

Kidney News

March 2015 | Vol. 7, Number 3

Peritoneal Dialysis Fluid Shortage Disrupted Growth of Popular Therapy

By Eric Seaborg



After several months of a sudden, unforeseen shortage, the supply of peritoneal dialysis (PD) fluid is expected to return to normal by the end of March, when Baxter

Healthcare says it will have more production capacity on line.

The supply disruption came as a surprise in August 2015, when Baxter sent dialysis clinics and patients letters informing them that “several factors, including limited manufacturing capacity, along with increased overall demand for sterile solutions, have resulted in temporary supply constraints ... expected to last for the next six months.”

Home PD has grown tremendously in recent years, particularly since the Centers for Medicare and Medicaid Services changed payments in 2011 in ways designed to encourage its use. Demand grew 30% in the past three years alone.

Baxter said that it was committed to supplying patients currently on PD, but restricted expansion to new patients. The shortage disrupted provider operations and patient care in many important ways.

PD providers were given allocations for how many new PD patients they could accept based on the pro-

viders’ history of growth during the first six months of 2014. For example, Northwest Kidney Centers (NKC), the largest dialysis provider in the Puget Sound area of Washington, had been training seven or eight new patients a month. Their allocation was set at two new patients per month.

Dialysis Clinic, Inc. (DCI), a non-profit based in Nashville, Tenn., that operates 235 clinics in 28 states, was starting about 69 new patients per month with Baxter fluid. Its allocation was set at 17 or 18 new patients a month.

“Even as current PD patients predictably dropped off the rolls due to death or a switch to hemodialysis, NKC was not allowed to replace them with new patients,” said Connie Anderson, vice president of clinical operations at NKC. As a result, NKC’s PD patient count decreased from 200 to 192 in September, and has only slowly begun climbing back up.

Patient referrals decreased at both NKC and DCI, apparently because as word of the shortage spread, physicians

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Vessel Calcification May Underlie Link between Kidney Stones and Heart Disease

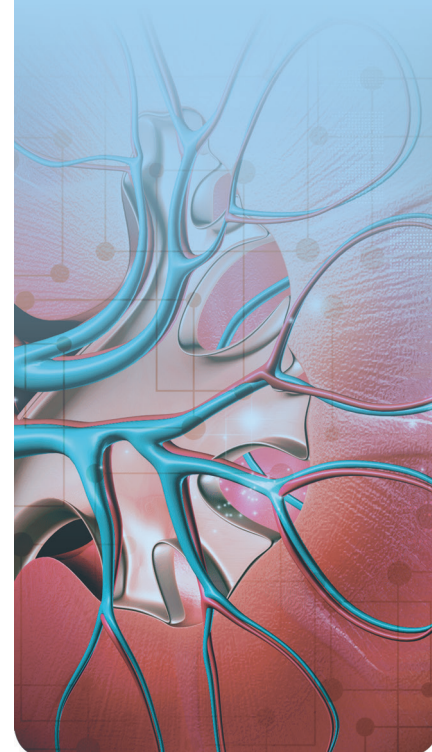
The development of kidney stones is a common problem that has traditionally been recognized as no more than an isolated and painful condition. Yet epidemiological studies have revealed links between nephrolithi-

asis and conditions such as the metabolic syndrome, hypertension, chronic kidney disease, and cardiovascular disease. In support of the concept that nephrolithiasis is a systemic disease, a new study published in the *Clinical Journal of the*

American Society of Nephrology shows that blood vessel calcification in recurrent kidney stone formers may put patients at increased risk of heart disease, and kidney stones’ effects on the bones may increase osteoporosis risks.

“This is the first study to our knowledge to provide controlled evidence for a possible role of vessel calcification and associated osteoporosis in cardiovascular morbidity among kidney stone formers,” said lead author Linda Shavit, MD, of

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clinics could simply switch large numbers of patients over to it.

