent in blood with one single measurement to obtain an estimate of the calcification propensity of individual serum samples.

The researchers found that when serum is artificially challenged with high amounts of calcium and phosphate, so-called primary calcification particles (CPPs) are formed. CPPs are protein-mineral aggregates that consist mainly of calcium, phosphate, and the two calcification-inhibiting serum proteins fetuin-A and albumin. Calcium and phosphate form an amorphous or colloidal state in primary CPPs, but with time, primary CPPs transform into secondary CPPs, which consist of a spectrum of proteins as well as crystalline (as opposed to colloidal) calcium phosphate. "The speed of transformation is a measure of calcification inhibition," Pasch said. "The longer the delay of transformation, the stronger the calcification-inhibiting forces in a given serum.” In the presence of lower calcium and phosphate concentrations, CPP formation progresses only over weeks to months.

The transformation from primary CPPs, which are spherical, to secondary CPPs, which are spindle-shaped, causes turbidity that can be optically monitored with a commercial nephelometer, a photometer measuring scattered light. The test by Pasch and his team measures the kinetics of CPP transformation by detecting the changes in light scatter in a sample of serum. In its current format, the assay can measure approximately 200 serum samples per day.

Getting to the clinic

To prove the test’s utility, the researchers showed that in the presence of artificially elevated calcium and phosphate concentrations, their new nanoparticle-based assay detected the spontaneous transformation of primary CPPs to secondary CPPs. Also, the test found that both the sera of mice deficient in fetuin-A, a serum protein that inhibits calcification, and the sera of patients receiving hemodialysis had reduced intrinsic properties to inhibit calcification. Blood from healthy volunteers did not.

“The test by Pasch et al. could show clear differences in calcification inhibitory capacity of calcification-prone fetuin-A knockout mice and dialysis patients versus wild-type mice and healthy volunteers, respectively,” said Georg Schlieper, MD, an assistant professor at the RWTH Aachen University Hospital, in Germany. "This discrimination appears as a very promising approach in identifying patients at high risk for calcification and has the later potential to guide through decalcification therapy.”

In other words, the test may also become an important tool for identifying and testing calcification inhibitors and may provide the basis for treatment monitoring in patients who receive such inhibitors. Whereas the findings and their implications are promising, "future experimental and clinical studies are essential in order to establish this calcification test for clinical use. These data need to be confirmed in patient cohorts in prospective studies, especially in conjunction with outcome parameters,” Schlieper said.

Ketteler added that "in addition to systemic or circulating calcification-modifying factors, there are some potent locally expressed and active calcification inhibitory systems at work—including matrix Gla protein, or MGP, and pyrophosphates—which may not be detected here.”

The test in its current form requires strict temperature control and liquid handling. Further automation and simplification could help make the test more useful for basic and clinical research, the investigators said.

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Setting the Standard for Education: ASN Kidney Week and Beyond

Kidney Week 2012 includes several exciting new features and resources. The theme of the meeting, “Curing Kidney Disease,” will be incorporated in the President’s Address as well as in several oral abstract sessions via invited lectures. The lectures will address topics such as acute kidney injury, autoimmunity, channelopathies, diabetes, dialytic therapy, glomerulopathies, hypertension, lupus nephritis, polycystic kidney disease, and thrombotic microangiopathies.

Early Programs
ASN offers 16 Early Programs on Tuesday, October 30, and/or Wednesday, October 31, preceding the Annual Meeting (November 1–4). New Early Programs are:

- **Dialysis Facility Medical Directorship**, covering all aspects of the roles and responsibilities of a medical director for a CMS-approved dialysis facility.
- **Renal Relevant Radiology**, covering the mechanistic bases of radiology techniques useful for the practicing nephrologist to improve selection and interpretation of ordered tests.

Diabetes Learning Pathway
The new Diabetes Learning Pathway includes sessions on medical management, glycation, the renin–angiotensin system blockade, uric acid, and renal structure. The *Onsite Program* includes a list of all Learning Pathways and their associated sessions.

High-Profile Oral Abstract Sessions
The best abstracts from both regular and late-breaking submissions will be profiled in the following sessions:

- **“Hot Science,”** scheduled for Friday, November 2, from 2 to 4 p.m., will feature abstracts focused on laboratory and translational science.
- **“High Impact Clinical Studies,”** scheduled for Saturday, November 3, from 10:30 a.m. to 12:30 p.m., will highlight clinically focused abstracts, particularly clinical trials.

Each abstract presentation will be followed by audience questions, facilitated by session moderators.

Scientific Exposition
A vital part of the Kidney Week educational experience is found on the scientific exposition floor, in Halls A/B/C of the convention center. New features include:

- **Fellows Case Reports in the Posters Section** feature clinical cases or pedigrees that demonstrate novel clinical findings; illustrate classic conditions in new or unusual ways; or illuminate and expand knowledge concerning physiology, cell biology, genetics, or molecular mechanisms.
- **Innovators Place** offers the opportunity for scientific discourse between medical device innovators and the nephrology community.
- **The Career Fair** allows attendees to meet face-to-face with representatives of top employers in the nephrology field—all in one place.

Education and Membership for Nurses, Pharmacists, and Physician Assistants
Kidney Week 2012 attendance may convey eligibility for continuing medical education (CME) credits for physician assistant (PAs), continuing nursing education (CNE) credits for nurses, and continuing pharmacy education (CPE) credits for pharmacists. More information is available in the *Onsite Program*.

Nurses, pharmacists, and PAs who are not ASN members and who register for Kidney Week 2012 at the nonmember rate will receive complimentary ASN Affiliate Membership for 2013. Bring your registration receipt to the ASN Services Counter or Booth in the convention center to complete your membership application.
Sample: Urine or plasma

Assay platform: Automated chemistry analyzers from Roche, Siemens, Beckman, Abbott, etc.

Assay time: Just 10 minutes

For more information please visit our booth 1516 at the ASN Kidney Week

For in vitro diagnostic use in selected countries only. For Research Use Only in the United States— not for use in diagnostic procedures.
During the last year, ASN continued to serve its 14,000 members and the kidney community worldwide, providing the best educational resources in nephrology, working with policymakers to improve kidney care, and adding exciting new programs that will advance research and patient care. The society is proud of its history of adding meaningful programs and member benefits every year to advance the careers and support the important achievements of kidney professionals worldwide.

Educating health professionals
Since its inception, ASN has committed resources and expertise to providing the best professional education in nephrology. In the last year, ASN:

- Hosted the premier kidney meeting in the world in Philadelphia, helping more than 13,000 kidney professionals improve research and patient care.
- Added new features to Kidney Week 2012, including:
  - Continuing education credits for nurses, pharmacists, and physician assistants
  - Launching ASN Innovators Place
  - Adding an early program on dialysis facility management
  - Offering the In-Service Exam as an early program
  - Expanding the medical students and residents program at Kidney Week
  - Expanding the employment opportunities through a career fair at Kidney Week and online at ASN Career Center.
- Held regional meetings in Berlin, Chicago, Dallas, New York, Ouro Preto, Panama City, and Washington, DC, as well as held the Board Review Course and Update (BRCU) meeting.
- Continued expanding efforts to help nephrologists generate Maintenance of Certification (MOC) points through the Nephrology Self-Assessment Program (NephSAP) and Practice Improvement Modules (PIMs).
- Launched an onco-nephrology forum (http://www.asn-online.org/about/committees/committee.aspx?panel=OncoNeph) to encourage and promote the exciting advances in this field.
- Expanded distance learning opportunities: ASN Highlights Online, BRCU Online, Kidney Week On-Demand, American Society of Transplantation/ASN Transplant Nephrology Core Curriculum, and the ASN Dialysis Curriculum.

Advancing research and advocating the highest quality care for patients
Research is essential to improving kidney health, and nephrology is forging the path for changes in patient care that will affect many other areas of medicine. In the last year, ASN:

- Established the ASN Foundation for Kidney Research. The Foundation will raise funds to ensure continued support of innovative research in kidney disease. ASN created and funded the first fellowship, the Sharon Anderson Research Fellowship, in honor of the society’s first female president.
- Launched a new program to foster the next generation of investigators who will help reach a cure for kidney disease. The ASN Research Fellowship Program funded nine new research fellows in 2012.
- Launched the William E. Mitch International Scholars Program to offer key support to international nephrology fellows and fellows from under-represented minority groups.
- Launched the Kidney Health Initiative (KHI), an innovative program created in concert with the FDA. Through KHI, patient advocates and kidney professionals will work with the FDA and industry groups to assess unmet needs in kidney treatment and evaluate the best options for developing new treatments that meet those needs.
- Coordinated ASN Hill Day 2012. More than 30 ASN leaders visited 60 congressional offices, informing congressional leaders about kidney health disparities and key advances in kidney care that require a sustained investment in research.
- Partnered with the American Kidney Fund, Dialysis Patient Citizens, the Urban League, and the American Society of Pediatric Nephrology to host congressional briefings on kidney health disparities and research in nephrology (see sidebar).

Sharing new knowledge
ASN produces the most referenced, read, and respected kidney publications in the world. The society continues to provide a hub of innovative approaches to providing key information to its members and the entire kidney community and to raising general public awareness of kidney health. In the last year, ASN:

- Participated in launching the American Board of Internal Medicine Foundation’s Choosing Wisely campaign to help improve patient care. http://www.asn-online.org/policy_and_public_affairs/choosingwisely/
- Selected the next Editor-in-Chief of the Journal of the American Society of Nephrology (JASN): Karl Nath, MD.
- Increased impact factor rankings (JASN. 9.663; Clinical Journal of the American Society of Nephrology, 5.227)
- Added mobile apps for JASN and CJASN, and mobile-friendly journal sites.
- Expanded ASN Kidney News readership to 41 countries.
- Redesigned its website to improve resources and features for ASN members.
- Produced educational films on geriatric nephrology care.
- Launched monthly video updates from the ASN Executive Director to help keep the kidney community informed.
- Developed resources to help physicians meet new meaningful use requirements regarding providing educational resources to patients.
- Increased the number of social media followers five-fold.

 ASN looks forward to a successful annual meeting at Kidney Week 2012 and to the opportunity to continue to advance the interests of its members and the global kidney community in order to improve the care and lives of millions of patients with kidney disease.
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An Interview with Ronald J. Falk, MD, FASN

You have led ASN toward a number of new initiatives this year. One is the creation of the ASN Foundation for Kidney Research. Why does ASN need a foundation?

ASN needs a foundation to concentrate effort on support for kidney research. The society needs to develop funds for long-term preservation of fellowship programs, and the foundation allows industry and individuals to contribute to these important efforts.

Treatment will advance only if we train the next generation of researchers in kidney disease. These fellowships offer the best and the brightest the opportunity to concentrate two years of time on nephrology research, and they promote the long-term success of the young investigators who will help cure kidney disease.

You spearheaded a new program called the Kidney Health Initiative (KHI). What is that?

The Kidney Health Initiative is a wonderful new program that allows the U.S. Food and Drug Administration (FDA), patient support groups, kidney organizations, and industry to work together to develop opportunities for drugs, devices, biologics, and food safety that benefit patients. Intuitively, everyone understands the potential of this partnership, a collaborative based on a similar effort in cardiovascular disease.

Kidney as a specialty has not produced adequate outcome measures or strongly encouraged new drug development and approval. Through a signed agreement with FDA, ASN can help rally the kidney community to overcome this gap. The Kidney Health Initiative encourages an iterative process in which all stakeholders work with the FDA to set appropriate guideposts for safe and beneficial development of drugs, devices, and biologics and for better food labeling.

Why is food labeling important?

As I sit here today, I’m drinking a bottle of water. The water probably contains phosphorus, and may in fact have as much phosphorus as a glass of milk. It is essential for kidney patients to understand what they are ingesting. And the kidney community must do a better job of addressing food safety, including toxin-induced kidney diseases such as hemolytic uremic syndrome.

ASN is focusing more effort on promoting the concept of kidney professionals working “shoulder to shoulder.” What does this mean?

In the practice domain physicians don’t work in isolation. Physicians work with nurses, pharmacists, and physician assistants. These professionals work shoulder-to-shoulder to provide excellent care to patients with kidney disease. In the past, ASN focused its educational services on physicians, and as a society we now recognize the importance of educating the health care team. This is why ASN has expanded continuing education credits to allow all members of the kidney community to benefit professionally from attending the best nephrology meeting in the world.

You speak often about the joys of being a nephrologist. What do you find most satisfying when you see patients?

Being a nephrologist is a wonderful occupation. The patients we see have complex and fascinating problems that require astute insights and creative solutions. Nephrologists encounter a broad range of challenges, everything from transplants to stones to bone disease. The opportunity to care for these patients, to help someone get through a medical crisis and help restore their function, the opportunity to see someone recover so much quality of life after a transplant, or to help someone at the end of life die with dignity and respect—these are true privileges. It is for these kinds of opportunities that most of us went to medical school, and in helping our patients we make our own lives better.

What is new at ASN Kidney Week 2012?

Among the new offerings at this meeting are a diabetes learning pathway that includes sessions on medical management, the renin–angiotensin system blockade, uric acid, and renal structure. In addition, this year’s meeting provides an opportunity for trainees to present case reports. ASN has not encouraged case reports in the past, and I am really excited to learn more about what our trainees will share with us from their clinical experiences. More than 200 case reports will be presented at Kidney Week, and I encourage all meeting participants to visit these posters. This opportunity also helps nephrology training programs meet the requirements of the Accreditation Council for Graduate Medical Education.

