

# Kidney News

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## New Physician Pay Program May Give ESCOs a Boost

By Bridget M. Kuehn



New value-based payment incentives from the Centers for Medicare and Medicaid Services (CMS) may entice more nephrologists and possibly dialysis organizations to participate in ESRD Seamless Care Organizations (ESCOs). CMS recently announced a second round of applications for participation in ESCOs; those

accepted would begin the model in January 2017.

A proposed rule published in April provided a first peek at how CMS' new system for paying physicians might work, including for physicians participating in "Alternative Payment Models" (APMs) such as ESCOs.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed the Sustainable Growth Rate formula previously used to establish Medicare payments for physicians. It provides incentives for doctors to participate in care delivery models that count as "Advanced APMs," which allow them to earn bonus payments and avoid potential Medicare reimbursement cuts. Un-

der the proposed rule, nephrologists who participate in ESCOs on the "Large Dialysis Organization" track would count as participating in an Advanced APM.

"It will definitely incentivize participation in ESCOs," said Suzanne Watnick, MD, a member of the ASN Public Policy Board and a professor at Oregon Health & Science University in Portland.

Thirteen dialysis organizations currently participate in ESCOs, the Comprehensive ESRD Care (CEC) Model launched in 2015. The CEC Model was intended to help evaluate and improve ESRD care. In the program, dialysis clinics, nephrologists, and other care providers partner to coordinate care for a population of Medicare beneficiaries with ESRD. Participating organizations reap the benefits of more streamlined and improved care for the population by sharing a portion of the savings to Medicare. Participants in the Large Dialysis Organization track, those with 200 or more dialysis facilities, also are liable for losses if they fail to yield cost savings. Small dialy-

*Continued on page 2*

## Nephrology Goes All-In: An Update on the Match

By Michael J. Ross and Kurtis Pivert

In the first year of the All-In Nephrology Match, the number of participating programs and training tracks rose to the highest level since the specialty joined the National Residency Matching Program's (NRMP's) Medical Specialties Matching Program. Although there was a slight increase in applicants choosing neph-

rology, the recent trend of increasing numbers of unfilled positions and programs continued. Nearly 60 percent of training tracks and over 40 percent of positions were left open on Match day.

The vast majority of nephrology training programs participated in All-In and potential nonparticipation was

circumscribed. NRMP's final Match data report released on March 7 noted that a total of 140 programs offered 158 training tracks (Clinical, Clinical Research, Research, and Other) and a record 466 fellowship positions for appointment year (AY) 2016. All-In's first year was therefore quite successful in increasing the number and percentage of nephrology fellowship positions offered through the Match.

Despite an increase in the overall number of candidates choosing nephrology (298, up from 252 in AY 2015), the number of non-US international

*Continued on page 3*

### Inside

#### NIH Director Interview

National Center for Complementary and Integrative Health Director on what kidney professionals should know about mind-body approaches to pain, herbal supplements, and more

#### Findings

Study urges increased awareness and education about preemptive transplant prior to dialysis initiation

#### Fellows Corner

My Journey to Nephrology, by Silvi Shah

#### International Collaboration

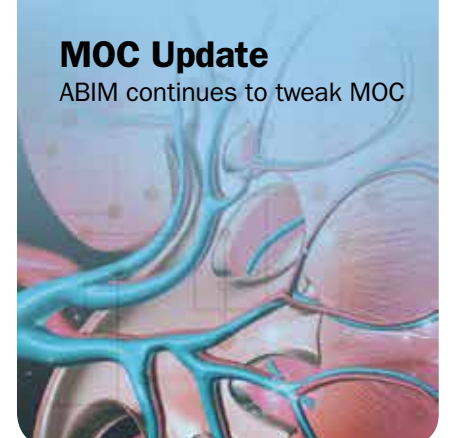
ASN, the International Society of Nephrology, and the European Renal Association-European Dialysis and Transplant Association announce declaration of collaboration

#### Policy Update

A patient, a fellow, and an MD on advocating for the Living Donor Protection Act, plus will 21st Century Cures advance?

#### MOC Update

ABIM continues to tweak MOC



## Physician Pay Program

Continued from page 1

sis organizations were not asked to take on this level of risk in CMS' first round of requests for ESCO participation—but those small dialysis organizations' ESCOs would not count as Advanced APMs under the new proposed rule.

Despite the lower risk requirements, the hurdles to participation in the ESCO program proved too much for many small dialysis organizations, and only one—the New York City-based Rogosin Institute—chose to participate. Many didn't have the resources to create necessary infrastructure or provide enough personnel to monitor patient care, Watnick said. Small organizations were also concerned that the outcomes they were being graded on weren't available upfront, she noted.

"It was going to be hard for small organizations with the resources they had," Watnick said. "People weren't clear they could realize a financial benefit."

"The challenges have been numerous for us and all [ESCOs]," said Jeffrey Silberzweig, MD, Rogosin's chief medical officer. The biggest challenges were creating the infrastructure, figuring out the role of care coordinators, and working with staff inside Rogosin and with specialists who see its patients elsewhere to reconcile patient medications. But he said he and his colleagues have found the effort worthwhile.

"It's really affording us an opportunity to evaluate the care we are providing our patients and to ensure we are providing the best level of care we can," Silberzweig said.

Large dialysis organizations like DaVita HealthCare Partners, based in Denver, Colorado, were drawn to the program because they were confident that their experience in integrated health care would help them be successful at meeting CMS' triple aim: improving patient experience, population health, and reducing health care costs.

"The model wasn't perfect, but we felt it was an opportunity to prove we could achieve the triple aim," said Stephen McMurray, MD, medical director of DaVita's integrated care wing, Village Health.

The ESCO model provides new resources for meeting patients' clinical and social needs inside and outside of the health care setting, said Nathan Lohmeyer, DaVita's Vice President of Government Programs.

"We think the model of care that can be provided through the [CMS ESCO program] is phenomenal," Lohmeyer said.

But success relies on full participation of nephrologists and other members of the care team, said McMurray. "It just doesn't work if the whole team isn't involved," he said.

Financial incentives in the MACRA rule as well as changes to the ESCO model are likely to entice more nephrologists and dialysis organizations to join the program, Watnick said.

Under the MACRA rule, beginning in 2019 physicians will be reimbursed either through the Merit-based Incentive Payment System (MIPS) or through participation in an Advanced APM. Physicians participating in Advanced APMs, entities that take on financial risk as well as benefit and meet certain other financial, electronic health record (EHR), and

quality criteria, would be eligible for their Medicare reimbursement plus a 5% bonus, Watnick explained. Physicians participating in MIPS could see their reimbursement increase—or decrease—4% in 2019 and up to 9% in subsequent years depending on their performance on four criteria (quality, clinical practice improvement activity, resource use, and EHR use).

Large dialysis organizations participating in ESCOs automatically qualify as an APM, according to the MACRA rule. Small organizations must take on some risk in order to qualify as an advanced APM, Silberzweig noted.

"We do think it's a good outcome for our participating nephrologists that our ESCO will be classified as an Advanced APM," said Lohmeyer. "The opportunity to participate in the Advanced APM track and possibly earn a bonus is a nice benefit."

But Lohmeyer said it wasn't clear whether these incentives for nephrologists alone would be enough to encourage organizations to form an ESCO. He noted that geography, startup costs, and other factors may make forming an ESCO impossible for some organizations.

Silberzweig noted that 2 to 3 small dialysis organizations have expressed interest in joining in the second round of the program.

CMS is accepting its second round of applications for participation in ESCOs through July 15. This time it has provided more detailed information about performance measures upfront, according to Watnick.

"It's not 100% clear, but it's a lot clearer than in the first round," she said.

Plus, dialysis organizations participat-

ing in the second round of ESCOs will have the advantage of learning from experienced programs, Silberzweig said. He also noted that CMS has been very responsive to his organization's concerns and has been willing to adapt the program.

"It makes us very enthusiastic about continuing to work with them," he said.

Many questions remain about the final form the MACRA rule will take. Among them are whether MACRA payments will start in 2019 based on 2017 performance as proposed or be pushed back, noted Lohmeyer. It's also unclear how the agency will calculate bonus eligibility for nephrologists participating in an ESCO, he said.

"CMS encourages and welcomes all interested parties to submit their suggestions on the proposed rule during the comment period, and is listening to the feedback we are receiving," said a CMS official in an emailed statement.

This provides an opportunity for nephrologists and dialysis organizations to really shape the MACRA rule to make sure their patients have access to the best care, said Watnick. For example, she said, it should be easy for patients to receive kidney transplants or palliative care if that's the best choice for them.