The shortage's long-term implications for the spread of PD remain to be seen, but it is likely to be only a temporary glitch. "It has been a long-stated goal of CMS to expand the proportion of patients with end stage renal disease that are dialyzed at home. When people are aware of their options, a lot

more people choose to dialyze at home, and so the growth of patients on PD in the United States has happened at an unprecedented rate," said Raj Mehrotra, MD, professor of medicine at the University of Washington and chair of the dialysis advisory group of the American Society of Nephrology. "I think the shortage teaches us that we need to have some redundancy in the

system, whether it is with regards to the number of manufacturers, or number of plants a single manufacturer has, which would have ensured the availability of solution to patients."

As the supply returns to levels to meet the growing demand, Johnson said that the shortage could actually lead to greater use of home PD in the future because of the attention it

brought to the treatment. Johnson's involvement in the allocation process made a great impression: "I now know even more than I did before how valuable it is to be able to dialyze at home, and the way it can change a person's life. I was already a very strong advocate for home dialysis, but I am a stronger advocate today than I was before the shortage. ●

ASN Innovations in Kidney Education Contest

Submission Site Closes Thursday, March 12

ASN invites the kidney community to participate in the 2015 ASN Innovations in Kidney Education Contest to develop innovative tools to teach medical students and residents aspects of kidney physiology, including how it relates to human health, disease diagnosis, and a disease state.

Contest Goals

- Develop and share tools to enhance teaching kidney physiology using nondidactic, interactive teaching instruments
- Generate excitement among medical students and residents about the field of nephrology
- Engender interactions between medical students, residents, graduate students, nephrology fellows, post-doc trainees, faculty, practicing nephrologists, and researchers
- Engage learners in ASN activities
- Create novel ideas for additional curricula development for medical and graduate students in the field of nephrology

What Is the Contest?

There are two parts to the contest.

Part 1: Idea Submission

Submission of ideas for an innovative teaching tool that will help teach kidney physiology

Part 2: Teaching Tool Submission

Development and submission of the new teaching tool

More information, including the contest rules and FAQs is available at www.asn-online.org/contest





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ASN Kidney News is published by the American Society of Nephrology
1510 H Street NW, Suite 800, Washington, DC 20005. Phone: 202-640-4660

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Postmaster: Please send address changes to *ASN Kidney News*, c/o Customer Service, American Society of Nephrology 1510 H Street NW, Suite 800, Washington, DC 20005.

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

ASN Kidney News (ISSN print 1943-8044 and online 1943-8052) is an official publication of the American Society of Nephrology, 1510 H Street NW #800, Washington DC 20005, and is published monthly. Periodicals postage paid at Washington, DC and at additional mailing offices. Subscription rates: \$12 per year. To order, please email bhenkel@asn-online.org. Subscription prices subject to change. Annual ASN membership dues include \$12 for *ASN Kidney News* subscription.

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Vessel Calcification

Continued from page 1

the University College London Medical School in the UK and the Shaare Zedek Medical Center in Israel.

Approximately 10% of men and 7% of women develop kidney stones or nephrolithiasis. Although the mechanisms involved in the potential link between nephrolithiasis and increased cardiovascular risks are unknown, Shavit and her colleagues suspected that abnormal deposits of calcium in the blood vessels may play a role. Such vascular calcification is considered a strong risk factor for heart-related disease and death.

In a 111-participant study that included 57 recurrent kidney stone formers and 54 healthy controls, the researchers used computed tomography (CT) scans to evaluate the severity of abnormal calcium deposition in the abdominal aorta, one of the largest blood vessels in the human body.

Individuals with kidney stones had more calcification in the abdominal aorta, which could explain their increased risk for heart disease. They also had less dense bones and more prominent bone demineralization compared with individuals who did not develop kidney stones. Average vertebral bone mineral density was 159 Hounsfield Units in stone formers vs. 194 in controls. Previous studies have shown that vascular calcification often occurs alongside bone loss, suggesting a relationship between osteoporosis and atherosclerosis.