The theme for Kidney Week 2012 is Curing Kidney Disease. You believe this specific phrase is important. Why?

Many other medical specialties use the word “cure” as a rallying cry, to highlight advances in their fields and to give patients hope. Kidney specialists hardly ever use that word, yet they work every day to restore patients’ health and quality of life and to advance kidney research. Historically, kidney professionals have employed poor word choices—“chronic,” “progressive,” “end-stage”—that give a sense of poor outcomes. These words diminish the impressive accomplishments and many successes of the last 40 years, and our vocabulary doesn’t reflect the positive changes this specialty has made in improving the lives of millions of patients.

Will you still be able to conduct the Kidney Week podcast interviews this year?

Absolutely. I enjoy the interviews and learn so much from the people who share their meeting experiences with me.

You have served on ASN Council for six years. What are ASN’s most notable strengths?

Without question the ASN’s greatest strength is its members. This community of professionals makes incredible contributions to medicine, science, and education. ASN’s members benefit from the support of a phenomenally dedicated and experienced staff whose efforts allow members to have an effective voice in all areas of education, policy, and research. ASN’s volunteer leaders bring a great sense of purpose to their work at ASN; their efforts reflect the immense contributions of the entire community.

President’s Address

Launch of New Programs Marks 2012 Accomplishments
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*while supplies last
Meet ASN’s Next President

Innovation and Translation to Top 2013 Agenda

Bruce A. Molitoris, MD, FASN, is Professor of Medicine and Director of the Indiana Center for Biological Microscopy at Indiana University. He graduated from the Washington University School of Medicine in St. Louis and completed his residency and fellowship training at the University of Colorado School of Medicine in Denver.

In addition to his work on ASN Council, Dr. Molitoris has chaired the ASN Kidney Week Program Committee, served on the ASN Training Program Directors Committee and the Nominating Committee, chaired the AKI Advisory Board, and played a central role in launching the ASN Workforce Committee. He has been involved in numerous NIH committees, NIH study sections, and National Kidney Foundation committees including the National Scientific Advisory Board.

The major area of his research studies over the last 25 years has centered on the cell biology of acute kidney injury, with an emphasis on proximal tubule cell injury secondary to ischemia and/or nephrotoxins. He also focuses on the use of 2-photon microscopy in live animals to understand the normal physiology, disease pathophysiology, and therapeutic responses. He has been continuously funded by both the NIH and the VA for over 25 years. He presently is the principal investigator of two NIH RO1s, P-30 O’Brien Core, a phase II STTR, a VA Merrit Review, and numerous industry grants. He is a founding member of two biotechnology companies dealing with 2-Photon and fluorescent technology.

What are your areas of expertise in nephrology?
The two areas I enjoy most are acute kidney injury (AKI) and the use of intravital imaging to understand renal physiology and pathophysiology. Both areas are experiencing rapid and tremendous strides making this a very dynamic and exciting time. We have now expanded our use of imaging out beyond AKI into other areas where it has the tremendous opportunity to enhance our understanding of cell biologic processes and therapeutic mechanisms.

What made you decide to become a nephrologist?
I had always wanted to be an endocrinologist. Because I had a master’s degree in nutrition from the University of Illinois, it was a natural progression toward endocrinology. I performed research with both endocrinologists and a nephrologist, Dr. Keith Hruaska, during my medical school time at Washington University School of Medicine. I then went to the University of Colorado School of Medicine to work with a specific endocrinologist during my residency. However, after exposure to the outstanding nephrology faculty at the University of Colorado, I rapidly became enamored with both the acute care aspects of nephrology and also the tremendous opportunity to do the type of research I was interested in within nephrology. In particular, there was little going on in the cell biology of disease processes, and the physiology had been well worked out. This left an opening for a young nephrologist to create a career in an important basic science area with minimal competition, an opportunity I could not resist.

You have been on ASN Council for five years. How do the leaders of ASN serve all 14,000 members?
ASN’s goal is always to improve patient care whether through direct patient care, research, education, or public policy. An integrated network of MDs and PhDs comprise advisory groups, committees, strategic task forces, and the public policy board and provide expertise and guidance to the ASN Council on nearly all issues. The passion and dedication shown by these individuals exceeds my expectations. An incredibly energetic, talented, and well coordinated ASN staff direct, assist, and facilitate all matters involving clinical, research, education, communication, and public policy aspects of what the ASN does. The ability of these individuals, and the particular structure now developed within the ASN executive director Tod Ibrahim’s position, is an especially effective way to conduct an organization that interacts with all areas of nephrology. Since beginning on Council five years ago, the capabilities and contributions of all of these aspects of the leadership have been enhanced tremendously.

How were you able to advance within the society to attain this position of leadership?
Advancement within the society is a difficult question to answer. In no way did I try to “advance,” but I did try to serve ASN in a capacity in which I felt I could benefit the society. I was lucky in that my research had been successful and I was passionate about several areas within nephrology. My friend Dr. Norman Siegel invited me to be the Chair of the ASN Program Committee and I was identified as someone who could contribute. I would say the keys to recognition are to get involved in different ASN venues, do your job well, be positive, and be a consensus builder.

What do you think ASN’s primary focus should be over the next year?
It is hard to identify a “primary focus” for the ASN. I do like the way the Kidney Health Initiative (or “KHI”) can be used as a focal point from which to foster and develop areas primarily benefiting patient care. This can involve direct patient care in the line of developing therapeutics, devices, and foods. It can also involve research leading to breakthroughs and translation to patient care, and it can involve education of physicians, health care workers, and the public at large. In working with the FDA, industry, and the NIH, ASN has an opportunity to focus on improving patient care at multiple sites. KHI is extremely exciting to me.

What do you consider the most stimulating recent advances in nephrology?
There have been a number of recent advances in nephrology including the APOL1 susceptibility for focal segmental glomerular sclerosis (FSGS), anti-PLA2 receptor antibodies in membranous nephropathy, rapid advancement in AKI and CKD biomarkers, and the burgeoning therapeutic advances in preventing AKI and forestalling CKD. However, once an opportunity becomes a success, it is time to refocus on new opportunities and challenges that will benefit patients in either the short or long term. Nephrology is now experiencing a tremendous birth of excitement and interest by pharmaceutical companies as the opportunities listed

Continued on page 12
above offer unbelievable prospects for improving patient care and halting the progression to end stage renal disease. To do this, nephrology, with the ASN’s help, must increase its scientific diversity and be open to scientific and clinical innovation and ideas.

The kidney is a vastly understudied organ when it comes to specific cellular and molecular processes because of the lack of public awareness of the importance of kidney disease and the lack of involvement of scientific disciplines outside of nephrology. We need to work hard to facilitate involvement of other scientific disciplines including immunology, cell and molecular biology, biomedical engineers, and many more outside the field of nephrology to apply their expertise to important processes that directly relate to kidney disease. This can take many forms including education but also should include research dollars for individuals working within these scientific areas to encourage them to study aspects of kidney diseases. Therefore, multidisciplinary educational and research programs and associated funding opportunities are necessary. Industry’s focus on nephrology and a growing involvement of widely diverse scientific disciplines will pay major dividends in therapeutic success in the future.

If you could change one thing about kidney care, what would it be?

This is an easy question and one that I have pondered for some time. I believe public awareness of the importance of kidney disease is extremely low and needs to be dramatically enhanced. Although many attempts are being made to improve the situation, I believe one of the best ways to do this is a grass roots movement involving the public. Think about the cholesterol or blood pressure campaigns and their success. Until we do this, we will not receive the recognition necessary for the funding required to enhance disease detection and therapeutics for improving kidney disease patient care. This type of campaign is beyond the ASN, but it seems to me professional societies, patient support groups, the National Institutes of Health, and industry should come together around this need.

My greatest desires are to be able to identify those patients likely to develop kidney disease early and to be able to monitor them in ways that will allow appropriate therapies to be administered earlier than we are capable of doing today. I believe this is well within our reach and that’s why the meeting will emphasize innovation, translation, and individualization as it relates to improving patient care at an early stage, thus minimizing the number of patients who require dialysis as a final therapy.

What do you tell young people who are considering whether to study nephrology?

First I tell them that nephrology is not as difficult as they have been led to believe by medical school physiology. Nephrology is an extremely exciting clinical field and an equally exciting research field. The opportunities in nephrology research are the greatest within medicine subspecialties and are waiting for young, dynamic, and bright individuals to take up the cause. Clinical nephrology is also an exciting and rewarding area: we tend to over-expose our students and residents to extremely challenging patients with many comorbidities and underexpose students to the many successes of the transplant and outpatient areas. This question is directly tied into the next question involving the ASN Workforce Committee.

You have been very closely involved with the creation of ASN’s Workforce Committee. What do you consider the major workforce challenges in nephrology?

The challenges facing the ASN Workforce Committee are enormous and difficult to get your arms around. Surveys have informed us that medical students and residents see nephrology as too difficult intellectually, too demanding clinically, and not as rewarding as other medical subspecialty areas in terms of...
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Adverse reactions: The most common adverse reactions in clinical studies in patients with CKD on dialysis treated with OMONTYS were dyspepsia, diaphoresis, nausea, cough, and arteriovenous fistula site complication. Please see accompanying Brief Summary.

OMONTYS® peginesatide


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Help Avert Cuts to Research: Join ASN in Call for Balanced Approach to Deficit Reduction

By Thomas H. Hostetter, MD

ASN needs your support to protect medical research funding. It’s one of the smartest investments our country can make.

Research generates jobs, stimulates the economy, and enables life-saving medical advances. If Congress doesn’t act by January 2013, federal funding for NIH will be cut by 8.2 percent, eliminating up to 2,300 NIH research grants.

We can’t let these cuts happen. ASN has joined more than 3,000 other organizations urging Congress to adopt a balanced approach to deficit reduction that would protect medical research and other essential federal programs like education, public safety, and infrastructure.

The society needs your help, too. Tell your Congressional representatives that cuts alone will not solve our federal budget problems.

Go to www.asn-online.org for all the tools to connect you with your members of Congress, including talking points and fact sheets.

Congress won’t act unless they hear from constituents like you. I’m going to meet with my representatives. I urge you to join me.

Thomas H. Hostetter, MD, is ASN Public Policy Board Chair.
By Rachel Shaffer

The ASN Quality Metrics Task Force and Public Policy Board spent the summer analyzing the proposed rule’s potential impact on patient outcomes, access, and safety, and the integrity of the patient-physician relationship. The society submitted feedback to CMS on August 31, 2012, emphasizing support for CMS’ goal of monitoring access to appropriate dialysis care within a bundled payment system, and providing suggestions for improvement to the agency’s proposals. ASN underscored the vital importance of only implementing measures that are substantiated by rigorous, scientifically validated evidence. ASN’s complete comments are available online; this article summarizes some key conclusions from the task force.

Although ASN supported several of CMS’ proposals related to the ESRD Quality Incentive Program (QIP), the society conveyed that, overall, the existing and proposed new measures for the QIP are not as relevant as others CMS might have suggested. Many measures focus on processes—such as monitoring and collecting data—rather than on outcomes that affect quality and value. ASN encouraged CMS to—

• Address the potential for standardizing and provider choice of palliative care.
• Implement its proposal to require facilities to report QIP data on 98 percent of patients, suggesting that a more reasonable alternative would be to consider only patients who received seven or more dialysis sessions per month eligible for QIP measures.

Mineral metabolism

CMS proposed expansion of an existing mineral metabolism measure and adoption of a measure assessing the number of patients with uncorrected serum calcium >10.2 mg/dL. ASN recommended that CMS not implement these suggestions, emphasizing that insufficient evidence exists to substantiate a 10.2 mg/dL calcium level. “The only evidence supporting this benchmark is observational data, which is not sufficiently rigorous to substantiate an incentivized measure. Implementing this measure would effectively cement a practice based on observation—

Table 2

| Time Period of Trial | CMS | France | US
|----------------------|-----|--------|-----
| Pre-Market Testing | N = 1432 | N = 4038 |
| Patients with CKD on hemodialysis or peritoneal dialysis | 11.0 | 12.0 | 12.0 |
| Patients with CKD on hemodialysis or peritoneal dialysis, type II diabetes, hemoglobin ≤11 g/L | 12.0 | 12.0 | 12.0 |
| Hemoglobin Target: Higher Lower (g/dL) | 14.0 10.0 | 13.0 11.0 | 12.0 9.0 |
| Median (IQR), g/dL | 12.6 (11.6, 13.3) | 13.0 (12.2, 13.6) | 12.5 (12.0, 12.8) |
| All-cause mortality | 10.3 (10.2, 10.7) | 11.4 (11.1, 11.8) | 10.6 (9.9, 11.3) |
| All-cause mortality, MI, hospitalization for CHF, or stroke | 1.2 (1.0, 1.4) | 1.3 (1.0, 1.4) | 1.3 (1.0, 1.4) |
| All-cause mortality, MI, hospitalization for CHF, or stroke | 1.20 (0.94 – 1.51) | 1.34 (1.03 – 1.74) | 1.29 (0.94 – 1.77) |
| Patients with Chronic Kidney Disease Not on Dialysis | 1.32 (1.04 – 1.64) | 1.48 (0.97 – 2.27) | 1.32 (1.08 – 2.68) |

Omontys is not indicated and is not recommended for the treatment of anemia in patients with CKD who are not on dialysis. A higher percentage of patients (22%) who received Omontys experienced a composite cardiovascular adverse event compared to 17% who received darbepoetin alfa in two randomized, active-controlled, open-label, multi-center trials of 982 patients with anemia due to CKD who were not on dialysis. The trials had a pre-specified, exploratory analysis of a composite safety endpoint consisting of death, myocardial infarction, stroke, or serious adverse events of congestive heart failure, unstable angina, or angina pectoris (hazard ratio 1.32, 95% CI 1.00, 1.78).

Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence in Patients with Cancer

Omontys is not indicated and is not recommended for reduction of CBC transfusions in patients receiving treatment for cancer and whose anemia is not due to CKD. Omontys has shown a harm in some settings and the benefit-risk factors for Omontys in this setting have not been evaluated.

The safety and efficacy of Omontys have not been established for use in patients with anemia due to cancer chemotherapy. Results from clinical trials of EPOs in patients with anemia due to cancer therapy showed decreased (localized control, progression-free survival and/or decreased overall survival). The findings were observed in clinical trials of other EPOs administered to patients with: breast cancer receiving chemotherapy, advanced head and neck cancer receiving radiation therapy, lymphoid malignancy, cervical cancer, non-small cell lung cancer, and with various malignancies who were not receiving chemotherapy or radiation therapy.

Hypotension

OMONTYS is contraindicated in patients with uncontrolled hypertension.

Adequately control hypertension prior to initiation and during treatment with OMONTYS. Reduce or withhold OMONTYS if blood pressure becomes difficult to control. Advise patients of the importance of compliance with antihypertensive therapy and dietary restrictions.

Lack of or Loss of Response to OMONTYS

Inadequate response to treatment with OMONTYS. Initiate a search for causative factors (e.g., iron deficiency, infection, inflammation, bleeding). If typical causes of lack or loss of hemoglobin response are excluded, evaluate the patient for the presence of antibodies to peginesatide. In the absence of antibodies to peginesatide, follow dosing recommendations for management of patients with an insufficient hemoglobin response to OMONTYS therapy. Contact Affymax, Inc. (1-855-466-6668) to perform assays for binding and neutralizing antibodies.

Dialysis Monitoring

Patients may require adjustments in their dialysis prescriptions after initiation of OMONTYS. Patients receiving OMONTYS may require increased anticoagulation with heparin to prevent clotting of the extracorporeal circuit during hemodialysis.

Laboratory Monitoring

Evaluate transferrin saturation and serum ferritin prior to and during OMONTYS treatment. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L, or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course

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of ESA therapy. Following initiation of therapy and after each dose adjustment, monitor hemoglobin every 2 weeks until the hemoglobin is stable and sufficient to minimize the need for RBC transfusion. Thereafter, hemoglobin should be monitored at least monthly provided hemoglobin levels remain stable. 

**ADVERSE REACTIONS**

The following serious adverse reactions observed during clinical trials with OMONTYS are discussed in greater detail in other sections of the labeling:

- Increased Mortality, Myocardial Infarction, Stroke, and Thrombembolism (see Warnings and Precautions)
- Hypertension (see Warnings and Precautions)

**Clinical Trials Experience**

Because clinical trials are conducted under widely varying surveillance conditions, adverse reaction rates observed in the clinical studies of OMONTYS cannot be directly compared to the rates in clinical trials of other drugs and may not reflect the rates observed in practice.

**Patients with Chronic Kidney Disease**

Adverse reactions were determined based on pooled data from two active controlled studies of 1066 dialysis patients treated with OMONTYS and 543 treated with epoetin, including 313 exposed for at least 6 months and 825 exposed for greater than one year to OMONTYS. The population for OMONTYS was 20 to 93 years of age, 56.5% male, and the percentages of Blacks (including African American race patients) were 57.9%, 34.7%, and 3.1%, respectively. The median weight adjusted dose of OMONTYS was 0.07 mg/kg and 1.13 (units/kg of epoetin).

Table 3 summarizes the most frequent adverse reactions (≥10%) in dialysis patients treated with OMONTYS.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>OMONTYS Patients Treated with OMONTYS (N = 1066)</th>
<th>Epoetin Patients Treated with Epoetin (N = 543)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial System Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>14.4%</td>
<td>12.0%</td>
</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>15.3%</td>
<td>17.4%</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>14.7%</td>
<td>16.7%</td>
</tr>
<tr>
<td>Back pain</td>
<td>12.2%</td>
<td>13.2%</td>
</tr>
<tr>
<td>Arthritis</td>
<td>10.7%</td>
<td>9.8%</td>
</tr>
<tr>
<td>Vascular Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td>14.2%</td>
<td>14.6%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>13.2%</td>
<td>11.4%</td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>12.2%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Metabolism and Nutrition Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>11.4%</td>
<td>11.8%</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>11.0%</td>
<td>12.4%</td>
</tr>
</tbody>
</table>

Seizures have occurred in patients participating in OMONTYS clinical studies. During the first several months following initiation of OMONTYS, blood pressure and the presence of premonitory neurologic symptoms should be monitored closely. Advise patients to contact their healthcare practitioners for new-onset seizures, premonitory symptoms, or other seizure-related symptoms. Anaphylactic allergic reactions have been reported in patients treated with OMONTYS. Discontinue OMONTYS and administer appropriate therapy if a serious allergic, anaphylactic, or an infusion-related reaction occurs. Immunogenicity of the 2051 patients tested, 29 (1.2%) had detectable levels of peginesatide-specific binding antibodies. There was a higher incidence of peginesatide-specific binding antibodies in patients dosed subcutaneously (1.5%) as compared to those dosed intravenously (0.7%). Peginesatide neutralizing antibodies were defined as levels ≥50% of a cell-based functional assay in ≤1 of these patients (0.9%). In approximately half of all antibody-positive patients, the presence of antibodies was associated with declining hemoglobin levels, the requirement for increased doses of OMONTYS to maintain hemoglobin levels, and/or transition for anemia of CKD. No cases of pure red cell aplasia (PRCA) developed in patients receiving OMONTYS during clinical trials.

**DRUG INTERACTIONS**

No formal drug/drug interaction studies have been performed. Peginesatide does not bind to serum albumin or lipoproteins as demonstrated in in vitro protein binding studies in rat, monkey and human sera. In vitro studies conducted with human hepatocytes or microsomes have shown no potential for peginesatide to induce or inhibit CYP450 enzymes.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Peginesatide does not cross the placenta and is not known to cause fetal harm when administered to pregnant animals at doses and/or exposures that resulted in adverse effects in the rat. Peginesatide should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.

Administration of peginesatide by intravenous injection to rats and rabbits during organogenesis was associated with embryotoxicity and malformations. Dosing was every third day in rats for a total of 5 doses and every fifth day in rabbits for a total of 3 doses (0.01 to 0.02 mg/kg/dose). In rats and rabbits, adverse embryotoxic effects included reduced fetal weight, increased resorption, embryonic lethality, cleft palate (rats only), sternum anomalies, ossification of sterna and metatarsals, and reduced ossification of some bones. Embryotoxicity was evident in rats at peginesatide doses of 0.1 mg/kg and the malformations (cleft palate and sternebrae, and stigmatisations in blood vessels) were mostly evident at doses of ≥0.1 mg/kg. The dose of 0.1 mg/kg results in exposures (AUC) comparable to those in humans after intravenous administration at a dose of 0.35 mg/kg in patients on dialysis. In a separate embryological developmental study in rats, reduced fetal weight and delayed ossification were observed at a lower dose of 0.25 mg/kg. Reduced fetal weight and delayed ossification in rabbits were observed at ≥0.5 mg/kg doses which exceeded 10 times the peginesatide. In a separate embryological developmental study in rabbits, adverse findings were observed at lower dose in peginesatide treated rats and included incidence of sternebra at 0.25 mg/kg. The effects in rabbits were observed at doses lower (≤ 5%) than the dose of 0.35 mg/kg in patients.

**Nursing Mothers**

It is not known whether peginesatide is excreted in human milk. Because many drugs are excreted into human milk, caution should be used when administering peginesatide to a nursing woman.

**Pediatric Use**

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

**Geriatric Use**

The safety and efficacy of OMONTYS in dialysis patients, 75 years of age and older, have been assessed in two studies. In the first study, 33 patients aged ≥75 years were administered 0.35 mg/kg in patients on dialysis. In the second study, 33 patients aged ≥75 years were administered 0.7 mg/kg in patients on dialysis. The studies demonstrated that peginesatide was safe and effective in patients aged ≥75 years.

**OVERDOSAGE**

OMONTYS is an extravascular agent that can elevate hemoglobin levels above the desired level, which should be managed with discontinuation or reduction of OMONTYS dosing and/or by phlebotomy, as clinically indicated. Cases of severe hyperhemolysis have been observed following overdose with Epoetin (see Warnings and Precautions).

**PATIENT COUNSELING INFORMATION**

See FDA-approved patient labeling (Medication Guide).

**Marketed by:**

Affymax, Inc.  
Palo Alto, CA 94304

**Distributed and Marketed by:**

Takeda Pharmaceuticals America, Inc.  
Deerfield, IL 60015

For more detailed information, see the full prescribing information for OMONTYS at www.OMONTYS.com. On the site, download the Prescribing Information for OMONTYS: it is a trademark of Affymax, Inc. registered in the U.S. Patent and Trademark Office and used under license by Takeda Pharmaceuticals America, Inc. All other trademarks are the property of their respective owners.

**ASN suggested.**

ASN suggested that the nephrology community, including CMS—reframe the language that it uses to describe Kt/V, using an alternative term such as “urea removal.” This terminology shift would help the nephrology community focus on more comprehensive ways to monitor and improve the overall adequacy of dialysis therapy.

**Anemia management**

CMS did not propose any changes to the existing anemia management measure; however, ASN recommended that CMS consider assessing hemoglobin/hematocrit levels on a rolling 3-month or 6-month basis rather than assessing the levels on a monthly basis. Assessing a single value per month has limited clinical utility or insight into the quality of care that an individual patient receives in a dialysis facility. A longer assessment period would provide a more complete picture of patients’ overall anemia management.

**Standardized hospitalization ratio**

A standardized hospitalization ratio is one measure CMS is considering adding to the QIP in future years. However, ASN is concerned that this measure could make it challenging for patients with multiple comorbid conditions or generally compromised health to gain admission to a dialysis unit. The task force also considered that it is currently impossible to accurately case-mix adjust for changes in patients’ comorbid conditions unrelated to dialysis. ASN suggested that CMS not implement the measure at this time, and at a minimum, pilot it before applying it to the entire ESRD patient population to assess whether these serious issues can be addressed.

“Hopefully, CMS will find ASN’s feedback informative and useful as it continues to develop the QIP,” Hostetter said. “A robust system assessing the accessibility and quality of dialysis services is critically important for our patients. Many challenges remain in developing an evidence-based system that accurately reflects the level of care offered, and ASN looks forward to continued interaction with CMS to make progress in this arena.”
On Friday, September 14, 2012, the White House Office of Management and Budget (OMB) released a highly anticipated report on the likely effects of sequestration (the automatic across-the-board cuts of $1.2 trillion passed as part of the Budget Control Act in 2011 that are slated to take effect beginning January 2013). The report confirmed what everyone already knew—sequestration would bring massive budget cuts that would devastate federal programs.

Sequestration would reduce funding for the National Institutes of Health (NIH) by $2.5 billion in FY 2013, or 8.2 percent, eliminating up to 2300 NIH research grants. NIH “would have to halt or curtail scientific research, including needed research into cancer and childhood diseases,” the White House said.

Moreover, Medicare would face a 2 percent cut of $11 billion, costing up to 766,000 jobs. The Centers for Medicare & Medicaid Services (CMS), which has much of the federal responsibility for implementing the 2010 Patient Protection and Affordable Care Act, would take a $65 million hit to its program management budget. The prevention fund that the 2010 health care law created would be sliced by 7.6 percent, or $76 million. Grants to states to create health insurance exchanges would be cut by $66 million.

The OMB report said that “on the nondefense side, sequestration would undermine investments vital to economic growth, threaten the safety and security of the American people, and cause severe harm to programs that benefit the middle class, seniors, and children.” Nondefense discretionary (NDD) spending funds essential government programs such as medical research, education, public safety, and infrastructure.

The goal of the NDD community is to speak with one voice in educating policymakers and the public about what NDD programs are as well as what the nation will stand to lose as a result of sequestration, and to encourage Congress to take a balanced approach of cuts and new revenue as it works toward a budget deal to replace sequestration.

“We can’t just cut our way out of debt. Eliminating all NDD programs will not balance the budget and is not the answer,” ASN Research Advocacy Committee Chair John R. Sedor, MD, said. “ASN knows medical research generates jobs, stimulates the economy, and enables life-saving medical advancements. That is why the society has joined more than 5000 national, state, and local organizations, including other medical specialty societies and research organizations, to raise awareness of and build support for federal NDD programs.”

ASN has been collaborating with the NDD community in a number of ways. In July 2012, ASN joined the “Rally to Restore Balance and Protect America’s Families” on Capitol Hill for the formal launch of the NDD campaign with Sen. Tom Harkin, Sen. Patty Murray (D-WA), Rep. Rosa DeLauro, (D-CT) Rep. George Miller (D-CA), and Phoenix Mayor Greg Stanton.