"We are in a period where we can impact what MACRA will look like," she said. "Patients with ERSD are some of the most socially and economically disadvantaged patients and are among the most chronically ill patients. Any new changes have to be patient-centric and improve not just quantity of life but also quality of life."

CMS is accepting comments on the MACRA rule through June 27. ●

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- Maintenance Dialysis
- Maintenance of Certification Review

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# Nephrology Goes All-In

*Continued from page 1*

medical graduates (IMGs) fell to its lowest level since Nephrology entered the Match (100 candidates, down from 331 in AY 2009). This decline is of concern because IMG physicians have comprised a majority of nephrology fellowship candidates over the past 8 years. Numbers of candidates applying to nephrology training programs from other educational backgrounds were stable (US medical graduates and osteopaths) or rose slightly (US IMGs) over AY 2015.

The increased participation and rebound in candidates doesn't obscure the shrinking pipeline of candidates choosing careers in nephrology. For every fellowship position offered in AY 2016, there were only 0.60 candidates, a marked decrease from 4 years ago when there were 1.1 candidates per fellowship position. The Match rate remained flat at 92.6 percent.

ASN Council has approved multiple initiatives to increase interest in nephrology careers at every stage of the educational continuum, such as the Kidney STARS and Kidney TREKS programs. ASN's ongoing nephrology workforce research collaboration with George Washington University has provided insights into the current and future generations of nephrologists, and informed the kidney community on trends for specialty researchers identified as "in transition." Recent publications have also highlighted the need for nephrology programs to consider resizing their training programs to optimize the balance between supply and demand for nephrologists, which should lead to an improved job market for graduating fellows.

## Monitoring the Match

After the declining participation in the nephrology Match, the ASN Council unanimously approved an All-In Policy for the Nephrology Match in 2015. As the official sponsor of the Nephrology Match, ASN believes All-In is the best approach for the specialty in the long term and helps ensure all candidates: 1) have fair and equal access to programs, and 2) can examine the full range of training opportunities before making a final decision. Moreover, the All-In Policy provides programs with an equitable system to evaluate candidates on an orderly and transparent schedule.

As part of the move to All-In, ASN established the ASN Match Oversight Task Force to monitor outcomes, assess participation, and make recommendations to ASN Council (Table 1). Convened in December 2015, the Task Force reviewed available data from NRMP and the Electronic Residency Application Service (ERAS) and

identified a limited number of programs potentially nonparticipating in ASN's All-In Policy. ASN is following up with a small number of programs to discuss their participation in the Match, and solicit their input and concerns about the process and recommendations on how ASN can better support their efforts in training the next generation.

## New features in the AY 2017 Application Cycle

As announced in 2015, programs participating in the All-In Nephrology Match will be listed in, and have access to, ERAS starting with the AY 2017 application cycle (Table 2). Because ERAS and NRMP have different processes and timelines for administering their Match responsibilities, ASN is asking programs to sign a memorandum of understanding (MOU) to provide ERAS the information it needs to verify programs/tracks participating in the AY 2017 All-In Nephrology Match. Programs and training tracks that enter into the MOU by Wednesday, June 15, 2016, at 5 p.m. EDT will be available for candidates to apply to when ERAS opens on Friday, July 1. Programs that enter into the MOU after June 15 will be listed, but ERAS will not inform candidates of any additions.

The ASN Match Oversight Task Force recommended, and ASN Council approved, extending eligibility for ASN benefits to participating programs, effective with the AY 2017 application cycle (Table 3). Additionally, ERAS has agreed to inform PGY-3 internal medicine residents that the Nephrology Match follows an All-In Policy. A series of emails will direct residents to ASN resources that can inform their consideration of additional subspecialty training and a career in nephrology. Finally, an annual census of fellows reporting for training in July will provide definitive data on nephrology training programs.

ASN's move to All-In will be followed by Infectious Diseases and Sleep Medicine this year, and other specialties are considering implementing similar policies. The level playing field All-In offers candidates in the Residency Match could someday be the norm for all specialties, giving candidates the best opportunity to make informed and unpressured choices about their careers.

For more information about the All-In Nephrology Match, please visit <https://www.asn-online.org/education/training/match/> or contact [nephrologymatch@asn-online.org](mailto:nephrologymatch@asn-online.org).

*Michael J. Ross, MD, FASN, is Chair of the ASN Match Oversight Task Force, Associate Professor, Director of the Nephrology Fellowship Program at the Icahn School of Medicine at Mount Sinai, and Chief of the Division of Nephrology at the James J. Peters VA Medical Center, in New York, NY.*

**Table 1. ASN Match Oversight Task Force**

**Chair: Michael J. Ross, MD, FASN**  
Icahn School of Medicine at Mt. Sinai  
James J. Peters VA Medical Center

**Sharon G. Adler, MD, FASN**  
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**Steven Cheng, MD**  
Washington University School of Medicine

**Scott J. Gilbert, MD, FASN**  
Tufts University School of Medicine

**Council Liaison: Mark E. Rosenberg, MD, FASN**  
University of Minnesota School of Medicine

**Table 2. All-In Nephrology Match Application Cycle for AY 2017**

<b>June 15, 2016</b>	Deadline to return signed All-In Nephrology Match MOU
<b>July 1, 2016</b>	Candidates begin submitting applications to ERAS
<b>August 31, 2016</b>	Match Opens
<b>October 5, 2016</b>	Rank Order List Entry Opens
<b>November 2, 2016</b>	Quota Change Deadline
<b>November 16, 2016</b>	Rank Order List Certification Deadline
<b>December 7, 2016</b>	Match Day

**Table 3. ASN All-In Nephrology Match—Benefits of Participation**

Training Program Directors (TPDs), faculty, and staff from participating programs will have access to the TPD toolkit information on the ASN site.

Participating programs will be included in the ASN website program listing with comparative search function for candidates.

TPDs and Division Chiefs from participating programs are eligible to serve as speakers at ASN Kidney Week.

TPDs and faculty from participating programs are eligible to be nominated for ASN committees.

TPDs and faculty from participating programs are eligible to apply for ASN and ASN Foundation for Kidney Research grant funding.



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## ASN President's Column

By Raymond C. Harris, MD, FASN



Raymond C. Harris, MD, FASN

Nephrologists have always been considered among the best educators in medicine. Our commitment to excellence in patient care and research extends to finding innovative ways to teach students, residents, and fellows about some of the most complex (and interesting) issues physicians and scientists face. Nephrologists also know how to provide complete care for a complex patient population in ways that most other specialties do not.

ASN has always honored its members' focus on training the next generation of nephrologists by devoting resources to educational programs. In the last 18 months, this commitment has included restructuring the Nephrology Match to implement an All-In policy. Last year, 95% of nephrology training programs in the US complied with this policy, and our goal for the upcoming year is 100% compliance.

The All-In policy offers candidates and programs the most fair and equitable Match process. I am pleased that a number of other specialty societies have approached ASN as a leader in this arena, asking for guidance as they begin to implement their own All-In policies.

However, while recognizing that the All-In policy is an important and necessary step for the good of our profession, such a change tends to amplify details of implementation and, temporarily, obscure larger goals and challenges. We are now entering our second year under the All-In policy, and, as educators we must focus on the strategies that optimize our

ability to equip the next generation of nephrologists for the challenges they will face.

- Does the size and scope of the program match the number of slots—is each fellow offered an enriching training experience?
- Does the fellowship advance workforce diversity?
- Does the institution adequately support the program, including program faculty?
- Do graduating fellows find jobs consistent with their career and personal objectives?
- Do program graduates pass the boards on their first attempt?
- Are physician-investigator graduates obtaining independent funding?

These are by no means the only questions we should ask ourselves, but they begin a conversation vital to strengthening both the field and the profession. And yes, we must do a better job attracting the best and brightest students to kidney care. ASN has developed an array of programs aimed at building the pipeline and supporting kidney professionals, and the society recently coalesced all training and workforce efforts in order to provide the most cohesive support for members and future members throughout their careers.

Still, the core of professional excellence in medicine remains providing the most inspired education and training programs to advance research, treatment, and policy. There is increasing awareness of the importance of outstanding educators in medical education, and it should be our goal to develop opportunities for training at all career levels. However, I think that it is especially vital that we provide an outstanding introduction to kidney function and disease to those early in training in order to “imprint” them, to sustain their interest in nephrology.