“Our findings raise several important questions that may be relevant to the care of patients with kidney stones,” Shavit said. “Existing CT can be a useful tool for assessment of aortic calcification and osteoporosis, along with kidney stone number and distribution. Moreover, preliminary experimental and clinical evidence suggests that therapeutic strategies aimed to treat osteoporosis may have a favorable effect on vascular calcification.”

According to the authors, CT technology for both aortic and spine measurements provides clear benefits over conventional radiographs, which are less precise and do not permit clinicians to obtain graded quantifications.

“This interesting study confirms one previous observation of my group that in calcium renal stone formers, arteries are rigid and calcified,” said Giovanni Gambaro, MD, PhD, who was not involved with the study and is head of the Division of Nephrology and Dialysis at

Columbus-Gemelli University Hospital, in Rome. “We advanced that in nephrolithiasis, a liaison exists between bone and vessels. This is probably a general phenomenon since it has been observed in osteoporosis, in hypertension, and in chronic kidney disease.”

While the study cannot prove direct causality, it provides controlled evidence for a possible role of vessel calcification, and associated osteoporosis, in cardiovascular morbidity among kidney stone formers, and it suggests that prospective trials are warranted to explore the potential benefits of targeting the bones and cardiovascular system to help protect kidney stone formers’ heart health.

In an accompanying editorial, Eric Taylor, MD, MSc, of the Maine Medical Center and Brigham and Women’s Hospital, noted that the study has several strengths, including its systematic process to generate abdominal calcification scores and its use of existing imaging data obtained for other indications. However, he also pointed to several limitations, such as the presence of certain factors including race and body size that may confound the observed associations. Also, it is unclear whether the greater severity of calcification in stone formers was independent of differences in bone mineral density between patients and controls.

Taylor noted that the study raises a number of important unanswered questions. “The nexus between calcium kidney stone formation, bone demineralization, and atherosclerosis should be an active area of investigation pursued by the clinical investigator and basic scientist alike,” he wrote. “Future studies will require careful assessment of calcium-phosphorus regulatory hormones and inhibitors of tissue calcification hypothesized to play important roles in the complex pathophysiology of all 3 disease states.”

For now, while it is too early to incorporate a history of calcium nephrolithiasis into screening guidelines for osteoporosis or cardiovascular risk factors, the findings suggest that addressing heart disease risk factors may also help prevent kidney stones and bone fractures. ●

Disclosures: Robert Unwin is currently on secondment as a chief scientist with AstraZeneca Cardiovascular & Metabolic Diseases Innovative Medicines and Early Development Science Unit (Mölnådal, Sweden).

The article is entitled “Vascular Calcification and Bone Mineral Density in Recurrent Kidney Stone Formers.”

Correction

The article “New Combo Drug for Hypertension” (February 2015 *Kidney News*) contained errors in the first sentence.

The corrected sentence reads: “The U.S. Food and Drug Administration (FDA) has approved a fixed-dose antihypertensive pill combining angiotensin-converting enzyme inhibitor and calcium channel blocker compounds.”



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Findings

Increased Use, Good Outcomes of Living Kidney Transplants from Older Donors

Kidney transplants from living donors (LDs) aged 60 or older are increasing, with recipient survival rates at least as good as those after deceased standard donor criteria (SDC) transplantation, reports a study in *Transplantation*.

The researchers analyzed United Network for Organ Sharing data from 1994 to 2012, focusing on trends in the use of older LD kidneys and their outcomes. Of the total 250,827 transplants, 92,646 were from LDs.

Overall, 4.5 percent of recipients of LD transplants received organs from donors aged 60 or older. The percentage of older LD transplants increased from 3.6 percent in 1994 to 7.4 percent in 2011; most of the growth was among donors aged 60–69. Older LD kidneys were associated with lower graft and overall survival compared with younger LD kidneys.