ASN joined the NDD community in calling upon Congress for a balanced approach to deficit reduction in July, and participated in an NDD community-wide national action day in September. ASN members were asked to Tweet or call their congressional representatives. Throughout the fall ASN will join the NDD community for congressional briefings and various meetings on Capitol Hill.

In addition to these NDD activities, the society offers a toolkit at www.asn-online.org to help ASN members meet with their congressional representatives in their home offices in November and December, including talking points and fact sheets.

Currently, there is no serious plan in Congress to repeal or replace sequestration. Instead, Congress has tacitly agreed to table this issue until after the November election, which is why ASN members are being asked to meet with their representatives in Congress during the lame-duck session. What Congress decides to do is anyone’s guess at this time. What happens largely depends on the outcome of the election and the balance of power in Washington. The hope, however, is that the combined efforts of the entire NDD community will generate enough support for replacing sequestration with a more balanced approach to deficit reduction that includes new revenues.
promote more patient-centered care. Include patients with end stage renal disease as well as later stages of chronic kidney disease. Allow a diversity of dialysis provider sizes and types to participate. These are among the suggestions for a potential nephrology integrated care delivery model pilot program that ASN—joined by eight other patient and health professional organizations—discussed with leadership from the Centers for Medicare & Medicaid Services (CMS) and the CMS Innovation Center at CMS headquarters in early September (Table 1). Although CMS and the Innovation Center have not formally announced any plans for a nephrology integrated care delivery model pilot program or demonstration project, ASN and the other participants commended them for their interest in examining strategies to improve care and reduce costs for patients with kidney disease and voiced strong support for such a program.

In addition to thanking CMS administrator Jonathan Blum, Innovation Center Acting Director Richard Gilfillan, MD, and their staffs for their consideration of a pilot project focused on patients with kidney disease, ASN and the other groups provided recommendations for key considerations the agency should take into account to ensure the success of a pilot project and yield the most meaningful improvements for patients. Although CMS and the Innovation Center are still considering the project, at this time, it is generally anticipated that a pilot program would likely entail a dialysis provider assuming responsibility for the care of a set number of patients with kidney disease, ASN and the other groups provided recommendations for key considerations the agency should take into account to ensure the success of a pilot project and yield the most meaningful improvements for patients.

One theme that ASN and the other participating patient and health professional groups emphasized was the importance of considering including late-stage CKD patients—as well as patients with ESRD—in a pilot program. Improving care coordination and enhancing access at that stage could provide significant patient benefit, through means such as establishing appropriate vascular access, selecting the optimal modality, and arranging for nutritional supplements. It could also help defray costs, such as by reducing the number of patients who “crash” into dialysis in the emergency room, or have increased morbidity and mortality due to catheter infections.

Among the challenges to including this population are how to define “late stage CKD,” and whether it is possible to involve patients with CKD who are not yet Medicare beneficiaries. Yet CMS and the Innovation Center possess a unique opportunity to profoundly transform care for patients with kidney disease, and ASN hopes the agency will engage with the nephrology community to develop creative solutions.

Other suggestions that participants in the meeting encouraged Mr. Blum, Dr. Gilfillan, and their staffs to consider included:

- Prospectively specifying the evaluation methodology that will be used to define success or failure.
- Improving patient access to transplantation, including pre-emptive transplantation.
- Including a role for patient peer mentoring.
- Incentivizing timely placement of appropriate vascular accesses.
- Allowing provider organizations that are large and small, and for-profit and non-profit, to participate.
- Utilizing the patients’ time during in-center dialysis treatments to coordinate care for other comorbidities, such as heart disease or diabetes, and to provide educational interventions.

“Overall, I think that ASN and the other patient and health professional groups thought it was a constructive, interactive meeting, and sincerely appreciated CMS and the Innovation Center’s consideration of the ideas our groups presented,” said L. Lee Hamm, ASN Accountable Care Organization Task Force Chair, who represented ASN at the meeting. “Accounting for the perspectives and experiences of these two key constituencies in the design of a pilot program will be important for CMS and the Innovation Center to ensure its success. We all look forward to continuing the dialogue with them to capitalize on this exciting opportunity to improve care for our patients.”

Table 1. Patient and health professional organization participants in meeting with CMS and the Innovation Center

- American Association of Kidney Patients
- American Kidney Fund
- American Nephrology Nurses Association
- American Society of Nephrology
- American Society of Pediatric Nephrology
- Dialysis Patient Citizens
- National Kidney Foundation
- Renal Physicians Association
- Renal Support Network

Announcing the ASN Foundation for Kidney Research

“Only through innovative research will the kidney community continue to implement advances that improve the lives of kidney patients and cure kidney disease.”

—American Society of Nephrology President Ronald J. Falk, MD, FASN

The American Society of Nephrology established the ASN Foundation for Kidney Research in March 2012 with one mission: to prevent and cure kidney diseases through research and innovation.

The foundation’s first goal is to establish sustained funding to support the research of 20 fellows a year (10 with initial funding and 10 with continued funding). “This $20 million commitment to nephrology ensures support to the next generation of researchers for years to come,” said ASN President Ronald J. Falk, MD, FASN.

The first organization to contribute and help the foundation accomplish this goal was Fresenius Medical Care, which contributed $10 million to establish the Ben J. Lipps Research Fellowship Program. This program will fund 10 new research fellows annually at $50,000 for up to two years, including five Ben J. Lipps Research Fellows. The program also includes:

- The Sharon Anderson Research Fellowship, funded annually through a $2 million donation from ASN to honor its first female president.
- The George B. Rathmann Research Fellowship, funded every other year through a $1 million educational donation from Amgen.

With a combined $13 million in funding, the foundation strives to reach its $20 million goal by ASN’s 50th anniversary in 2016.

ASN announced its commitment to fund research fellows in 2011. Out of 68 applicants, ASN awarded nine fellows with research funding beginning on Sunday, July 1, 2012. This year’s program was partially funded by Amgen, Global Exposition Specialists (GES), Reata Pharmaceuticals, and Sanofi.

The ASN Foundation for Kidney Research is committed to maintaining and expanding this important program. The foundation welcomes the input of new partners and contributors to its research mission.

“Rates of kidney disease and kidney failure are rising globally, affect millions, and will increase in concert with the rise in major underlying causes: diabetes, hypertension, and obesity,” said Dr. Falk, adding that the foundation is proud to contribute to the role medical and scientific research plays in improving human health.

Dr. Falk will announce the establishment of the ASN Foundation for Kidney Research—as well as the Ben J. Lipps Research Fellowship Program and the Ben J. Lipps Research Fellows, the Sharon Anderson Research Fellowship, and the George B. Rathmann Research Fellowship—during the Opening Plenary Session at ASN Kidney Week 2012 on Thursday, November 1, in San Diego.
Effect of Quality Improvement Interventions on Health Disparities Unclear

Are quality improvement interventions effective at reducing disparities in health care? It’s not clear, according to a recent literature review by the Agency for Healthcare Research and Quality. The analysis included articles from 1983 to 2011, and the reviewers looked for studies that evaluated the effect of strategies on disparities in the prevention or treatment of asthma, breast and colorectal cancers, cardiovascular disease, cystic fibrosis, depression, diabetes, end stage renal disease (ESRD), pneumonia, and pregnancy.

“The most striking finding of the AHRQ report to me is that only 19 studies met the criteria for evidence-based quality improvement interventions to reduce health disparities in a broad population of conditions. This is a very low number,” said Emory University School of Medicine’s Rachel Patzer, PhD, MPH, an expert in transplant disparities. “There is little evidence to guide quality improvement strategies to reduce disparities, and it is clear that more research studies on quality improvement interventions are needed.”

Limited information

The 19 articles in the review represented 14 studies of cancer, cardiovascular disease, depression, and diabetes. Although the investigators did not find any studies that assessed quality improvement interventions in the kidney failure population that met their inclusion criteria, the findings in many ways apply to kidney care.

Fourteen articles targeted or described disparities associated with differences in race or ethnicity, three pertained to socioeconomic status, two related to insurance status, two related to language, one dealt with health literacy, and one pertained to sex.

“I think it’s helpful to look at other successful quality improvement interventions in other fields or diseases to see what may work in kidney disease,” Patzer said.

Most interventions included education of patients and health care providers, although the specific approaches differed substantially across the studies. Overall, quality improvement interventions were not shown to reduce disparities, but the authors noted that the review should not be construed to assess the general effectiveness of quality improvement in the health care setting.

One challenge in conducting a systematic review in this area is the breadth and heterogeneity of clinical conditions, populations with the clinical conditions, quality improvement intervention strategies, and clinical outcomes. Compounding this heterogeneity are challenges to indexing quality improvement strategies in the medical literature.

Reducing disparities in kidney care

Despite a vast number of research studies that have documented the existence of health disparities in kidney disease, there seem to be few evidence-based quality improvement interventions to reduce health disparities among kidney disease patients, Patzer said.

The lack of large-scale quality improvement interventions is due in part to the disconnect between community partners and researchers. “A population-based, regionally coordinated intervention would have the highest impact on health disparities,” Patzer said. “It’s important for researchers to work with community members to ensure that the quality improvement initiatives are conducted in a way that provides sufficient evidence, such as ensuring an adequate comparison group to evaluate effectiveness.”

“I think the kidney disease community should see this as a call to action for collaboration on quality improvement initiatives to reduce health disparities among kidney disease patients,” Patzer said.
ASN SCIENTIFIC EXPOSITION

Thursday, November 1 – Saturday, November 3 | 9:30 a.m. – 2:30 p.m.

Highlights Include:

- Over 130 Exhibiting Companies
- ASN Services
  - CME Information, General Information, Membership Services, Publications, NephSAP, Foundation and Web Services
- Career Fair – New! The Kidney Week Career Fair is an opportunity to meet face to face with professionals from around the country.
- Complimentary Refreshment Breaks
- Cyber Center
- Exhibitor Spotlights
- Innovators Place – New! Innovators Place is designed to offer the opportunity for scientific discourse between medical device innovators and the nephrology community.
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Exhibitor Spotlights
ASN has built a special theater in the scientific exposition hall to spotlight industry’s latest advances in nephrology practices, products, services, and technologies during 60 minute presentations (no continuing medical education credit). Seating is first come, first served and limited to 75 participants.

All presentations include breakfast (morning presentations) or lunch (afternoon presentations).

Schedule

Thursday, November 1
10:00 a.m. – 11:00 a.m. Glucose and Peritoneal Dialysis: Getting to the Heart of the Matter
Presented by Baxter

12:30 p.m. – 1:30 p.m. The Risks and Clinical Consequences of Secondary Hyperparathyroidism
Presented by Amgen

Friday, November 2
10:00 a.m. – 11:00 a.m. Understanding and Managing Hyponatremia: A Specific Approach to Treatment
Presented by Otsuka

12:30 p.m. – 1:30 p.m. Rituxan for the Treatment of Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)
Presented by Genentech
Plenary Session

Transplantation Tolerance Pioneer to Describe Progress in Preventing Rejection

Tolerance and Kidney Transplantation is the title of the state-of-the-art lecture to be delivered on Thursday, Nov. 1. Transplant tolerance researcher David H. Sachs, MD, is the speaker.

Dr. Sachs is director of the Transplantation Biology Research Center at Massachusetts General Hospital and the Paul S. Russell/Warner-Lambert Professor of Surgery (Immunology) at Harvard Medical School in Boston.

Two of the major limitations in the field of transplantation today are complications from the drugs used to prevent acute rejection and chronic rejection, which causes the loss of some 5 percent of transplanted organs per year. Dr. Sachs has been active in exploring methods for inducing transplantation tolerance in order to avoid acute and chronic rejection without the need for long-term immunosuppressive medications. He will describe the work of his laboratory on the mechanisms involved in transplantation immunity at the basic level.

Dr. Sachs has published more than 700 articles in scientific journals. His research achievements include the development of monoclonal antibodies to major histocompatibility complex antigens, development of a unique large animal model for transplantation using miniature swine, use of mixed marrow reconstitution as a means of inducing specific tolerance, and studies of specific transplantation tolerance to allografts and xenografts in murine, swine, and primate models.

Dr. Sachs received his MD from Harvard Medical School and then was a surgical resident at the Massachusetts General Hospital from 1968 to 1970. He moved to the National Institutes of Health in Bethesda, MD, where he developed a major program in transplantation research. He became chief of the immunology branch of the National Cancer Institute in 1982, where he stayed until returning to Harvard in 1991.

He is one of the three North American editors of Transplantation and was the founding editor of Xenotransplantation. He has served the Transplantation Society as councilor and vice president for several terms. He was elected to the Institute of Medicine of the National Academy of Sciences in 1996. He has received the Jean Borel Award in Transplantation, the ASTP/Novartis Established Investigator Award, the Medical Foundation Award, the Roche AST Distinguished Achievement Award, and the Martin Prize for Excellence in Clinical Research. He holds an honorary degree from the University of Nantes, France.
Robert A. Star

The complex relationship between sepsis and acute kidney injury will be examined in the Robert W. Schrier Endowed Lectureship, titled, "Sepsis AKI: Kidney as Amplifier and Target," on Thursday, Nov. 1, at 2 p.m.