I encourage you to send me your thoughts ([info@kidneynews.org](mailto:info@kidneynews.org)) on how we can encourage and recognize the most inspiring educators, continue to build excellence in educating and training leaders, and continue to advance kidney care. ●

*The ASN President's Column also appears in Kidney News Online at [www.kidneynews.org](http://www.kidneynews.org).*

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**Hypomagnesemia:** VELTASSA binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of patients treated with VELTASSA. Approximately 9% of patients in clinical trials developed hypomagnesemia with a serum magnesium value



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\*Across 4 studies up to 1 year.

<sup>†</sup>Approximately 69% of all patients studied completed treatment at 52 weeks.

**Reference: 1.** Bakris GL, Pitt B, Weir MR, et al; for AMETHYST-DN Investigators. Effect of patiromer on serum potassium level in patients with hyperkalemia and diabetic kidney disease: the AMETHYST-DN randomized clinical trial. JAMA. 2015;314(2):151-161.



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# Findings

## Consider Preemptive Kidney Transplantation, New Guidance Suggests

Despite limitations of the current evidence base, preemptive kidney transplant programs “should be stimulated”—offering the option to consider transplantation before dialysis becomes necessary—concludes a systematic review and position statement published in *Nephrology Dialysis Transplantation*.

A systematic literature review by the

Descartes Working Group and the European Renal Best Practice Board identified 29 retrospective observational cohort studies providing information on preemptive living kidney donation. There were no randomized trials. Twenty-one papers reported on adult and 8 on pediatric recipients. Most studies used living-donor kidneys; only 2 studies reported using deceased-donor kid-

neys exclusively.

Patient survival was better with preemptive versus post-dialysis transplantation in 9 of 19 adult studies, with equivalent results in 4. Most studies reported better graft survival and acute rejection rates with preemptive transplantation. Outcomes were not significantly affected by dialysis periods of less than one year. Rates of delayed graft

function with preemptive transplantation ranged from 2.0 to 3.7%, compared to 4.0 to 9.7% with post-dialysis transplantation.

All papers were considered at high risk for selection bias; patients preemptively placed on the waiting list were in better health. There was no evidence of increased non-adherence among patients who had

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#### WARNINGS AND PRECAUTIONS

**Binding to Other Orally Administered Medications** VELTASSA binds many orally administered medications, which could decrease their gastrointestinal absorption and lead to reduced efficacy. Administer other oral medications at least 6 hours before or 6 hours after VELTASSA. Choose VELTASSA or the other oral medication if adequate dosing separation is not possible [see Drug Interactions].

**Worsening of Gastrointestinal Motility** Avoid use of VELTASSA in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because VELTASSA may be ineffective and may worsen gastrointestinal conditions. Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in the clinical studies.

**Hypomagnesemia** VELTASSA binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of patients treated with VELTASSA [see Adverse Reactions]. Monitor serum magnesium. Consider magnesium supplementation in patients who develop low serum magnesium levels on VELTASSA.

#### ADVERSE REACTIONS

The following adverse reaction is discussed in greater detail elsewhere in the label:

- Hypomagnesemia [see Warnings and Precautions]

**Clinical Trials Experience** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of VELTASSA cannot be directly compared to rates in the clinical trials of other drugs and may not reflect the rates observed in practice. In the safety and efficacy clinical trials, 666 adult patients received at least one dose of VELTASSA, including 219 exposed for at least 6 months and 149 exposed for at least one year. Table 1 provides a summary of the most common adverse reactions (occurring in  $\geq 2\%$  of patients) in patients treated with VELTASSA in these clinical trials. Most adverse reactions were mild to moderate. Constipation generally resolved during the course of treatment.

**Table 1: Adverse Reactions Reported in  $\geq 2\%$  of Patients**

Adverse Reactions	Patients treated with VELTASSA (N=666)
Constipation	7.2%
Hypomagnesemia	5.3%
Diarrhea	4.8%
Nausea	2.3%
Abdominal discomfort	2.0%
Flatulence	2.0%

During the clinical studies, the most commonly reported adverse reactions leading to discontinuation of VELTASSA were gastrointestinal adverse reactions (2.7%), including vomiting (0.8%), diarrhea (0.6%), constipation (0.5%) and flatulence (0.5%). Mild to moderate hypersensitivity reactions were reported in 0.3% of patients treated with VELTASSA in clinical trials. Reactions have included edema of the lips.

**Laboratory Abnormalities** Approximately 4.7% of patients in clinical trials developed hypokalemia with a serum potassium value  $< 3.5$  mEq/L. Approximately 9% of patients in clinical trials developed hypomagnesemia with a serum magnesium value  $< 1.4$  mg/dL.

#### DRUG INTERACTIONS

No formal drug interaction studies have been conducted in humans.

In *in vitro* binding studies, VELTASSA was shown to bind about half of the oral medications that were tested. Binding of VELTASSA to other oral medications could cause decreased gastrointestinal absorption and loss of efficacy when taken close to the time VELTASSA is administered. Administer other oral medications at least 6 hours before or 6 hours after VELTASSA. Monitor for clinical response and/or blood levels where possible.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

###### Risk Summary

VELTASSA is not absorbed systemically following oral administration and maternal use is not expected to result in fetal risk.

##### Lactation

###### Risk Summary

VELTASSA is not absorbed systemically by the mother, so breastfeeding is not expected to result in risk to the infant.

**Pediatric Use** Safety and efficacy in pediatric patients have not been established.

**Geriatric Use** Of the 666 patients treated with VELTASSA in clinical studies, 59.8% were age 65 and over, and 19.8% were age 75 and over. No overall differences in effectiveness were observed between these patients and younger patients. Patients age 65 and older reported more gastrointestinal adverse reactions than younger patients.

**Renal Impairment** Of the 666 patients treated with VELTASSA in clinical studies, 93% had chronic kidney disease (CKD). No special dosing adjustments are needed for patients with renal impairment.

#### OVERDOSAGE

Doses of VELTASSA in excess of 50.4 grams per day have not been tested. Excessive doses of VELTASSA may result in hypokalemia. Restore serum potassium if hypokalemia occurs.

#### PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

**Drug Interactions** Advise patients who are taking other oral medication to separate the dosing of VELTASSA by at least 6 hours (before or after) [see Drug Interactions].

**Dosing Recommendations** Inform patients to take VELTASSA as directed with food and adhere to their prescribed diets. Instruct patients to prepare each dose separately using the preparation instructions provided in the FDA-approved patient labeling (Medication Guide). Inform patients that VELTASSA should not be heated (e.g., microwaved) or added to heated foods or liquids and should not be taken in its dry form.

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Version 01; October 2015



no previous experience with dialysis. Few studies assessed the effects of preemptive transplantation on long-term complications such as malignancy or infection.

Based on the findings, the authors call

for increased awareness and early education about possible preemptive kidney transplantation. They add that decisions about preemptive transplantation should consider both clinical and biochemical

findings, rather than any fixed level of glomerular filtration rate [Abramowicz D, et al. Does preemptive transplantation versus post-start-of-dialysis transplantation with a kidney from a living donor improve out-

comes after transplantation? A systematic literature review and position statement by the Descartes Working Group and ERBP. *Nephrol Dial Transplant* 2016; 31:691–697]. ●

## Even Stage 1 AKI Increases CKD Risk

Even in mild cases with fast recovery, acute kidney injury (AKI) developing in the hospital is a strong risk factor for chronic kidney disease (CKD) at follow-up, reports a study in *The American Journal of Kidney Diseases*.

Using Veterans Health Administration data for 2011, the investigators identified nearly 105,000 hospitalized patients with normal baseline kidney function, no diagnosed kidney disease, and at least 2 inpatient serum creatinine

measurements. With varying follow-up times, the risk of CKD associated with AKI was analyzed. The analysis included not only the stage of AKI, but also the pattern of recovery: within 2 days (fast), 3 to 10 days (intermediate), and no recovery within 10 days (slow or unknown).

Ninety-one percent of AKI episodes were stage 1; recovery occurred within 2 days in 71% of cases. By one year, CKD had developed in 18.2% of patients:

31.8% of those with AKI versus 15.5% without AKI. Among patients with stage 1 AKI, risk of CKD increased with time to recovery. Adjusted relative risk ratio for CKD stage 3 or higher was 1.43 for fast, 2.00 for intermediate, and 2.65 for slow/unknown recovery. The relative risks were about the same on subgroup and sensitivity analyses.

In this cohort of veterans, inpatient AKI is associated with an elevated risk of developing CKD during follow-up.