Graft survival was also lower with LD kidneys from donors aged 70 or older, compared with deceased SCD transplants. However, overall survival was similar between these groups. Both graft and overall survival were higher for older LD kidneys compared with expanded criteria donor (ECD) transplants.

As the use of older LD kidneys increases, questions remain about their safety and efficacy. The new study shows that although younger LD transplants still have the best outcomes, older LD kidneys yield overall survival similar to that with deceased SCD transplants and better than with ECD kidneys. The investigators conclude, “[T]he comparable long-term outcomes of kidneys from older living donors compared to SCD or ECD kidneys with the short-term advantages of avoiding dialysis promote the expanded use of this resource” [Englum BR, et al. Outcomes in kidney transplant recipients from older living donors. *Transplantation* 2015; 99:309–315]. ●

Dietary Metabolite Linked to CKD Development and Progression

Higher levels of the gut bacterial by-product trimethylamine N-oxide (TMAO)—associated with consumption of red meat, eggs, and dairy products—are linked to the development of and mortality from chronic kidney disease (CKD), reports a study in *Circulation Research*.

The researchers examined the prognostic value of TMAO levels in patients with CKD and the potential role of TMAO in the development and progression of kidney disease. A gut microbiota-dependent metabolite

formed during the digestion of choline and carnitine, TMAO is cleared by the kidneys. Previous studies have shown that TMAO is associated with heart disease and have identified it as a strong predictor of major adverse cardiovascular events.

In 521 patients with CKD in stable condition, the median fasting plasma TMAO level was 7.9 $\mu\text{mol/L}$ —signifi-

cantly higher than in control individuals without CKD. For CKD patients in the fourth versus first quartile of TMAO, the unadjusted hazard ratio (HR) for all-cause mortality at 5 years was 2.76. The association was smaller but still significant (HR 1.93) after adjustment for traditional risk factors, high-sensitivity C-reactive protein, and estimated GFR.

Measurement of TMAO provided additional prognostic value in CKD patients, with net reclassification index of 17.26 percent and differences in the area under the receiver operator characteristic curve of 63.26 versus 65.95 percent. Among control individuals without CKD, higher TMAO levels were associated with increased mortality in those with normal or elevated cystatin C levels.



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INDICATION

AURYXIA is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

IMPORTANT SAFETY INFORMATION

Contraindication: AURYXIA is contraindicated in patients with iron overload syndromes.

Iron Overload: Iron absorption from AURYXIA may lead to excessive elevations in iron stores. Assess iron parameters, serum ferritin and TSAT, prior to and while on AURYXIA. Patients receiving IV iron may require a reduction in dose or discontinuation of IV iron therapy.

Overdose: AURYXIA contains iron. Iron absorption from AURYXIA may lead to excessive elevations in iron stores, especially when concomitant IV iron is used.

Accidental Overdose of Iron: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep this product out of the reach of children.

Patients with Gastrointestinal Bleeding or Inflammation: Safety has not been established.

Pregnancy Category B and Nursing Mothers: Overdosing of iron in pregnant women may carry

In animal models, higher dietary choline or TMAO levels were directly linked to progressive renal tubulointerstitial fibrosis and decreased kidney function.

The results suggest that dietary-induced, microbiota-dependent differences in levels of TMAO may contribute to CKD development, progression, and mortality. Further studies of these associations are needed, including the

possible effects of a diet designed to limit TMAO precursors (low in red meat, egg yolk, and high-fat dairy products) on the rate of CKD progression [Tang WHW, et al. Gut microbiota-dependent trimethylamine N-oxide (TMAO) pathway contributes to both development of renal insufficiency and mortality risk in chronic kidney disease. *Circ Res* 2015; 116:448–455]. ●

Cognitive Function Linked to Mortality in Hemodialysis Patients

Cognitive impairment, especially impaired executive function, is associated with an increased risk of death among patients receiving maintenance hemodialysis, reports a study in *American Journal of Kidney Diseases*.