The speaker will be Robert A. Star, MD, director of the Division of Kidney, Urologic, and Hematologic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). He is also a senior investigator and chief of the renal diagnostics and therapeutics unit at the NIDDK.

Dr. Star has a particular interest in translational research. His laboratory focuses on the early identification, prevention, and preemption of sepsis and acute kidney injury. His research has produced more than 120 published manuscripts. He has written eight textbook chapters and holds several patents.

Dr. Star was a postdoctoral fellow at the National Institutes of Health (NIH) in the mid-1980s before joining the faculty of the University of Texas Southwestern Medical Center in Dallas. In 1999, he returned to NIH as a senior scientific advisor for kidney disease and to run a lab studying acute kidney injury. In 2002, he became senior advisor for clinical research in the NIH Office of Science Policy and Planning, where he worked on the NIH roadmap for medical research initiatives to re-engineer the clinical research enterprise. The roadmap aims to stimulate research and develop resources for cross-cutting, large, and complex projects with profound potential impact. He also led training and career programs for clinical researchers and helped develop the clinical and translational science awards.

Dr. Star graduated summa cum laude in applied mathematics from Harvard College and cum laude from the Harvard Medical School-Massachusetts Institute of Technology Joint Program in Health Sciences and Technology. His internship and residency in internal medicine were performed at Michael Reese Hospital in Chicago.

Dr. Star has received honorary awards and research support from NIH and the U.S. Food and Drug Administration. He received the Young Investigator Award recognizing excellence in nephrology research, jointly awarded by the American Society of Nephrology and the American Heart Association.

ASN gratefully acknowledges Otsuka America Pharmacuetical, Novartis, Astellas Pharma US, and several individuals for support of the Robert W. Schrier Endowed Lectureship.

Richard P. Lifton

Research showing that somatic mutations in a gene encoding a potassium channel lead to 40 percent of aldosterone-producing adenomas in the adrenal gland, a common cause of severe hypertension worldwide, will be the subject of the Barry M. Brenner Endowed Lectureship on Thursday, Nov. 1, at 2 p.m. Richard P. Lifton, MD, PhD, will speak on "Mutations in the K+ Channel KCNJ5 Produce Primary Aldosteronism."

Dr. Lifton is Sterling Professor of Genetics and Internal Medicine, chair of the genetics department, executive director of the Yale Center for Genome Analysis, and investigator at the Howard Hughes Medical Institute at Yale University School of Medicine in New Haven, CT. Dr. Lifton completed his clinical training in internal medicine at Brigham and Women's Hospital in Boston, served as chief medical resident there, and continued on the faculty at Harvard Medical School before being recruited to Yale in 1993.

Dr. Lifton's team used a DNA sequencing strategy called whole exome sequencing to sequence all 25,000 human genes in DNA from adrenal adenomas from four patients. They compared those sequences to each patient's own blood-cell DNA, searching for mutations that had occurred somatically in the tumors. They found very few protein-altering somatic mutations, only about two per tumor. However, a gene encoding the KCNJ5 potassium channel was mutated twice. When the researchers studied other aldosterone-producing adenomas, they found one of the two mutations in KCNJ5 present in nearly 40 percent of them. These mutations alter the selectivity filter of the channel, allowing the passage of sodium into the cells. The resulting cell depolarization leads to increased intracellular calcium, the signal for aldosterone secretion and cell proliferation.

Dr. Lifton says that these findings reveal a surprisingly simple biology for the adrenal tumors and raise the possibility of developing a screening test to identify patients with these tumors by finding one of these two mutations in cells or tumor DNA in the blood.

Dr. Lifton has been a pioneer in using human genetics and genomics to identify more than 35 disease genes involved in key pathways underlying common diseases, including hypertension, myocardial infarction, osteoporosis, cerebral hemorrhage, congenital heart disease, and neoplasia. In the case of hypertension, these studies have led to new approaches to treatment and prevention strategies for the general population. His group recently developed a method for rapidly and inexpensively sequencing all the genes in the genome that is being widely used for disease gene discovery and clinical diagnosis.

Dr. Lifton is an elected member of the National Academy of Sciences and the Institute of Medicine. He chairs the scientific advisory board of Merck Pharmaceuticals and is a member of the governing councils of the Institute of Medicine, Association of American Physicians, and Coalition for the Life Sciences.

He has received the highest scientific awards of the American Society of Nephrology, Council for High Blood Pressure Research, American Society of Hypertension, American Heart Association, International Society of Hypertension, and International Society of Nephrology. He received the Wiley Prize for Biomedical Sciences in 2008.

ASN gratefully acknowledges Monarch Pharmaceuticals for support of the Barry M. Brenner Endowed Lectureship.
Health care reform remains one of the hottest issues of the day, so an expert who has seen the system from many angles in a multifaceted career will share his insights into what lies ahead in the state-of-the-art lecture on Friday, Nov. 2. A medical school dean, former health care company executive, and former high-level government official, William L. Roper, MD, MPH, has a unique perspective to share in his address, “Health Care Reform in America—Past, Present, and Future.”

Dr. Roper is dean of the school of medicine and vice chancellor for medical affairs at the University of North Carolina at Chapel Hill (UNC) and chief executive officer of the UNC Health Care System. He also is professor of health policy and administration in the School of Public Health and professor of pediatrics and of social medicine in the School of Medicine at UNC. He was dean of the UNC School of Public Health from 1997 to 2004.

Before joining UNC in 1997, Dr. Roper was senior vice president of Prudential HealthCare. He joined Prudential in 1993 as president of the Prudential Center for Health Care Research.

Dr. Roper was director of the U.S. Centers for Disease Control and Prevention from 1990 to 1993, a member of the senior White House staff from 1989 to 1990, and administrator of the Health Care Financing Administration (now the Centers for Medicare & Medicaid Services) from 1986 to 1989. He has also been a White House fellow.

He received his medical degree and his masters from the University of Alabama at Birmingham. He completed his residency in pediatrics at the University of Colorado Medical Center.

Dr. Roper is a member of the Institute of Medicine of the National Academy of Sciences. He is a member of the board of directors of DaVita, Inc.; a member of the board of directors of Express Scripts, Inc., a company that handles millions of prescriptions through home delivery and at retail pharmacies; a member of the Scientific Management Review Board of the National Institutes of Health; a member of the board of directors of the Partnership for a Healthier America, a nonprofit organization devoted to working with the private sector to address childhood obesity; and chair of the board of directors of the National Quality Forum, a private sector, consensus-standard–setting organization aimed at health care performance measurement.
**Expert on Rare Renal Disorder Tapped to Deliver Coburn Lectureship**

Studies of unusual disorders can shed light on the working of the kidney, and the lessons from one of these disorders will be the subject of the Jack W. Coburn Endowed Lectureship on Friday, Nov. 2, at 2 p.m. “Stone Formation in Dent’s Disease” will be the topic addressed by Rajesh V. Thakker, MD.

Dr. Thakker is the May Professor of Medicine at the University of Oxford. He was previously professor of medicine at the Royal Postgraduate Medical School, The Hammermith Hospital, London, and took up his present position in Oxford. Dent’s disease is a renal tubular disorder characterized by low-molecular-weight proteinuria, hypercalciuria, nephrolithiasis, nephrocalcinosis, and progressive renal failure. The disorder is caused by mutations in the X-chromosome-linked renal-specific chloride channel CLC-5. CLC-5 belongs to the family of voltage-gated chloride channels that function as homodimeric proteins.

Dent’s disease has been reported in some 250 families. The main symptoms are generally found in males only, and may be present in early childhood. The care is supportive, focusing on the treatment of hypercalciuria and the prevention of kidney stones. Progression to end stage renal failure occurs between the third and fifth decades of life in 30 to 80 percent of affected males.

Dr. Thakker will discuss how molecular studies and the generation of mouse models of the disease have increased our understanding of the renal tubular mechanisms that regulate mineral homeostasis. The findings fit with his main research focus on the molecular basis of disorders of calcium homeostasis.

Dr. Thakker is currently chair of the UK’s National Institute for Health Research/Medical Research Council (MRC) Efficacy and Mechanisms Evaluations Board. He has served on the MRC Physiological Medicine and Infections Grants Committee (1994 to 1997), the MRC Clinical Training and Career Development Panel (1997 to 2000), the MRC Physiological Medicine and Infections Board (2000 to 2005), and the Council for the Society for Endocrinology (2003 to 2006). He served as secretary to the Forum on Academic Medicine for the Royal College of Physicians (United Kingdom) and the Academy of Medical Royal Colleges (2002 to 2005).

He has received many prizes, including the Young Investigator Award and the Louis V. Avioli Founder’s Award from the American Society for Bone and Mineral Research, the Raymond-Horton Smith Prize (Cambridge University, United Kingdom), the Society for Endocrinology Medal (United Kingdom), the European Journal of Endocrinology Prize (European Federation of Endocrine Societies), and the Graham Bull Prize from the Royal College of Physicians (United Kingdom).

**Authority to Address Allocation of Dialysis and Other Scarce Resources**

The controversial issues involved in the future allocation of health care resources will be the subject of the Christopher R. Blagg Endowed Lectureship in Renal Disease and Public Policy. An expert with broad experience with Medicare and other programs, Bruce C. Vladeck, PhD, will speak on Friday, Nov. 2, at 2 p.m. on “Allocation of Health Care: Dialysis and Beyond.”

Dr. Vladeck is a senior adviser to Nexera, Inc., a consulting subsidiary of the Greater New York Hospital Association, which he joined in 2009. His varied career has included senior leadership roles in the public, nonprofit, academic, and business communities. He is a widely recognized expert in health care policy and finance.

Dr. Vladeck was administrator of the Health Care Financing Administration (HCFA, the predecessor of the Centers for Medicare & Medicaid Services) from 1993 through 1997, a period that included the Clinton administration’s failed health care reform attempt, the Contract with America and switch to Republican control of Congress, budget stalemates, and the Balanced Budget Act of 1997.

Dr. Vladeck’s time at HCFA was marked by innovation in Medicare programs through demonstration waivers, the development of Medicare prospective payment systems for many providers, and the implementation of the first quantitative quality measures for managed care plans. His work at HCFA was recognized in 1995 by a National Public Service Award. From 1998 to 1999 he served as a presidential appointee to the National Bipartisan Commission on the Future of Medicare.

After leaving HCFA, Dr. Vladeck spent 6 years as senior vice president for policy and as professor of health policy and geriatrics at Mount Sinai Medical Center in New York City. His assignments there ranged from managing the medical school’s affiliation with New York’s public hospital system to acting as interim chair of the department of geriatrics.

He served as interim president of the University of Medicine and Dentistry of New Jersey, which had lost its academic accreditation. During his 16-month tenure, he restored fiscal stability to the system; rebuilt its governance, compliance, and internal control processes; and laid the groundwork for restoration of its accreditation.

A graduate of Harvard College and the University of Michigan, Dr. Vladeck holds full-time faculty positions at Columbia University and Mount Sinai and has served as adjunct faculty at several institutions. He is a member of the Institute of Medicine of the National Academy of Medicine and serves on the boards of the Medicare Rights Center, a nonprofit consumer service organization; Ascension Health; and the New York City Board of Health.

ASN gratefully acknowledges the Northwest Kidney Centers and its contributors for support of the Christopher R. Blagg Endowed Lectureship in Renal Disease and Public Policy.
ASN FOUNDATION FOR KIDNEY RESEARCH
Mission: To prevent and cure kidney diseases through research and innovation

The Ben J. Lipps Research Fellowship Program

- Fund 10 new research applications and ten continuing projects a year beginning July 2013.
- Distribute $50,000 a year per fellow for two years to conduct original, meritorious research.
- Announce Thursday, November 1, 2012, during the Opening Plenary Session of ASN Kidney Week 2012 in San Diego, CA.

Funds 10 new research fellows annually, including:

- One Sharon Anderson Research Fellow (annually)
- Five Ben J. Lipps Research Fellows (annually)
- One George B. Rathmann Research Fellow (every other year)
- Three ASN Research Fellows (annually)
2013
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Founders Circle

The ASN Foundation Founders Circle recognizes donors year round for their generous contributions to the Ben J. Lipps Research Fellowship Program. Through this program, donors provide vital support to the next generation of physician scientists.

The ASN Foundation for Kidney Research gratefully acknowledges the following donors for their generous contributions.

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NIH Leader to Speak on Directions in Genomic Medicine

Eric D. Green

The head of the National Human Genome Research Institute (NHGRI) will deliver a state-of-the-art lecture on “Entering the Era of Genomic Medicine: Research Opportunities and Challenges.” Eric D. Green, MD, PhD, will speak on Saturday, Nov. 3.

As director of NHGRI at the National Institutes of Health (NIH) since 2009, Dr. Green is responsible for leading the investigative program and other initiatives of the largest organization in the world dedicated to genomics research.

He has been with the institute since 1994, previously serving as its scientific director (2002 to 2009), chief of its Genome Technology Branch (1996 to 2009), and director of the NIH Intramural Sequencing Center (1997 to 2009). While directing an independent research program for almost two decades, Dr. Green was at the forefront of efforts to map, sequence, and understand eukaryotic genomes, including significant, start-to-finish involvement in the Human Genome Project. This work blossomed into a productive program in comparative genomics that provided important insights about genome structure, function, and evolution.