The risk is significant even for the large group of patients with stage 1 AKI, and increases further with longer time to recovery. The authors discuss the implications for postdischarge follow-up of patients with inpatient AKI [Heung M, et al. Acute kidney injury recovery pattern and subsequent risk of CKD: an analysis of Veterans Health Administration data. *Am J Kidney Dis* 2016; 67:742–752]. ●

## New Equations Can Estimate Residual Kidney Function

Residual kidney function (RKF) in dialysis patients can be estimated by equations based on serum measures of endogenous filtration markers, avoiding the need for prolonged timed urine collections, reports a study in *Kidney International*.

Closely supervised 24-hour urine clearance values were obtained in a cohort of 44 dialysis patients in Baltimore. The researchers developed dialysis-specific equations to estimate urinary urea clearance, based on serum endogenous filtration markers. They then validated

the equations in 826 patients from an external cohort of Dutch dialysis patients.

Median urinary urea clearance values were 2.6 mL/min in the development cohort and 2.4 mL/min in the validation cohort. During 24-hour urine collection, concentrations of most serum filtration markers increased over time, with the exception of  $\beta$ -trace protein (BTP).

The equations developed in the Baltimore cohort showed low bias in the Dutch cohort. Compared to an equation using urea plus creatinine, precision was

higher for BTP and  $\beta$ 2-microglobulin (B2M) equations, while accuracy was higher for BTP, B2M, and cystatin C equations. For detection of a measured urinary urea clearance of 2 mL/min or greater, area under the receiver operator characteristic curve was 0.821 for the BTP equation, 0.850 for the B2M equation, and 0.796 for the cystatin C equation (compared to 0.663 for the urea plus creatinine equation).

Residual kidney function is strongly associated with survival in dialysis pa-

tients, but currently must be measured in timed urine collections. The new equations, based on serum filtration markers, can estimate RKF with good performance and diagnostic accuracy.

Further study is needed to evaluate the use of these equations for modifying dialysis dose. An online calculator can be found at [www.kidneymodels.org/rkf](http://www.kidneymodels.org/rkf) [Shafi T, et al. Estimating residual kidney function in dialysis without urine collection. *Kidney Int* 2016; 89:1099–1110]. ●

## HLA Mismatch Still Linked to Decreased Allograft Survival

Even in more recent periods, HLA mismatches show a linear association with the outcomes of kidney allograft survival, concludes a study in *Transplantation*.

The analysis included more than 189,000 first adult, deceased-donor, kidney-only transplants performed in the US from 1987 through 2013. Number of HLA mismatches was evaluated for associated-with-kidney-allograft survival, with adjustment for recipient and

donor characteristics.

In nearly 995,000 years of follow-up, HLA mismatch was significantly related to allograft survival. In the fully adjusted model, hazard ratio for allograft failure increased in linear fashion with each additional HLA mismatch: from 1.13 with 1 mismatch to 1.98 with 6 mismatches (compared to zero mismatches).

The effect of HLA mismatch remained significant after considering the

increasing success of kidney transplantation in recent years. Nearly all mismatch categories showed equal effect on the risk of transplant failure, independent of locus.

There are conflicting reports as to the importance of HLA matching as a determinant of kidney allograft survival. The new analysis shows a significant linear relationship of hazard ratios for allograft failure with the number of

HLA mismatches—even at a time of better transplant success rates. The investigators conclude that their results “reinforce the importance of optimizing HLA matching to further improve survival in renal allografts in the future” [Williams RC, et al. The risk of transplant failure with HLA mismatch in first adult kidney allografts from deceased donors. *Transplantation* 2016; 100:1094–1102]. ●

## Rosuvastatin Linked to Increase in Postoperative AKI

For patients undergoing heart surgery, treatment with rosuvastatin doesn't reduce the rate of adverse outcomes, but is associated with an increased risk of postoperative acute kidney injury (AKI), according to a randomized trial in *The New England Journal of Medicine*.

The Statin Therapy in Cardiac Surgery (STICS) trial included 1922 patients undergoing elective coronary artery bypass grafting and/or aortic valve replacement. All were in sinus rhythm and not taking antiarrhythmic drugs. Patients were randomly assigned to receive rosuvastatin 20 mg/d or

placebo, starting up to 8 days before surgery and continuing until 5 days afterward.

The 2 primary outcomes were atrial fibrillation developing within 5 days after surgery (based on Holter electrocardiographic monitoring) and myocardial injury developing within 120 hours (based on troponin T measurement). The wide range of secondary outcomes included AKI, based on Acute Kidney Injury Network criteria.

Postoperative atrial fibrillation occurred in 21% of patients in the rosuvastatin group and 20% in the placebo group.

Troponin I release was also similar between groups; primary outcomes were no better with rosuvastatin in any patient subgroup.

Most secondary outcomes were also no different with rosuvastatin versus placebo. However, plasma creatinine increased to a greater extent with rosuvastatin, and remained elevated up to 5 days after surgery. Rates of any AKI at 48 hours were 24.7% with rosuvastatin and 19.3% with placebo. While most cases of AKI were stage 1, there was also a significant excess of stage 2 or 3 AKI (1.8 percentage points).

The STICS results question the recommendation to use perioperative statins to prevent atrial fibrillation and other complications after cardiac surgery. The findings also raise concern about an increased risk of AKI in patients assigned to rosuvastatin. The researchers write, “Given the lack of good evidence of beneficial effects of perioperative statin therapy... the adverse effects on renal function warrant careful consideration [Zheng Z, et al. Perioperative rosuvastatin in cardiac surgery. *N Engl J Med* 2016; 374:1744–1753]. ●

# Complementary and Integrative Health in Kidney Care

*This month, Kidney News interviews Josephine P. Briggs, MD, director of the NIH National Center for Complementary and Integrative Health.*



Josephine P. Briggs, MD

**KN:** You direct a center that underwent a name change from the National Center for Complementary and Alternative Medicine to the National Center for Complementary and Integrative Health (NCCIH). What is the significance of the change from “alternative medicine” to “integrative health,” especially with regard to kidney care?

**Dr. Briggs:** Many population surveys have shown that the use of true “alternative” medicine by Americans—that is, alternative practices instead of conventional care—is not common. Americans are generally using complementary approaches as adjuncts to conventional care, integrated with conventional care. And integrative care, especially for pain management, is increasingly offered in a variety of health care settings across the country, including hospices, nursing homes, and military facilities. Mind-body approaches such as relaxation techniques have potential application in dialysis units.

**KN:** At Kidney Week 2014, you were presented with the John P. Peters Award for outstanding contributions to improving the lives of patients and to furthering the understanding of the kidney in health and disease. Tell us how your focus on translational research brings a better understanding to the usefulness and safety of complementary and integrative health.

**Dr. Briggs:** As a researcher and physician I have long been aware of the challenge of building rigorous clinical evidence. In many areas of science we talk about the challenge of moving from the bench to the bedside—turning the ideas that we pursue in the laboratory into improved health strategies for patients in need. But we also face the challenge of going from the bedside back to the bench—capturing the observations and wisdom of experienced practitioners to aid in building clinical studies that help develop a rigorous evidence base. Translational research helps us address these challenges. It also addresses a third hurdle—ensuring that new scientific insights actually lead to improved health care in our communities. All of these challenges are as relevant to the NCCIH as any other National Institutes of Health (NIH) institute or center.

For promising complementary approaches, we need and continue to constantly ask ourselves tough questions:

- Do we have the understanding and needed methodologic tools to perform definitive human subject studies on this therapy?
- Do we have adequate proof-of-concept data to justify the investment?
- Do we understand dosage and bioavailability?
- Have we developed surrogate markers that establish that the intervention has an effect?

If we can’t answer “yes” to these questions, then what do we need to do to move this research to the next step? To address gaps in this area, the NCCIH has funded several initiatives to develop tools and methods for translational research.

**KN:** How many people in the US use complementary or integrative approaches to health care?

**Dr. Briggs:** Approximately one-third of American adults use complementary and integrative health approaches.

**KN:** Recent reports have found a large degree of contamination or faulty labeling of herbal and dietary products available for purchase as complementary remedies. Does the NCCIH provide resources for, or recommend any best practices for, selecting complementary therapies that have clearly identified safety profiles?

**Dr. Briggs:** Our web site provides a great deal of information about the safety of dietary supplements. As well, we link to safety alerts and recalls from the US Food and Drug Administration: <https://nccih.nih.gov/health/supplements/wiseuse.htm>

**KN:** Are kidney patients who use complementary herbs or supplements along with traditional medical approaches in their care likely to tell their physicians about the complementary approaches?

**Dr. Briggs:** We do not have data collected specifically on kidney patients. However, we do know from past surveys that a large number of patients do not discuss the use of complementary health approaches with their physicians.