The researchers analyzed the results of baseline and annual neurocognitive assess-

ments in 292 patients receiving maintenance hemodialysis. The patients' mean age was 63 years, and 90 percent had at least a high school education. Patients with dementia were excluded.

Associations between cognitive func-

Continued on page 8

For the control of serum phosphorus levels in patients with chronic kidney disease on dialysis

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References:

1. Fosrenol [package insert]. Wayne, PA: Shire US, Inc.; 2014. 2. Phoslyra [package insert]. Waltham, MA: Fresenius Medical Care North America; 2011. 3. PhosLo Gelcaps [package insert]. Waltham, MA: Fresenius Medical Care North America; 2012. 4. Renagel [package insert]. Cambridge, MA: Genzyme Corporation; 2014. 5. Renvela [package insert]. Cambridge, MA: Genzyme Corporation; 2014. 6. Velphoro [package insert]. Waltham, MA: Fresenius Medical Care North America; 2014. 7. National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis*. 2003;42(4 Suppl 3):S1-S201. 8. Data on File 1, Keryx Biopharmaceuticals, Inc.

a risk for spontaneous abortion, gestational diabetes, and fetal malformation. Rat studies have shown the transfer of iron into milk. There is possible infant exposure when AURYXIA is taken by a nursing woman.

Pediatric: The safety and efficacy of AURYXIA have not been established in pediatric patients.

Adverse Events: The most common adverse events with AURYXIA were diarrhea (21%), nausea (11%), constipation (8%), vomiting (7%), and cough (6%). Gastrointestinal adverse reactions were the most common reason for discontinuing AURYXIA (14%).

Drug Interactions: Doxycycline should be taken at least 1 hour before AURYXIA. Consider separation of the timing of the administration of AURYXIA with drugs where a reduction in their bioavailability would have a clinically significant effect on safety or efficacy.

Please see Brief Summary on following page.

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Findings

Cognitive Function

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tion and all-cause mortality were assessed, with adjustment for demographics and dialysis and cardiovascular (CV) risk factors. Test results were broken down into domain scores representing memory and executive function.

There were 145 deaths during a median follow-up time of 2.1 years. Each one SD increase in executive function score was associated with a 35 percent reduction in mortality—hazard ratio (HR) 0.65. The as-

sociation remained significant after adjustment for demographics and dialysis-related factors (HR 0.81) but lost significance after adjustment for CV disease and heart failure. In time-dependent models, the unadjusted HR was 0.62, and the association remained significant after adjustment for demographic, dialysis, and CV factors (HR 0.79).

On univariate analysis, better memory scores were associated with lower mortality: HR 0.82 per one SD. However, this association became nonsignificant after adjustment for demographics.

Many hemodialysis patients have cogni-

tive impairment, which is associated with increased morbidity. The new study shows that impaired performance on neurocognitive testing is associated with increased mortality. The association with memory appears to be explained by demographic factors, whereas the association with executive function may partly reflect the effects of CV disease. The authors call for new approaches to improving or stabilizing cognitive impairment in dialysis patients [Drew DA, et al. Cognitive function and all-cause mortality in maintenance hemodialysis patients. *Am J Kidney Dis* 2015; 65:303–311]. ●

Kidney Donors at Increased Risk of Gestational Hypertension and Pre-Eclampsia



Women who become living kidney donors are at increased risk of gestational hypertension and pre-eclampsia, suggests a study in the *New England Journal of Medicine*.

The retrospective cohort analysis included 85 women in Ontario who donated a kidney between 1992 and 2010 and subsequently become pregnant. The median age at donation was 29 years; the women had a total of 131 pregnancies after entering the cohort.

They were matched to 510 healthy nondonors for age, year, urban versus rural residency, income, number of pregnancies, and time to first pregnancy. The control women had a total of 788 pregnancies. The rates of hospital-diagnosed gestational hypertension or pre-eclampsia were compared for donors versus nondonors, along with other maternal and fetal outcomes.