Most recently, Dr. Green led NHGRI’s strategic planning process, which yielded a new vision for the future of genomics research, titled “Charting a Course for Genomic Medicine from Base Pairs to Bedside.”

He is a founding editor of the journal Genome Research and a series editor of Genome Analysis: A Laboratory Manual. He is co-editor of Annual Review of Genomics and Human Genetics. He has authored or co-authored more than 280 scientific publications.

Prior to being recruited to join NIH in 1994, Dr. Green was assistant professor of pathology, genetics, and internal medicine and a co-investigator in the Human Genome Center at Washington University in St. Louis, the university where he received his medical degree and doctorate. For his doctorate in cell biology, Dr. Green studied sugar molecules attached to proteins. But when the Human Genome Project began to be discussed in the 1980s, he switched scientific fields to follow his clinical interests in molecular diagnostics.

Dr. Green has received many awards and honors, including the Helen Hay Whitney Postdoctoral Research Fellowship, a Lucille P. Markey Scholar Award in Biomedical Science, the Lilian M. Gilbreth Lectureship for Young Scientists, and awards for his contributions in the fields of fluid-electrolyte and acid-base physiology. Dr. Narins has also contributed to developing new Accreditation Council for Graduate Medical Education guidelines for nephrology, initiating development of nephrology fellowship curricula including geriatric nephrology, creating travel grants and programs for medical students at Kidney Week, developing learning experiences for residents at Kidney Week, creating Kidney Week pathways for educators including education-based abstracts and symposia, promoting awareness of nephrology workforce shortages, creating an ASN nephrology TPD retreats, creating a course for new TPDs, redefining the structure of the TPD executive committee, and developing ASN webpages that contain extensive information for TPDs and nephrology fellows.

Dr. Kohan obtained a PhD in renal physiology in 1980 and an MD in 1982. For the past 25 years, his laboratory has examined the role of distal nephron autacoids, including endothelin, nitric oxide, prostaglandins, and other factors, in the control of urinary salt and water excretion and arterial pressure in health and in hypertension. His team pioneered renal cell-specific gene targeting.

Dr. Kohan has served on National Institutes of Health, VA, and American Heart Association study sections, including chairing the VA Nephrology Merit Review Committee. The importance of Dr. Kohan’s research has been recognized by virtue of his election to the American Society of Clinical Investigation and the Association of American Physicians.

Donald Kahn to be Given Narins Award For Contributions in Education

Donald E. Kohan

Donald E. Kohan, MD, PhD, FASN, who has been a leader in the educational efforts of ASN, will receive the Robert G. Narins Award for these and other contributions. Dr. Kohan is professor of medicine at the University of Utah Health Sciences Center in Salt Lake City.

He has served the University of Utah as chief of nephrology, nephrology fellowship training program director, and dean of graduate medical education. He has also been the chief of medicine at the Salt Lake City VA Medical Center.

The Narins Award honors those who have made substantial contributions to education and teaching, and that has been the focus of Dr. Kohan’s activities with ASN. He was the first ASN education director for nephrology fellowship training. He chaired the executive committee of the ASN training program directors (TPDs) from 2006 to 2011. He helped establish the subspecialty and ASN-in-training examinations. He contributed to developing new Accreditation Council for Graduate Medical Education guidelines for nephrology, initiating development of nephrology fellowship curricula including geriatric nephrology, creating travel grants and programs for medical students at Kidney Week, developing learning experiences for residents at Kidney Week, creating Kidney Week pathways for educators including education-based abstracts and symposia, promoting awareness of nephrology workforce shortages, creating an ASN nephrology TPD retreats, creating a course for new TPDs, redefining the structure of the TPD executive committee, and developing ASN webpages that contain extensive information for TPDs and nephrology fellows.

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Robert G. Narins

Robert G. Narins, MD, was the first recipient of the award now bearing his name. He taught and mentored countless students, serving on the faculties of the University of Pennsylvania, UCLA, Harvard University, Temple University, and Henry Ford Hospital. Well recognized for his contributions in the fields of fluid-electrolyte and acid-base physiology, Dr. Narins has also led numerous education efforts at the national and international levels. Among these, he has chaired the American Board of Internal Medicine’s Nephrology Board and worked on the American College of Physicians’ Annual Program Committee. From 1994 to 2006, he developed and guided ASN’s educational programs, including working to expand educational programs during Renal Week (Kidney Week). In addition, he was instrumental in the development of the Nephrology Self-Assessment Program (NephSAP) and the Clinical Journal of the American Society of Nephrology, and in establishing the Fellow of the American Society of Nephrology program. Dr. Narins is also credited for working with organizations in Europe and Asia to help promote education and teaching in nephrology.
ASN will recognize the wide-ranging contributions of Thomas D. DuBose Jr., MD, FASN, MACP, with the presentation of the John P. Peters Award.

Dr. DuBose is the Tinsley R. Harrison Chair of Internal Medicine and professor of physiology and pharmacology at Wake Forest School of Medicine in Winston-Salem, NC. The 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, and Dr. DuBose’s achievements span the field from research to service.

Dr. DuBose has served as division chief of nephrology at two institutions, the University of Texas Medical Branch, Galveston, and the University of Texas Medical School, Houston. Prior to being recruited to Wake Forest, he was the Peter T. Bohan Professor and chair of the department of medicine at the University of Kansas School of Medicine.

Throughout his research career, Dr. DuBose has focused on elucidating factors governing the regulation of tubule transporters involved in urinary acidification and potassium homeostasis. These transporters have been implicated in monogenic diseases associated with renal tubular acidosis, the chronic metabolic acidosis of chronic progressive kidney disease, and abnormalities in potassium balance and blood pressure regulation.

His studies with Dr. David Good at the University of Texas uncovered the interdependence of potassium homeostasis and ammonium excretion. Their studies in animal models provided a better understanding of the role of hyperkalemia in the development of metabolic acidosis and of hypokalemia in the perpetuation of metabolic alkalosis, underscoring the importance of the correction of these conditions for treatment.

His studies using microelectrode methodology validated the reliability of the urine minus blood CO2 tension as an index of distal tubule H+ secretion in the rat collecting duct, and extended these observations to experimental models of distal renal tubular acidosis. He and his colleagues were among the first to show that while both gastric and colonic α-subunits of H+,K+-ATPase play a role in urinary acidification in the kidney, the colonic α H+,K+-ATPase is site-specifically upregulated in the collecting duct by potassium deprivation in an animal model of chronic hyperkalemia. These studies showed the importance of this proton transporter in the metabolic alkalosis associated with hypokalemia.

Dr. DuBose is an author of 164 published papers and chapters in textbooks. With Dr. Lee Hamm he co-edited the text Acid-Base and Electrolyte Disorders.

Dr. DuBose served as ASN president in 2006. He has also served the society as chair of the Chronic Kidney Disease Advisory Group, a member of the board of advisors, and as its representative on the Council of Subspecialty Societies of the American College of Physicians. He chaired the American Heart Association Council on the Kidney in Cardiovascular Disease and served as a member of the board of regents of the American College of Physicians.

He has also received the Donald W. Seldin Award and the President’s Award of the National Kidney Foundation, and the Distinguished Achievement Award of the American Heart Association Council on the Kidney in Cardiovascular Disease.

Belding H. Scribner, MD, developed the arteriovenous shunt, which made possible long-term hemodialysis for chronic renal failure.

Dr. Scribner served as head of the University of Washington’s Division of Nephrology in the Department of Medicine from 1958 to 1982. He and his co-workers at the Seattle university made numerous contributions to helping patients with end-stage renal disease, including establishing the world’s first out-of-hospital dialysis unit, developing a home hemodialysis program, improving techniques and equipment for hemodialysis and peritoneal dialysis, and studying the adequacy and complications of chronic renal disease treated by dialysis.

Dr. Scribner’s work made a significant contribution to transforming nephrology into a major subspecialty of internal medicine.
Plenary Session

State-of-the-Art Lecture

Trailblazer Explores History and Outlook of Kidney Disease

The past and future of kidney disease will be the subject of a state-of-the-art lecture on Sunday, Nov. 4. Robert W. Schrier, MD, professor emeritus at the University of Colorado, Denver, will speak on “Where Kidney Disease Was and Where It Is Headed.”

Dr. Schrier chaired the department of medicine at the University of Colorado School of Medicine for 26 years and headed the division of renal diseases and hypertension for 20 years. In 1989, he was elected a member of the Institute of Medicine of the National Academy of Sciences. He has been president of the American Society of Nephrology, National Kidney Foundation, International Society of Nephrology, and Association of American Physicians.

He has authored more than 1000 scientific papers and edited numerous books, including editions in internal medicine, geriatrics, drug usage, and kidney disease. His research contributions center on autosomal dominant polycystic kidney disease; pathogenesis of acute renal cell injury; hypertension and diabetic nephropathy; and renal and hormonal control of body fluid volume in cirrhosis, cardiac failure, nephrotic syndrome, and pregnancy. The National Institutes of Health has funded his research for more than 40 years.

During Dr. Schrier’s tenure as chair of the department of medicine at the University of Colorado, the full-time faculty increased from about 75 to 500. The annual research grants the faculty received rose from $3 million to $100 million. As its staff and training programs became nationally prominent, the institution established 30 endowed research chairs. In recognition of these achievements, the governor of Colorado and mayor of Denver issued proclamations designating May 4, 2002, as Robert W. Schrier Day. That year, Dr. Schrier also received the prestigious Belle Bonfils-Stanton Award for Contributions in Science and Medicine.

Dr. Schrier has received honorary degrees from DePauw University, the University of Colorado, the University of Silesia, the University of Toledo, and the National Academy of Medicine of Belarus. He has received the highest awards of the American Society of Nephrology (John P. Peters Award), American College of Physicians (John Phillips Award), National Kidney Foundation (David Hume Award), International Society of Nephrology (Jean Humbel Award), German Society of Nephrology (Franz Vollhard Award), Western Society of Clinical Investigation (Mayo Soley Award), Association of Professors of Medicine (Robert H. Williams Award), American Kidney Fund (National Torchbearer Award), Association of American Physicians (Francis Blake Award), Acute Renal Failure Commission (Bywaters Award), New York Academy of Medicine (Edward N. Gibbs Memorial Award), University of Strasbourg (Louis Pasteur Medal), and American Association of Kidney Patients (Medal of Excellence). His international awards include the Grand Hamdan International Award for Medical Sciences (United Arab Emirates) and the Alexander von Humboldt Research Award (Germany).

Young Investigator Attains Recognition for Podocyte Research

ASN will present its Young Investigator Award to Tobias B. Huber, MD, for his groundbreaking research on podocyte biology. Dr. Huber will deliver the Young Investigator Address, titled “Podocyte Biology: The Key to Understanding Glomerular Diseases,” on Sunday, Nov. 4.

Begun in 1985, and co-sponsored by the American Heart Association’s Council of the Kidney, the Young Investigator Award recognizes an individual with an outstanding record of achievement and creativity in basic and patient-oriented research related to the functions and diseases of the kidney.

Dr. Huber is an associate professor of medicine, principal investigator of the Speman Graduate School, and attending physician in the renal division at the Freiburg University Medical Center in Germany. His translational research program involves model organisms, transgenic mouse models, high-throughput screening, systems biology, and high-resolution imaging approaches to studying glomerular signaling pathways in health and disease. His team elucidated several key molecular mechanisms of podocyte biology and progressive glomerular disease. They identified signaling programs that regulate podocyte cell survival, endocytosis, cytoskeletal organization, and polarity, which provided novel insights into how podocytes contribute to glomerular diseases. Recently, Dr. Huber’s team established a role of the mechanistic target of rapamycin (mTOR) gene and autophagy in progressive kidney disease and kidney aging. These studies have broad clinical implications, including for potential new therapeutic strategies.

Dr. Huber received his doctoral and medical degrees and completed his nephrology fellowship at the University Medical Center in Freiburg. He conducted his postdoctoral work with Thomas Benzing and Gerd Walz in Freiburg, and Andrey Shaw at Washington University in St. Louis, where his observations led to the discovery of novel protein complexes and functions of the slit diaphragm. Dr. Huber has received numerous honors, including three from the German Society of Nephrology: the Young Nephrologist Award in 2002, the Hans U. Zollinger Research Award in 2009, and the Franz Vollhard Award (the society’s highest research award) in 2010.
Thursday, November 1 • 12:45 p.m. – 1:45 p.m.
Emerging Concepts in Pathophysiology and Treatment of Uremic Pruritus
Support for this symposium is provided by an educational grant from
Mitubishi Tanabe Pharma

Membranous Nephropathy: Guidelines and Beyond
Support for this symposium is provided by an educational grant from

Targeting Progressive Kidney Disease: Can We Slow Progression?
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Friday, November 2 • 6:45 a.m. – 7:45 a.m.
Balancing Phosphorus Control and Adherence in Maintenance Dialysis Patients
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Friday, November 2 • 12:45 p.m. – 1:45 p.m.
Bundled Payments: Increased Transfusions, Changing Practice Patterns, No Quality Measures
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Clinical Approach to Hyponatremia: The Nephrologist’s Perspective
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It’s All About Balance: How Calcium and Phosphorus Influence Management of CKD-MBD
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New Approaches to Anemia Management in Chronic Kidney Disease
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Saturday, November 3 • 6:45 a.m. – 7:45 a.m
Calcineurin Inhibitors in Kidney Transplantation: What Have We Learned? Where Do Things Stand?
Support for this symposium is provided by an educational grant from

Innovation in a Bundled Payment Environment
This activity is supported by an educational donation provided by

Saturday, November 3 • 12:45 p.m. – 1:45 p.m.
Advances in Pathogenesis and Treatment of Complement-Mediated Thrombotic Microangiopathies: aHUS and STEC-HUS
Support for this symposium is provided by an educational grant from

Basic Science Symposium: Nanomedicine and Nephrology
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New Insights into the Management of Hyperparathyroidism in Dialysis and Kidney Transplant Patients
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As of 9/14/2012
Theophylline reduces contrast medium nephropathy risk

The adenosine receptor antagonist theophylline may lower the risk of acute kidney injury (AKI) induced by radiocontrast medium, according to a meta-analysis in Kidney International.