**KN:** How can nephrologists help make their patients more aware of potential herb–drug or supplement–drug interactions?

**Dr. Briggs:** We recommend that physicians or medical staff ask patients about their use of these supplements when asking about any other medication the patient may be taking. As well, patients should be encouraged to discuss these products with their physician in an open dialogue.

**KN:** Outbreaks of aristolochic acid nephropathy (also called Chinese herb nephropathy or Balkan endemic nephropathy) demonstrate the potential for nephrotoxicity that some herbs possess. What are the most common herb–drug or supplement–drug interactions that affect kidney health?

**Dr. Briggs:** Regarding nephrotoxicity, the Chinese herb that raised everyone’s awareness regarding aristolochic acid is *Aristolochia fangchi*. Several other plants in the *Aristolochia* genus also contain aristolochic acid and therefore should be avoided because of potential nephrotoxicity. I am not aware of other plants that cause this type of direct nephrotoxicity. For drug interactions, the first one that comes to mind is St. John’s Wort, which should be avoided by anyone who has had a kidney transplant because it will interact with the immunosuppressants that transplant patients commonly take and therefore could cause organ rejection.

**KN:** Kidney patients often have multiple other chronic conditions. How can a complementary or integrative approach fit into their care?

**Dr. Briggs:** Many of the mind and body therapies are used to help with symptoms, such as pain management. Some of these approaches may help promote a healthier lifestyle and provide patients who have limited mobility and other health concerns with more options for lower-impact exercise options, such as yoga and tai chi.



**KN:** Are there any special considerations or different methods investigators must use when conducting complementary health research and evaluating its outcomes?

**Dr. Briggs:** The research we fund uses the same rigor as any other institute and center at the NIH. Where we are unique at the NCCIH is that many complementary approaches are readily available in the marketplace. As a consequence, the NCCIH sits at the crossroads between research and real-world consumer use. The general public wants to know what works and what doesn't, and health care providers also want reliable information. Complementary health approaches are being integrated into the care offered in many nursing homes, hospices, and hospitals, and these health care organizations want good information to drive decisions about which therapies to provide or recommend.

The NCCIH wants to take on the challenge of meeting this need. Often, the kind of rigorous, high-quality data that would answer these questions are not yet available. This unique situation

has made us aware of the importance of better methods to do real-world, or pragmatic, research. Driven by this interest, we volunteered about 4 years ago to take on a major administrative and leadership role in an NIH Common Fund initiative called the Health Care Systems Research Collaboratory. This program is engaging health care delivery organizations as research partners, with the goal of building methods to conduct rigorous large-scale clinical trials in real-world settings. Through the Collaboratory, the NIH is pioneering the development of approaches to conduct large-scale, cost-effective clinical research studies in the settings where patients already receive their care.

**KN:** What is (are) the most common misconception(s) people have about complementary medicine in general, and the NCCIH in particular?

**Dr. Briggs:** I think some people are unaware of what we research here at the NCCIH. About half of our portfolio is dedicated to mind and body therapies, mostly looking at symptom manage-

ment, and the other half to dietary supplements, including safety and efficacy. About one-third of our portfolio is dedicated to pain research. The most common reason people turn to complementary health approaches is for pain management, which is why this area of research is so important to us at the NCCIH. Pain is a huge public health burden, and people are looking for options, outside of drugs and other conventional medicine, to help with their pain. We're researching options to give people gentler ways of managing their pain.

**KN:** What will be the most promising areas of research at the NCCIH over the next 5 to 10 years?

**Dr. Briggs:** Symptom management, mainly pain management, will continue to be a promising area of research, as will research on how complementary health approaches can help promote healthy lifestyles, wellness, and disease prevention. Another focus that is becoming more central to our research at the NCCIH is our work on pragmatic trials through the Health Care Systems Research Collaboratory. ●

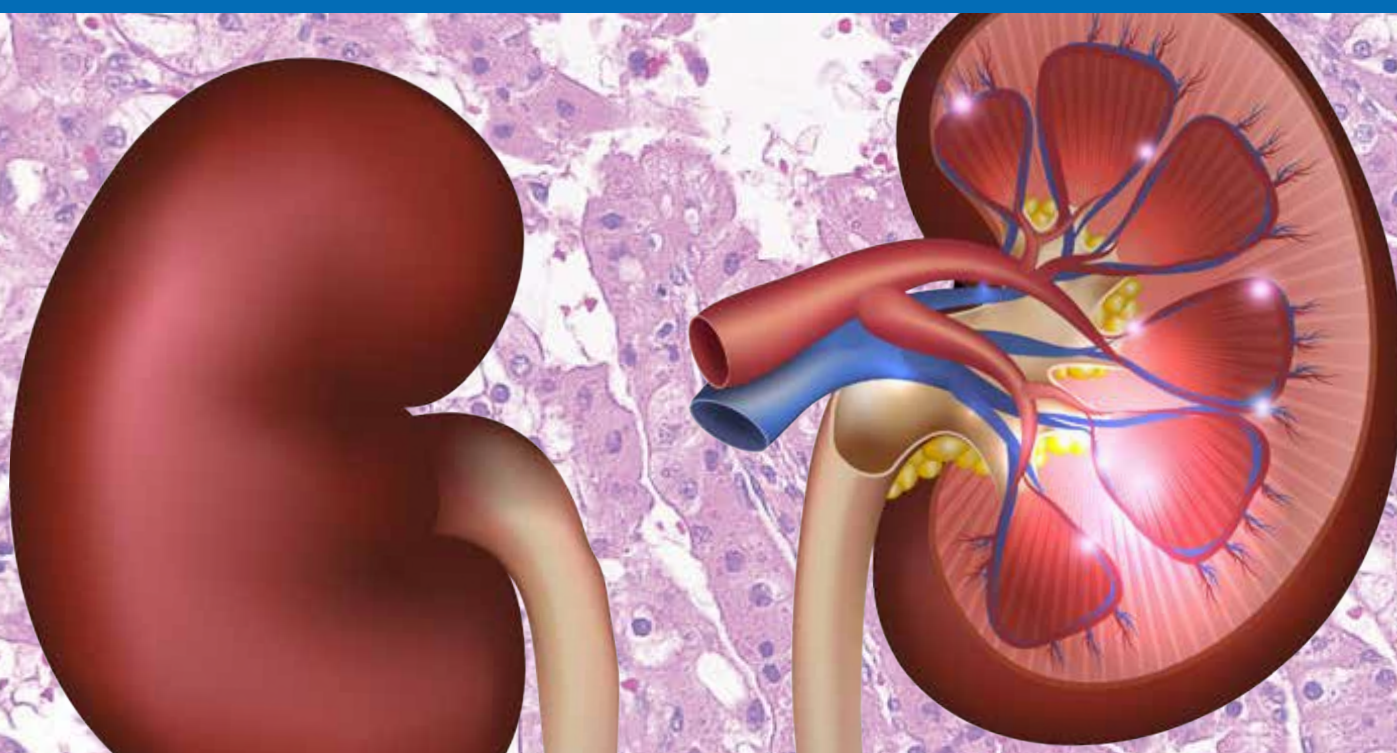
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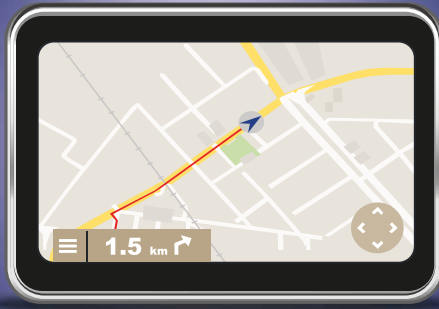
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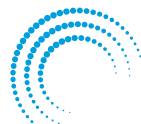
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## Policy Update

### ASN and AAKP: Forging Relationships on Capitol Hill

By David White



ASN President Raymond C. Harris MD, FASN, (left) and Raymond M. Hakim MD, PhD, (right) meet with congressional Representative Jim Cooper (D-TN, center) in his office on Capitol Hill to discuss the Living Donor Protection Act (S. 2584/H.R. 4616).

For the fourth consecutive year, the ASN Public Policy Board and Board of Advisors partnered with patient advocates from the American Association of Kidney Patients (AAKP) in Washington, DC, to host Kidney Health Advocacy Day 2016 in April. The goal of Kidney Health Advocacy Day 2016 was to bring kidney patients and kidney doctors together to meet with members of Congress and congressional staff to advocate for support and passage of the Living Donor Protection Act (LDPA – S. 2584/H.R. 4616). In addition, those patients and doctors used the opportunity to also raise awareness of the scope of kidney disease in America along with its impact on American lives and our health care system.

There were a total of 50 participants from both ASN and AAKP. On Capitol Hill, they attended 78 meetings with members of Congress—both Senate and House—and their staff. In the first week following the meetings, 11 new cosponsors were added to the LDPA in the House of Representatives and follow-up is ongoing.

Participants complimented current sponsors and cosponsors of LDPA for advancing sound policy to promote living organ donation and setting an excellent example of thoughtful legislation crafted for the good of all.

Three Kidney Health Advocacy Day 2016 participants offered reflections on their experiences.



#### Vanessa Grubbs, MD, MPH

University of California, San Francisco Nephrology  
San Francisco General Hospital Renal Center

I imagine most nephrologists have heard the story of how the combination of compelling data about young lives cut short by kidney failure and the presence of an actual dialysis patient before Congress undergoing just minutes of the treatment that could save those lives led to Medicare's End-Stage Renal Disease (ESRD) Program. The ESRD program is the first and only disease-specific Medicare program.

Similarly, my first time participating in Kidney Health Advocacy Day taught me how important data and patient stories are to making policy happen to this

very day. Armed with a streamlined training over breakfast and a few pages of easy-to-digest data to leave behind about why the Living Donor Protection Act needed to be passed, my team and I were able to educate seven young staffers representing senators and congressmen from California and Oregon, one-by-one.

However, it was my personal story of becoming a kidney donor that seemed to really get their attention. We finished the day feeling confident that our combination of data and story were enough to persuade those staffers to convince their bosses to support our mission!



#### Eugene Lin, MD

Stanford University, Nephrology Fellow

Having never participated in congressional advocacy before, I was definitely nervous about Kidney Health Advocacy Day. Excitement quickly eclipsed my anxiety, though, as we kicked off the day with a training session, which was expertly run by ASN and AAKP staff. Afterward, our team (big shout out to Drs. Nuria Pastor-Soler, Vanessa Grubbs, and Suzanne Watnick, from Team West Coast) eagerly set out for our first meetings on Capitol Hill.

Although we had a full day of seven meetings with congressional staffers, everything went by quickly. Our

meetings spanned close to the entire West Coast: Sen. Barbara Boxer (D-CA), Sen. Dianne Feinstein (D-CA), Rep. Anna Eshoo (D-CA), Rep. Nancy Pelosi (D-CA), Rep. Xavier Becerra (D-CA), Sen. Ron Wyden (D-OR), and Rep. Earl Blumenauer (D-OR). Sharing our patients' stories and experiences lent a powerful, yet personal, perspective to our message.

Advocating for the Living Donor Protection Act was a blast! It was an educational and fun experience for me, and I believe that our efforts helped push forward important protections for future kidney donors. #KidneyAdvocates





### Dave White

ASN Kidney Health Initiative Patient and Family Partnership Council Member, AAKP Member, Mid-Atlantic Renal Coalition Medical Review Board Patient Representative and Patient Advisory Committee Chair

Growth usually lies outside of one's comfort zone, and I grew by participating in Kidney Health Advocacy Day 2016. My team, "Team Maryland," consisted of Deidra Crews, MD, FASN, MPH (ASN Chronic Kidney Disease Advisory Group chair and Diversity and Inclusion Group member), AAKP Vice President Richard Knight, and little ol' me, a recent kidney transplant recipient. We spent the day meeting with members of Maryland's congressional staff in support of the Living Donor Protection Act (S. 2584 /H.R. 4616). If this legislation becomes law, it will remove barriers to organ donation, save lives, and improve the quality of life for many.

Throughout the day, my team had meetings with

congressional staff members for Sen. Ben Cardin (D-MD), Rep. Donna Edwards (D-MD), Rep. John Sarbanes (D-MD), and Rep./Democratic Whip Steny Hoyer (D-MD). All three of us took turns leading the meetings, and I was honored to add my perspective as a patient advocate and transplant recipient. The congressional staff were engaged and supportive of our cause in every meeting.

I look forward to participating in the next Kidney Health Advocacy Day. Representing other kidney disease warriors (and potential organ donors) was a humbling honor and a great way to pay my blessings forward.

## Major Medical Innovation Legislation Inches Forward in US Congress: Would Have Sweeping Impact on NIH and FDA

By Grant Olan and David White

Congress is not expected to accomplish much before the general election season begins in earnest this summer, but there is broad bipartisan support for accelerating the discovery, development, and delivery of promising new therapies.

With overwhelming support, the House of Representatives passed major legislation in July 2015 called the 21st Century Cures Initiative that would spur medical innovation and drug development at the National Institutes of Health (NIH) and Food and Drug Administration (FDA). The Senate is currently considering advancing a similar legislative package of its own. This spring, the Senate held three hearings and passed 19 bills that incorporate about 50 different legislative measures.

Measures in the House and Senate bills would remove barriers to increased research collaboration, help the next generation of scientists, streamline administrative burdens, promote the development of drugs for rare diseases, modernize clinical trials, incorporate patient perspectives in the drug development and regulatory review process, and remove regulatory uncertainty for the development of new medical apps.

ASN actively provided input on these measures during the drafting of the legislation. ASN's comment letters are online at <https://www.asn-online.org/policy/>.

### Similarities between the House and Senate bills

Both the House and Senate bills include a number of similar provisions. They would facilitate NIH opportunities for new researchers and research

independence, Precision Medicine Initiative research, development of new therapies for rare diseases, and the collection and use of patient experience data in drug development.

In addition, they would allow NIH's National Center for Advancing Translational Sciences to support certain clinical trials through Phase III, give the NIH director more discretion over the appointment of other NIH leaders, and require NIH to provide Congress intermittent strategic plan updates.

The bills would also include provisions to streamline the FDA's combination product review process, expedite the review process for medical devices, and exempt most health software and apps from device review requirements.

### Differences between the House and Senate bills

There are several notable differences between the House and Senate bills. On the House side, provisions would require NIH to prioritize pediatric disease research and maintain the scientific workforce, and require the Department of Health and Human Services (HHS) that administers NIH and the FDA to reconcile human test subject rules. House provisions would also require both the NIH and FDA to provide public data in a unified and accessible format and to initiate a study on the use of telehealth services for dual-eligible patients.

On the other side of the Capitol, Senate provisions would require NIH to identify opportunities for reducing health disparities, improving research related to minority populations, and increasing diversity in clinical research. Senate provisions would also require NIH to establish a working

group to enhance research rigor and reproducibility, and HHS to reduce administrative burdens associated with compliance of electronic medical records regulations.

### Next steps

Funding remains the chief obstacle to Senate passage. The House bill would increase annual funding for the NIH and FDA by \$1.86 billion through 2020, and negotiations continue in the Senate where there is limited support for a smaller increase specifically for a few NIH programs. Key Democrats in the Senate are refusing to support the legislative package unless it includes supplemental funding.

If a legislative package passes, the House and Senate would then need to reconcile their bills and vote on a joint, combined bill again. Unfortunately time is running out. There are a limited number of congressional working days before Congress recesses for the start of the general election season.

After the November election, lawmakers will return for a short lame duck session of Congress and have a number of other pressing priorities to address before the next session of Congress starts in early January 2017, when lawmakers would have to start all over again.

"ASN commends Congress for advancing these meaningful reforms to spur medical innovations and cures that will save lives and improve the care of patients with kidney diseases," ASN Secretary-Treasurer and Public Policy Board Chair John R. Sedor, MD, FASN, remarked. "I hope lawmakers act swiftly to send a bill that includes supplemental funding for NIH and the FDA to the President before the congressional calendar runs out." ●

## ASN, ERA-EDTA, and ISN Sign Declaration of Collaboration

On June 1, 2016, three major nephrology societies signed a declaration of collaboration. The agreement sets the stage for joint work by the American Society of Nephrology (ASN), the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA), and the International Society of Nephrology (ISN) to advance the profession of nephrology and to improve the care of kidney patients.

Recognizing that kidney disease is a global challenge without boundaries or borders, the organizations said in an announcement that “all available synergies should be used to fight kidney disease and improve the standard of care for kidney patients worldwide.”

“When pursuing political goals and addressing global policymakers, it is especially important to speak with one voice,” said ISN President Dr Adeera Levin, MD, of St. Paul’s Hospital and the University of British Columbia. “To shape policy it is necessary to advocate globally.”

“The information age in which we live means that networking becomes more and more vital,” said Professor Dr Andrzej Więcek, president of the ERA-EDTA, of the Medical University of Silesia in Katowice, Poland. “We follow the same goal of advancing educa-

tion, research, and science to achieve the highest quality care for everyone with kidney disease. Together we achieve more, so it is time to put our experience and knowledge together.”