A literature review identified 16 randomized controlled trials comparing adenosine antagonists with control treatments to prevent contrast medium–induced AKI. In both arms, treatment could be with or without N-acetylcysteine. Data on 1412 participants were pooled to compare contrast medium–induced AKI rates, change in serum creatinine, dialysis requirement, and in-hospital mortality.

On the basis of data from 13 trials (1412 patients), theophylline reduced the risk of contrast medium–induced AKI by about half: risk ratio 0.48. Theophylline also had a protective effect on absolute change in serum creatinine: standardized 4 mean difference −0.31 mg/dL, based on 13 trials (1170 patients). It did not appear beneficial in patients with serum creatinine of 1.5 mg/dL or higher.

On metanalysis, the risk of contrast medium–induced AKI was related to baseline serum creatinine level. There was no consistent effect on rates of dialysis or in-hospital death, both of which were infrequent.

Animal studies have suggested that theophylline and aminophylline have the potential to protect kidney function after the injection of contrast medium. However, clinical studies of adenosine receptor antagonist treatment have yielded conflicting results.

Existing data suggest that theophylline reduces the risk of contrast medium–induced AKI, with a modest but significant improvement in kidney function after exposure to contrast medium. The authors call for high-quality randomized trials, including patients at different levels of baseline risk and evaluation of long-term outcomes [Bai B, et al. J Am Soc Nephrol 2009;20:671A-672A].

Late episodes of acute rejection carry higher risk of graft loss

Acute rejection events become less frequent with time since transplantation, but later events may have a greater impact on graft survival, suggests a report in Transplantation.

The researchers analyzed U.S. Renal Data System data on 48,179 kidney transplantations from 2000 to 2007. The Organ Procurement and Transplant Network was used to gather data on acute rejection events, which were classified as antibody-treated or not. Acute rejection was analyzed for association with all-cause graft loss, by use of a time-varying Cox regression approach.

The rate of non–antibody-treated acute rejection events (per 100 graft-years at risk) decreased from 9.93 6 months after transplantation to 8.43 at 12 months, 5.71 at 24 months, and 4.70 at 36 months. The rate of non–antibody-treated acute rejection was more than double the rate of antibody-treated events, across risk periods and donor types. Antibody-treated events were associated with a higher risk of graft loss than were non–antibody-treated events.

For antibody-treated acute rejection, the relative risk of graft loss increased with the time between transplantation and the rejection event. By contrast, the risk from non–antibody-treated events was highest 13 to 24 months after transplantation. Regardless of when acute rejection occurred, the associated risk of graft loss was higher in the first 89 days after the event, compared with 90 days and later.

This large study helps to clarify the rates and clinical impact of acute rejection after...
kidney transplantation. Acute rejection occurring a longer time after transplantation may lose the patient the risk of graft loss, with risk being highest less than 90 days after the event [Lenentine KL, et al. The implications of acute rejection for allograft survival in contemporary U.S. kidney transplantation. Transplantation 2012; 94:360–376].

Peritransplantation NGAL and IL-18 predict 1-year graft function

Two biomarkers of kidney injury measured shortly after transplantation are associated with allograft function after 1 year, reports a study in the Clinical Journal of the American Society of Nephrology. The prospective, multicenter study included 154 patients, mean age 54 years, undergoing deceased-donor kidney transplantation. The levels of neutrophil gelatinase-associated lipocalin (NGAL) and interleukin-18 (IL-18) were measured in early posttransplantation urine specimens. These biomarkers were evaluated for association with poor allograft function—defined as an estimated GFR of less than 30 mL/min/1.73 m²—at 1 year.

There was a 42 percent rate of delayed graft function. At 1 year, 16 percent of recipients met the study criteria for poor allograft function. Elevated levels of both biomarkers were significantly associated with the 1-year outcome. For patients with upper median values on the first day after transplantation, the adjusted odds ratios were 6.0 for NGAL and 5.5 for IL-18. The net reclassification improvement was 86 percent for urine NGAL and 45 percent for IL-18. There was no significant interaction between the biomarkers and delayed graft function. Changes in biomarker levels over consecutive days showed a moderate trend with 1-year allograft function.

New approaches are needed to predict outcomes after kidney transplantation. This study suggests that elevated levels of urine NGAL and IL-18 are both associated with poor allograft function 1 year after transplantation. The biomarkers may have “potential for identifying patients for therapies that minimize the risk of additional injury,” the investigators conclude [Hall IE, et al. Association between peritransplant kidney injury biomarkers and 1-year allograft outcomes. Clin J Am Soc Nephrol 2012; 7:1224–1235].

Colonoscopy for screening after kidney transplantation?

Kidney transplant recipients have high rates of advanced colorectal neoplasia and cancers, which are better detected by colonoscopy than by fecal hemoglobin screening, suggests a study in the British Medical Journal.

The cross-sectional study included 229 Australian kidney transplant recipients, mean 9.0 years since transplantation. All were at least 50 years old, and, aside from kidney transplantation, at average risk of colorectal cancer. The patients underwent fecal immunochemical testing for hemoglobin followed by colonoscopy with histologic examination of biopsy specimens. The two tests were compared for detection of advanced colorectal neoplasia: adenoma at least 10 mm in diameter, villous features, high-grade dysplasia, or colorectal cancer.

Advanced colorectal neoplasias were detected by colonoscopy in 13 percent of patients and by fecal hemoglobin in 12 percent. Colonoscopy detected colorectal cancer in five patients, three of whom had abnormal results on fecal hemoglobin testing. The fecal test had 31 percent sensitivity and 90.5 percent specificity for the detection of advanced colorectal neoplasia; positive and negative predictive values were 52.1 percent and 90.1 percent, respectively. One additional case of advanced neoplasia would be detected for each eight colonoscopies performed.
CKD linked to increased stroke and embolism risk in AF

When chronic kidney disease (CKD) and atrial fibrillation (AF) occur together, the rates of stroke, thromboembolic events, and hemorrhage are higher than with AF alone, reports the New England Journal of Medicine.

A study from 1997 to 2008 were used to identify 132,372 patients with nonvalvular atrial fibrillation. The risks of stroke, systemic thromboembolism, and bleeding were compared for patients with and without CKD. The risks and benefits of treatment with aspirin and warfarin were also compared.

Of this population of AF patients, 2.7 percent had non–end-stage CKD and 0.7 percent had end-stage disease requiring renal replacement therapy. The risks of stroke and systemic thromboembolism were elevated in both kidney disease groups: hazard ratio 1.49 for those with non–end-stage CKD and 1.83 for those receiving renal replacement therapy. The excess risks associated with kidney disease were lower for patients receiving warfarin, but not aspirin.

The bleeding risk was also increased for patients with kidney disease: hazard ratio 2.24 for non–end-stage CKD and 2.70 for disease requiring renal replacement therapy. These risks were further increased for patients taking warfarin, aspirin, or both. In the non–end-stage CKD group, higher doses of loop diuretics were associated with increased bleeding risk. Atrial fibrillation and CKD are both associated with increased rates of stroke or thromboembolism. The new study reports that both risks are significantly increased for patients with both diagnoses, compared with AF alone. Warfarin can increase the risk of stroke or thromboembolism in patients with CKD and AF, but bleeding risk is increased with warfarin, aspirin, or both (Olesen JB, et al. Stroke and bleeding in atrial fibrillation with chronic kidney disease. N Engl J Med 2012; 367:625–635).

Kidney stones increase risk of later kidney disease

A history of kidney stones carries a small but significant increase in the risk of loss of kidney function—ESRD—reports a study in the British Medical Journal.

The researchers identified the Alberga Kidney Disease Network database, the researchers identified more than 3 million adult patients who were free of ESRD or a history of pyelonephritis at baseline. Nearly 2 million had available data on outpatient serum creatinine levels. During follow-up, one or more kidney stones developed in about 27,000 patients—a rate of 0.8 percent. Kidney stones were evaluated as a risk factor for adverse renal outcome including incident ESRD, stage 3b to 5 chronic kidney disease (CKD), or sustained doubling of serum creatinine level.

The rates of adverse renal outcomes during follow-up were 0.2 percent for
ESRD, 4.0 percent for stage 3b to 5 CKD, and 3.0 percent for doubling of serum creatinine. Compared with stone-free patients, those with even one episode of kidney stone recurrence had an increased risk of all three outcomes: adjusted hazard ratio 2.16 for ESRD, 1.74 for CKD, and 1.94 for doubling of serum creatinine.

The excess risk related to kidney stone recurrence was greater for women and for people younger than 50, although the association was significant for both sexes and all age groups. Absolute increases in risk were small: the unadjusted ESRD rate was 2.45 per million person-years in those with kidney stones versus 0.52 per million in those without stones.

Kidney stones are a common and potentially preventable problem. There are few data on their possible association with later kidney disease. This population-based study finds significant increases in the risk of ESRD and other adverse renal outcomes in patients with even a single episode of kidney stone recurrence. Absolute increases in risk are small. More research is needed to understand the mechanism of the associations and the best way to prevent kidney stones, particularly in young women. [Alexander RT, et al. Kidney stones and kidney function loss: a cohort study. BMJ 2012; 345:e5287].

Among kidney transplant recipients in stable condition, lower levels of kidney function are independently associated with increased mortality risk, according to a report in the American Journal of Transplantation.

The authors performed a post hoc analysis of a trial evaluating the effects of homocysteine-reducing B vitamins after kidney transplantation. The analysis included 4016 patients, mean age 52 years, 20 percent with a history of cardiovascular disease (CVD). Estimated GFR (eGFR) was evaluated for associations with incident CVD and all-cause mortality, adjusted for demographic factors, clinical and transplant characteristics, and traditional CVD risk factors.

Complete data were available for 3676 patients, who had 527 CVD events over a median follow-up time of 3.8 years. In the adjusted model, below a cutoff point of 45 mL/min/1.73 m², higher eGFR levels were associated with reduced risks of CVD and death. For both outcomes, the hazard ratio was 0.85 for each 5 mL/min/1.73 m² increase in eGFR. No association was present at eGFR levels ≥50 mL/min/1.73 m² or higher.

Although CVD is the main cause of mortality after kidney transplantation, it has been unclear how kidney function affects posttransplantation CVD outcomes. This study finds that below 45 mL/min/1.73 m², higher eGFR levels are independently associated with a lower incidence of CVD and a lower risk of death. “[Reduced] kidney function itself rather than preexisting comorbidity may lead to CVD,” the researchers conclude [Weiner DE, et al. Kidney function and risk of cardiovascular disease and mortality in kidney transplant recipients: the FAVORIT trial. Am J Transplant 2012; 12:2437–2445].
Higher anion gap linked to increased mortality

A higher serum anion gap early in the course of kidney disease is associated with significantly increased mortality, reports a study in *Kidney International*. Using data from 11,957 adults from the National Health and Nutrition Examination Survey 1995 to 2009, the researchers analyzed the relation between the anion gap, as an independent marker of kidney function, and mortality. Laboratory data were used to calculate the anion gap by the traditional method, with adjustment for albumin, or the full anion gap reflecting other electrolytes. The frequency of elevated anion gap relative to GFR was analyzed, including its association with mortality risk in study participants without advanced kidney disease.

The “traditional” anion gap was elevated only in participants with estimated GFR less than 45 mL/min/1.73 m². By contrast, significant findings were observed for the albumin-adjusted anion gap in patients with GFR values less than 60 mL/min/1.73 m², and for the full anion gap at GFR values of 90 mL/min/1.73 m².

With adjustment for body mass index, comorbidities, and other covariates, higher anion gap levels were associated with increased mortality. For the highest versus lowest quartiles, the relative hazard ratios were 1.62 for the albumin-adjusted anion gap and 1.64 for the full anion gap.

Uremia is associated with an increased serum anion gap, and it has been unclear whether elevations can occur earlier in the course of kidney disease. This study presents evidence that higher anion gaps can also occur with less advanced kidney disease and are associated with increased mortality. The authors call for further studies “to identify the unmeasured anions and to determine their physiological significance.” [Abramowitz MK, et al. The serum anion gap is altered in early kidney disease and associates with mortality. *Kidney Int 2012; 82:701–709*].

Rising rate of dialysis after major surgery

In Ontario, the use of short-term dialysis after elective major surgery has increased sharply since the mid-1990s, reports a study in the *Canadian Medical Association Journal*. Using Ontario health databases, the researchers analyzed more than 550,000 adults undergoing elective major surgery between 1995 and 2009. Trends in the rate of short-term dialysis (within 14 days) after surgery were analyzed, along with the outcomes of death within 90 days and the need for long-term dialysis.