The agreement was announced at the recent ERA-EDTA 53rd Congress in Vienna, Austria, and will be highlighted at Kidney Week 2016 in Chicago, IL, on Thursday, November 17, 2016, at 8 a.m., and during the World Congress of Nephrology 2017, April 21–25 in Mexico City, Mexico.

In finalizing a Declaration of Collaboration, the three organizations agreed to work together in 4 areas:

1. Helping physicians who have just started careers as nephrologists or are considering this possibility, locally, regionally, and nationally.
2. Providing kidney professionals worldwide with more consistent, complete, and up-to-date information about kidney diseases and treatments.
3. Advocating to ensure access to care and to harmonize efforts to prevent and treat kidney disease worldwide.
4. Creating joint initiatives to leverage the societies’ re-



spective strengths.

The three organizations also worked to jointly define certain terms regarding efforts both between and among the organizations. A policy statement setting out a “Universal” Lexicon for Terminology is intended to frame future discussions the societies have about 1) collaborating, 2) endorsing, and 3) seeking confluences and managing conflict.

“Facilitating communication among ASN, ERA-EDTA, and ISN, this collaboration represents an important step in strengthening the discipline of nephrology,” said ASN President Raymond C. Harris, MD, FASN, of Vanderbilt University School of Medicine. “International cooperation improves the standing of a discipline in the world of medical science.” ●

## ABIM Proposes New MOC Options

The American Board of Internal Medicine (ABIM) recently announced plans to begin offering physicians new Maintenance of Certification (MOC) options. The proposed changes come after months of pushback by the medical community and still may not go far enough in addressing concerns.

ABIM in 2014 announced that it was changing its MOC process from a 10-year program into one in which physicians had to complete new requirements every 2, 5, and 10 years. The announcement set off a backlash by individual physicians and medical specialty societies. In early 2015, ABIM issued a mea culpa, stating, “[We] clearly got it wrong. We launched programs that weren’t ready,” and announced suspension of the Practice Assessment, Patient Voice, and Patient Safety requirements of its MOC program for at least 2 years.

The concerns spilled over into a series of *Newsweek* articles that not only questioned the MOC changes but also ABIM’s governance structure and financial operations.

ABIM said the new MOC options will involve shorter assessments, or exams, that physicians may potentially take on their personal or office computer “more often than every 10 years but no more than once a year.” The 10-year exam will also be kept as a “second” option. ABIM said it will provide more details about the alternative assessment options by December 31, 2016. For now, ABIM said in a statement:

- The options will provide feedback on important knowledge gap areas so physicians can better plan their learning to stay current in knowledge and practice.
- Those who meet a performance standard on shorter assessments will not need to take the 10-year exam again to remain certified.

The proposed MOC assessment options—set to begin in January 2018 for internal medicine and perhaps 1 or 2 specialties—address some concerns but raise others.

For example, ABIM said it would continue to consider the possibility of offering open-book exams, but provided no additional clarity on this option, which was popular with almost half of the US nephrologists who are ASN members that the society surveyed in January 2016.

The new options also do not address the concerns of those individuals up for recertification before 2018.

“I am up for recertification in 2017 and among the diplomates caught between an outgoing program and a proposed new program for recertification,” said ASN Councilor Anupam Agarwal, MD, FASN. “Should I be handcuffed to ABIM’s existing program because my exam is before 2018? ABIM’s proposal to consider recertification is perhaps a step in the right direction, but it does not provide reasonable options for those in my situation and I am sure there are several others who are in the same situation as I am.”

In addition to surveying US nephrologist members of ASN for input regarding MOC, the society published “ASN’s Options for Helping Nephrologists Maintain Career Excellence” in the December 2015 *Kidney News* and co-wrote with 11 other medical specialty organizations a letter to ABIM posing several questions and concerns about how ABIM plans to reengineer MOC to reflect the changing nature of medical practice.

In the December 2015 article, ASN Councilor Mark E. Rosenberg, MD, FASN, and Executive Vice President Tod Ibrahim stated that “changes in the practice environment and the proliferation of institutional quality improvement programs have raised questions about the need for a recertification process.” Noting that the proposed Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 creates a Merit-Based Incentive Payment System (MIPS) that increases the relationship between payment and assessment, the authors stated, “ASN strongly supports the concept that physicians should receive credit for meeting existing requirements, such as the

forthcoming MIPS for MOC or vice versa.”

Also, on April 4, 2016, ASN and 11 other organizations (Table 1) sent a letter to ABIM asking it to clarify its vision regarding MOC, additional MOC changes under consideration, as well as the respective roles of the ABIM Board of Directors, Council, specialty boards, and staff in the MOC revision process. In the letter, the organizations noted that spotty communications and lack of shared vision make it difficult and costly to adapt to ABIM’s changes.

In response to concerns relayed in the letter that ABIM’s communications lacked transparency and consistency, ABIM stated that it would provide quarterly updates on progress in implementing the MOC changes. ABIM also promised to provide a “public comment period” before finalizing the details of the “new assessment option.” ●

**TABLE 1. Specialty organizations that co-signed letter to ABIM**

ASN
American College of Rheumatology
American Gastroenterological Association
Endocrine Society
Infectious Diseases Society of America
Society of Hospital Medicine
American Association of Clinical Endocrinologists
American College of Gastroenterology
American Geriatrics Society
Renal Physicians Association
American Society for Gastrointestinal Endoscopy
American Society of Clinical Oncology



## Industry Spotlight

### New Technology May Reduce Kidney Injuries

A research team at the University of Michigan (U-M), Ann Arbor, has devised a technique to use cultured kidney cells to simulate the way kidneys clear drug compounds.

The innovation could someday bring precise dosing, for example, to intensive care units where drug delivery is critical, researchers said. The invention uses a microfluidic chip device to deliver a precise flow of medication across cultured kidney cells. The research team tested their approach by comparing two different dosing regimens: a high concentration that quickly tapered, like an injection, versus a lower concentration

infused at a constant rate, like an IV drip. Both approaches used the same amount of drug. The device sandwiched a thin, permeable polyester membrane and a layer of cultured kidney cells between the top and bottom compartments. Researchers pumped a gentamicin solution into the top, and the drug gradually filtered through the cells and the membrane, and simulated the flow of medication through a human kidney.

In the journal *Biofabrication*, the team reported that a once-daily dose of gentamicin is significantly less harmful to kidney cells than a continuous infusion—even though both ultimately delivered the same

dose of medication. To commercialize the biomarker readout aspect of the technology, Shuichi Takayama, a U-M professor of biomedical engineering, has founded PHASIQ, an Ann Arbor-based spinoff company, in conjunction with the U-M Office of Technology Transfer.

Today's method of relying on lab animals to measure drug toxicity may not be precise enough to determine safe dosages, but "the goal for the future is to improve these devices to the point where we're able to see exactly how a medication affects the body from moment to moment, in real time," Takayama said. ●

### Filter Firm Aims for Positive Cash Flow

Nephros (River Edge, NJ), a medical device company that develops and sells high-performance liquid purification ultrafilters and a hemodiafiltration (HDF) system for use with a hemodialysis machine, reported in its first quarter 2016 results that it had gained "510(k) clearance on two additional products and successfully completed the software upgrade and additional training development for our H2H (company brand) modules needed to expand our hemodiafiltration footprint." Nephros said the company will aim

for positive cash flow from its products in the coming months.

The firm's SSUmini, launched in March 2016, is aimed at dialysis clinics that need an economical solution for a polish filter (to remove small particulate material or dissolved material) for smaller, portable reverse-osmosis systems that need hemodialysis-quality water. The SSUmini also provides hemodialysis-quality bicarbonate concentrate for dialysis clinics with centralized bicarbonate systems.

Nephros announced that EndoPur™ will become the brand name for all of its ultrafiltration products for dialysis water and bicarbonate concentrate, including the SSUmini, the DSU-D, the SSU-D, and the 10" cartridge platform.

For the quarter that ended March 31, 2016, total revenues were approximately \$590,000 and operating expenses were approximately \$1.1 million, compared to approximately \$544,000 and \$1,088,000 for the quarter ended March 31, 2015. ●



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## Fellows Corner

# My Journey to Nephrology

By Silvi Shah

**M**y grandmother's struggle with chronic kidney disease (CKD) motivated me to consider, and ultimately choose, medicine as a career. During medical school, I had the opportunity to work with a nephrologist and attend renal clinics with him. I was intrigued by the complexity of patients with kidney disease and felt pulled toward a career in internal medicine and nephrology, which brought me to the University at Buffalo for my internal medicine residency.

My decision to become a nephrologist was reinforced throughout my residency. During my nephrology elective, I liked the fact that it was both challenging and comprehensive. I felt that nephrologists were among the smartest physicians; they inspired me. The teachings of a stepwise approach to diagnose hyponatremia and the physiology of diuretics have been helpful to me to this day. And my research on the prevalence of clinical inertia in the management of cardiovascular risk factors in renal transplant clinic made me aware of the challenges faced by kidney transplant patients.

As a third year medical resident, I attended my first ASN meeting as part of the ASN Kidney STARS program. I was overwhelmed and thrilled to see eminent people from around the world all in one place. I attended clinical lectures and research sessions, which exposed me to career paths available to trainees.

My first poster presentation at Kidney Week 2012 in San Diego allowed me to showcase my research in front of distinguished people in an international forum. ASN meetings have given me a platform to present my research and interact with nephrologists from all around the world, further strengthening my decision to pursue nephrology as a career.

I went to Cleveland Clinic for my general nephrology fellowship. While there, I was excited to see my first case of ANCA vasculitis and my first case of Von Hippel Lindau syndrome. It was fascinating to find out how a simple test like urine microscopy could help determine the cause of

kidney dysfunction. Late evenings, I sat at my desk trying to figure out the etiology of metabolic acidosis in a patient with symptoms of dry eyes, and was thrilled to find out that Sjogren's syndrome was the cause. I felt an adrenaline rush during my first call when I started a patient on continuous dialysis following cardiac arrest. I liked the grueling discussion during rounds about the utility of statins in preventing contrast-induced nephropathy. Nephrology consults involved a lot of critical thinking, problem solving, and an eye for detail. The complexity and diversity of cases I saw, including acute kidney injury, glomerulonephritis, electrolyte abnormalities, kidney stones, CKD, end stage renal disease, and kidney transplant made my fellowship a very enriching experience.

I was always drawn to the field of kidney transplantation. A close friend of mine donated a kidney to his father and soon afterward lost his solitary kidney to antibiotic-induced acute interstitial nephritis. He ended up getting his own kidney transplant. I saw his journey from shock to acceptance, and finally to happiness. I researched outcomes in living kidney donors and the impact of histological abnormalities in time-zero biopsies on graft outcomes in renal transplant recipients. The American Society of Transplantation gave me the opportunity to present my work at its national meeting and doing so helped me decide the next phase of my career—my transplant nephrology fellowship at the University of Alabama at Birmingham. During this time, I also became interested in the use of social media for promoting education in nephrology and became part of the nephrology social media internship. In addition to all the learning I received from participating in NephMadness and online biweekly nephrology journal clubs, I had the opportunity to interact with this dynamic group of innovative educators.

At the end of the day, the gratification I receive from my patients is what I find most rewarding from my choice of nephrology as a career. With six years of training behind me, I have decided to join academic medicine to enable me

to practice clinical medicine, do research, and teach. I see myself evolving as a clinical investigator.

Nephrology is at an important crossroads currently with the increasing global burden of kidney disease and fewer people choosing it as a career. Nephrology continues to be one of the most diverse fields in internal medicine, encompassing the excitement of electrolyte disorders, physiology of dialysis, and immunology of glomerulonephritis. The practice of nephrology ranges from care of the sickest patient in the intensive care unit to the healthiest kidney transplant patient. There is the opportunity to do an additional year of transplant nephrology, interventional nephrology, palliative care nephrology, or critical care medicine (among others). Like any other fellowship, nephrology is tough but is very rewarding intellectually and professionally. Academics, private practice, and administration are among the possible career paths following fellowship. I would recommend that all students and residents follow their passion, which I believe is imperative to stay happy and content. It is important to stay motivated, identify your goals early, and reach out to mentors to help you achieve those goals.

As I look back, training to be a nephrologist has been a long journey. I can see my transition and growth from a naïve medical student to a confused intern to an excited resident and finally to a knowledgeable fellow. I have learned a lot at each phase of my career and am grateful for the fantastic training and the excellent mentorship I have received. Training in three different reputable institutions, interacting with my mentors, and attending national conferences exposed me to the diversity of the kidney field and helped me identify my goals. I eagerly look forward to my next transition and to furthering my ability to contribute to the nephrology profession in a meaningful way. ●

*Silvi Shah, MD, is currently a transplant nephrology fellow at the University of Alabama at Birmingham. She will join the University of Cincinnati as Assistant Professor of Clinical Medicine in the Division of Nephrology in July 2016.*

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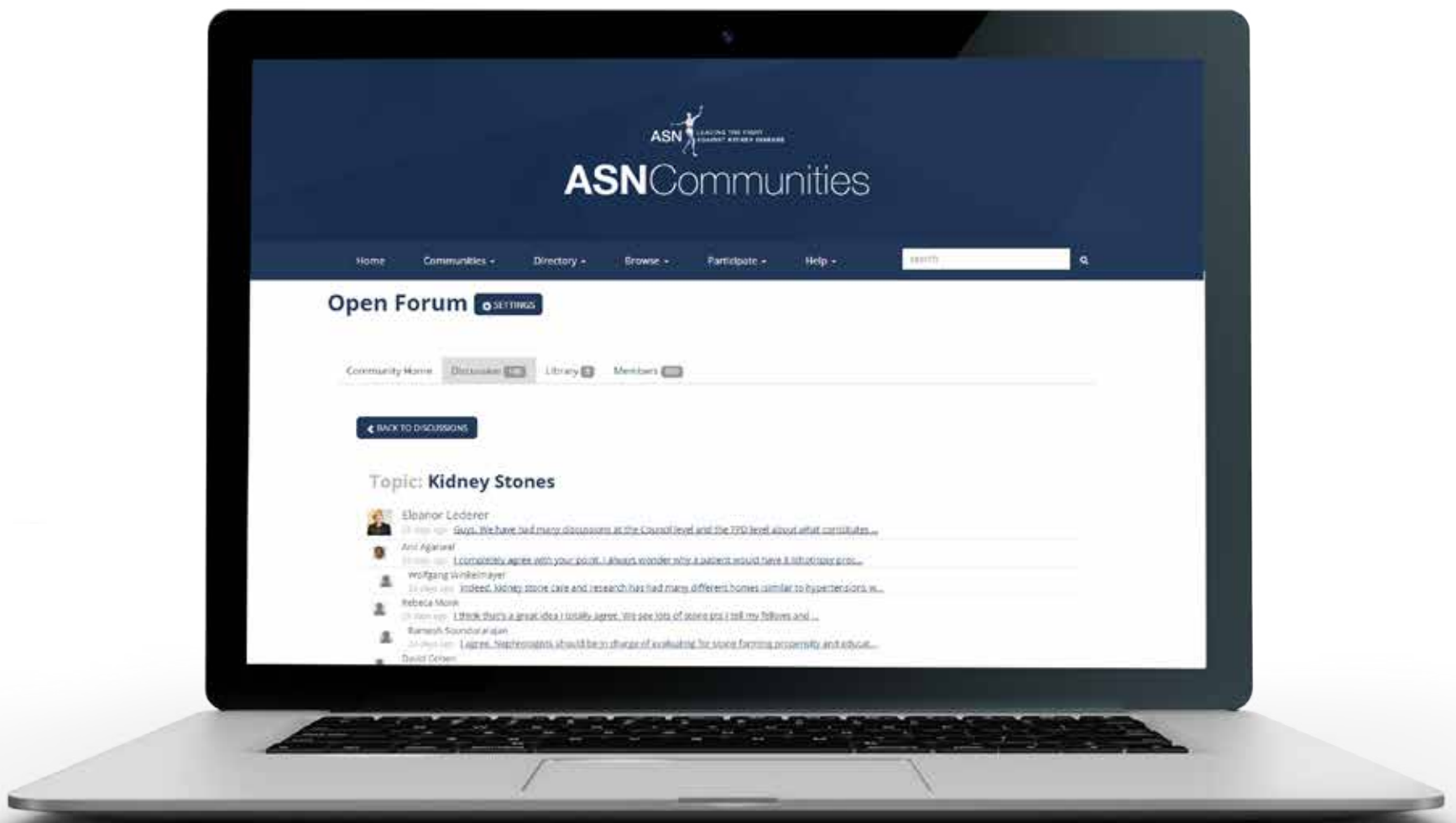


## Index to Advertisers

- Baxter . . . . .Pages 10-11
- MD Anderson . . . . .Pages 9
- Relypsa . . . . .Pages 5-6

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