The analysis included 2231 patients receiving short-term dialysis—overall rate 0.4 percent. However, the rate of short-term dialysis increased steadily: from 0.2 percent in 1995 to 0.6 percent in 2009. Patients undergoing cardiac and vascular surgery accounted for most of the increase. After cardiac surgery, the rate of short-term dialysis increased from 1 in 590 patients to 1 in 85 patients. The trend remained significant after adjustment for patient and surgical characteristics: odds ratio 1.7.

The 90-day mortality in patients receiving short-term dialysis was 42.0 percent, with no change over time. Of 1294 patients who received short-term dialysis and survived, 27.2 percent received dialysis.

The rates of short-term dialysis after surgery appear to be increasing. It is particularly important to understand the trends and outcomes of short-term dialysis associated with elective surgical procedures.

This study documents a substantial increase in the use of short-term dialysis after elective major cardiac and vascular surgery. The associated rates of death and long-term dialysis are stable and high. The results highlight the need for better approaches to the prevention and treatment of acute perioperative kidney injury. [Siddiqui NF, et al. Secular trends in acute dialysis after elective major surgery—1995 to 2009. *CMAJ 2012; 184:1257–1245*].

### Table 6: Viral and Fungal Infections (%) Reported Over 12–32 Months

<table>
<thead>
<tr>
<th>Drug</th>
<th>De Novo Renal Study</th>
<th>Maintenance Renal Study</th>
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<tr>
<td>MPA</td>
<td>1.44 g/day (n=273)</td>
<td>2.6 g/day (n=299)</td>
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<td>14.6%</td>
<td>19.1%</td>
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<tr>
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### Table 7: Adverse Events Reported in % of Patients Treated with Myfortic® in Combination with Ciclosporin® and Corticosteroids

<table>
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<tr>
<th>Adverse Event</th>
<th>De Novo Renal Study</th>
<th>Maintenance Renal Study</th>
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</thead>
<tbody>
<tr>
<td>Drug toxicity</td>
<td>Sodium/potassium</td>
<td>Sodium/potassium</td>
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<tr>
<td>Drug toxicity</td>
<td>Drug reaction</td>
<td>Drug reaction</td>
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<td>Drug reaction</td>
<td>Drug reaction</td>
</tr>
</tbody>
</table>

### Table 6: Viral and Fungal Infections (%) Reported Over 12–32 Months

- **Gastrointestinal**:
  - Diarrhea: 1.9%, 1.9%, 1.9% (de novo, maintenance, combined)
  - Indigestion: 3.8%, 3.8%, 3.8% (de novo, maintenance, combined)
- **Cardiac**:
  - Tachycardia: 1.9%, 1.9%, 1.9% (de novo, maintenance, combined)
- **Skin and Subcutaneous**:
  - Rash: 0.5%, 0.5%, 0.5% (de novo, maintenance, combined)
  - Acne: 0.5%, 0.5%, 0.5% (de novo, maintenance, combined)
- **General Disorders and Edema**:
  - Pyrexia: 0.5%, 0.5%, 0.5% (de novo, maintenance, combined)
- **Infections and Infestations**:
  - Nasopharyngitis, herpes simplex: 1.9%, 1.9%, 1.9% (de novo, maintenance, combined)

### Table 7: Adverse Events Reported in % of Patients Treated with Myfortic® in Combination with Ciclosporin® and Corticosteroids

- **Drug toxicity**:
  - Sodium/potassium: 1.9%, 1.9%, 1.9% (de novo, maintenance, combined)
  - Drug reaction: 3.8%, 3.8%, 3.8% (de novo, maintenance, combined)

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  - Tachycardia: 1.9%, 1.9%, 1.9% (de novo, maintenance, combined)
- **Skin and Subcutaneous**:
  - Rash: 0.5%, 0.5%, 0.5% (de novo, maintenance, combined)
  - Acne: 0.5%, 0.5%, 0.5% (de novo, maintenance, combined)
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- **Drug toxicity**:
  - Sodium/potassium: 1.9%, 1.9%, 1.9% (de novo, maintenance, combined)
  - Drug reaction: 3.8%, 3.8%, 3.8% (de novo, maintenance, combined)
A new review reports the use of bundled payments resulted in reduced health expenditures and small, but inconsistent, effects on patient care measures. The Agency for Healthcare Research and Quality (AHRQ) review did not evaluate the Medicare ESRD Prospective Payment System (PPS) and largely examined non-nephrology care. Researchers also examined how different designs for bundling services (e.g., payment methodology or risk-adjustment methods) and varying contextual factors (e.g., market variables or patient characteristics) influenced these outcomes. With health care spending continuing to rise and the report’s conclusion that bundled payments may reduce costs, AHRQ’s review should be assessed in the context of how the current dialysis bundled payment system influences care for patients with kidney disease.

The review Bundled Payment: Effects on Health Care (1) is part of a new AHRQ series—Closing the Quality Gap: Reviving the State of the Science—that “aims to provide critical analysis of the existing literature on quality improvement strategies for a selection of diseases and practices.” Bundled payments were evaluated because of “weak but consistent evidence” that these systems maintained the quality of health care while reducing associated costs. Researchers performed a literature review and selected 58 studies assessing the effects of bundled payments on health care spending and quality published between 1985 and 2011. Most studies were observational and in total examined 20 different implementations of bundled payments, including a Japanese study on bundling of hemodialysis medications.

Using bundled payments, physicians can apportion patient care in an effective manner, which “should create a financial incentive for providers to reduce the number and cost of services contained in the bundle,” according to the AHRQ review. Although researchers found evidence of this, the average reduction in expenditures after changing from a fee-for-service model to bundled payments was 10 percent or less, while the decrease in health care utilization ranged from 5 to 15 percent.

The effects on patient care were generally small but less uniform, with several studies on similar bundled payment systems reporting worse, similar, or improved quality measures after the change was introduced. A lack of both standardized outcome metrics and homogenous data contributed to this finding. Also missing was evidence on the negative consequences of bundled payments, although some studies did report a decrease in health care utilization through the transfer of patients to other care settings.

The diversity of bundling systems in the report precluded researchers from examining the impact of different designs and contextual factors. Also, the studies included focused on single institutional providers and were complete prior to recent implementations of PPSs (such as the Medicare ESRD PPS), which limited the generalizability of the findings. Despite observing consistent reductions in health care spending, AHRQ concluded “the strength of the body of evidence was rated as low,” and the results may not reflect the performance of current or future bundled payment models.

**Bundled payments and nephrology**

The AHRQ review included a Japanese study (2) on bundling payments for anemia medications for patients on hemodialysis. Investigators following 3,206 patients during the 1-year bundled payment rollout period found no change in the proportion of patients receiving recombinant human erythropoietin but an 11.8 percent reduction in dosage and a 9.6 percent increase in intravenous iron prescriptions. Patient care was assessed with hemoglobin levels, which remained stable during implementation of the bundling system.

Rajnish Mehrotra, MD, FASN—professor of medicine in the division of nephrology at the University of Washington and section chief at Harborview Medical Center in Seattle—recently co-authored a CJASN article (3) comparing mandated health care reforms, including the ESRD PPS and Quality Improvement Program (QIP), accountable care organizations, and the Affordable Care Act. He too has noted “evidence of reductions in use of erythropoietin-stimulating agents (ESAs) and increase in use of iron,” in the United States after the introduction of the ESRD PPS, which “could be deemed as a ‘reduction in healthcare utilization.’” He notes “if you take the quality measure and goal of reducing patients treated with ESAs with hemoglobin levels >12 g/dL, there has been a profound reduction in use, approximately a 10 percent absolute decrease. On the other hand, there have been some increases in the number of transfusions, which is a potentially adverse effect.”

The AHRQ report stated that quality incentives were not “an intrinsic part of the bundled payment mechanisms,” in many of the systems evaluated, even though the risk for negative effects exists. These include “unintended consequences within the bundle, avoidance of high-risk patients, and an increase in the number of bundles reimbursed,” the authors said. Ensuring a basic level of quality of care was a factor behind the ESRD Quality Improvement Program (QIP), the first mandated pay for performance initiative.

**Continued on page 39**
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Current quality measures for ESRD lack a strong evidence base, and Mehrotra said "there is a compelling need to identify additional metrics and determine whether they provide better information on patient risk and health, such as efficiency and patient centeredness of care." Comparative effectiveness research into how health care practices affect outcomes is needed because "there’s virtually no data on what it means to implement the bundle improves any of these other measures," he said.

The utilization of current metrics to assess performance in the QIP poses a threat to the individualization of patient care, Mehrotra said. "One size does not fit all, and this is particularly true with the management of a complex disease like ESRD." An example he points to is the proposed mineral metabolism measure, which will penalize facilities with a higher proportion of patients with calcium levels >10.2 mg/dL. "Yet the data that identifies calcium of 10.2 mg/dL as 'dangerous' or 'bad' is very weak, and a clinical trial that randomizes patients to different calcium levels is needed to determine whether it affects outcomes."

Just as the AHRQ review concluded, Mehrotra expects the use of bundled payments to expand, saying that "the perverse incentive of rewarding volume of care to diminish, otherwise it is difficult to see how health care costs will come down." But he sees benefits in the current dialysis bundle in "the rapid growth of the home dialysis population, which I personally believe to be a good development and is in line with the goals of CMS."

References

Kidney cancer roundup

Pfizer Inc. says that its oral drug Inlyta (axitinib) has been granted European approval for use as a second-line therapy for kidney cancer patients, according to Reuters News. The drug, already approved in the United States, has been approved in Europe as a second-line treatment for patients who have not responded to initial chemotherapy.

The company announced that the approval was based on data from a clinical trial showing that the drug significantly extended progression-free survival in patients who did not respond to treatment with a different Pfizer drug, Sutent.

In January 2012, axitinib was approved in the United States for the same indication as the European approval, Axitinib works by inhibiting proteins that can influence tumor growth and cancer progression.

Renal cell carcinoma (RCC) affects 102,000 people in Europe every year, the company reported.

In other kidney cancer news, Seattle Genetics has embarked on a clinical trial to assess the safety of its monoclonal antibody–based therapy for advanced RCC when certain other medications, such as sunitinib or sorafenib, have not worked.

SGN-75 is an antibody-drug conjugate composed of an antibody attached to a synthetic cell-killing agent, using Seattle Genetics' proprietary technology, according to the website Investor Report.

"We are encouraged by the preliminary single-agent activity and tolerability demonstrated by SGN-75 in RCC patients and by our preclinical data suggesting synergy," with drugs like everolimus, called mTOR inhibitors, said Jonathan Drachman, MD, senior vice president of research and translational medicine at Seattle Genetics. He said that his company looks forward to learning whether the combination "can provide therapeutic benefit to patients who currently have limited treatment options."

According to Seattle Genetics, the study is expected to enroll up to 40 patients at several centers in the United States and is enrolling patients who have previously been treated with one or two tyrosine kinase inhibitor drugs. Just as the AHRQ review concluded, Mehrotra expects the use of bundled payments to expand, saying that "the perverse incentive of rewarding volume of care to diminish, otherwise it is difficult to see how health care costs will come down." But he sees benefits in the current dialysis bundle in "the rapid growth of the home dialysis population, which I personally believe to be a good development and is in line with the goals of CMS."

References

Fresenius still largest nephrology quality data registry

For the fourth consecutive year since a federal data registry program was launched in 2007, Fresenius’ chronic kidney disease data registry has been the largest registry for nephrology. Fresenius and dozens of other registries have gained admittance as official registries in the federal program that requires physician quality-indicator reporting. That program, the Physicians Quality Reporting System (PQRS) is administered by the Centers for Medicare and Medicaid Services (CMS).

The Fresenius registry, known as Acumen PQRS, has been a qualified CMS data registry since 2009. In 2015, participation will be required of all eligible medical professionals who are eligible to report the work as described by the required indicators. The PQRS federal program was designed to enhance the quality of information reported by health care professionals.

"Acumen PQRS will continue to provide nephrologists with the best data registry for their practices," said Terry Ketchersid, MD, vice president and medical officer for Fresenius Medical Care, who directs the Acumen registry. "We are committed to maintaining our level of excellence."

The program uses both financial incentives and penalties to ensure high-quality reporting. The system pays physicians incentive bonuses for appropriate and correct use of registry reporting of quality measures. Beginning in 2015, eligible professionals who don’t participate will face a payment adjustment. The Acumen database added 700 new reporting members last year, Fresenius reported.

Each year, the measures can change in content. The Renal Physicians Association (RPA) has taken an active role in developing the nephrology measures used by the program. On September 4, the group wrote to Marilyn Tavenner, acting administrator for CMS, and asked for consideration of the same suggested quality measures submitted to CMS nearly a year ago, in October 2011. An example of a suggested quality measure would be percentage of calendar months within a 12-month period during which patients 18 years old and older with a diagnosis of ESRD who were receiving hemodialysis or peritoneal dialysis had a hemoglobin level below 10 g/dL.

The American Medical Association notes that "the CMS believes these quality initiatives aim to empower providers and consumers with information that would support the overall delivery and coordination of care, and ultimately would support new payment systems that provide more financial resources to provide improved quality care." Currently CMS reimburses for the volume of covered services.

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