The primary outcome of gestational hypertension or pre-eclampsia was more than twice as frequent among women who donated a kidney: 11 percent versus 5 percent of pregnancies: odds ratio 2.4. The odds ratios for the individual outcomes were 2.5 and 2.4, respectively.

Other maternal and fetal outcomes were similar between groups, including preterm birth and low birth weight. There were no cases of maternal death, stillbirth, or neonatal death among the donors.

Young women who are considering living kidney donation commonly ask about the possible effects on future pregnancies. Some studies have reported an increased risk of gestational hypertension and pre-eclampsia after donation, but these findings have been controversial.

The new study finds a significantly increased risk of gestational hypertension or pre-eclampsia in pregnancies occurring in woman after living kidney donation compared with similarly healthy nondonors. The authors believe that this information should be included in clinical practice guidelines and shared in the informed consent process. They note that most women in their donor cohort had uncomplicated pregnancies after donation [Garg AX, et al. Gestational hypertension and preeclampsia in living kidney donors. *N Engl J Med* 2015; 372:124–133]. ●

BRIEF SUMMARY

AURYXIA™ (ferric citrate) tablets contain 210 mg of ferric iron equivalent to 1 g ferric citrate for oral use.

INDICATIONS AND USAGE

AURYXIA is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

CONTRAINDICATIONS

AURYXIA is contraindicated in patients with iron overload syndromes (eg, hemochromatosis).

WARNINGS AND PRECAUTIONS

Iron Overload: Iron absorption from AURYXIA may lead to excessive elevations in iron stores. Increases in serum ferritin and transferrin saturation (TSAT) levels were observed in clinical trials. In a 56-week safety and efficacy trial in which concomitant use of AURYXIA and IV iron was permitted, 55 (19%) patients treated with AURYXIA had a ferritin level >1500 ng/mL as compared with 13 (9%) patients treated with active control.

Assess iron parameters (eg, serum ferritin and TSAT) prior to initiating AURYXIA and monitor iron parameters while on therapy. Patients receiving IV iron may require a reduction in dose or discontinuation of IV iron therapy.

Accidental Overdose of Iron: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Patients with Gastrointestinal Bleeding or Inflammation: Patients with inflammatory bowel disease or active, symptomatic gastrointestinal bleeding were excluded from clinical trials. Safety has not been established in these populations.

ADVERSE REACTIONS

Adverse reactions to a drug are most readily ascertained by comparison with placebo, but there is little placebo-controlled experience with AURYXIA, so this section describes adverse events with AURYXIA, some of which may be disease-related, rather than treatment-related. A total of 289 patients were treated with AURYXIA and 149 patients were treated with active control (sevelamer carbonate and/or calcium acetate) during the 52-week, randomized, open-label, active control phase of a trial in patients on dialysis.

A total of 322 patients were treated with AURYXIA for up to 28 days in three short-term trials. Across these trials, 557 unique patients were treated with AURYXIA; dosage regimens in these trials ranged from 210 mg to 2,520 mg of ferric iron per day, equivalent to 1 to 12 tablets of AURYXIA. In these trials, adverse events reported for AURYXIA were similar to those reported for the active control group. Adverse events reported in more than 5% of patients treated with AURYXIA in these trials included diarrhea (21%), nausea (11%), constipation (8%), vomiting (7%), and cough (6%).

During the 52-week active control period, 60 patients (21%) on AURYXIA discontinued study drug because of an adverse event, as compared to 21 patients (14%) in the active control arm. Patients who were previously intolerant to any of the active control treatments (calcium acetate and sevelamer carbonate) were not eligible to enroll in the study. Gastrointestinal adverse events were the most common reason for discontinuing AURYXIA (14%).

AURYXIA is associated with discolored feces (dark stools) related to the iron content, but this staining is not clinically relevant and does not affect laboratory tests for occult bleeding, which detect heme rather than non-heme iron in the stool.

DRUG INTERACTIONS

Doxycycline is an oral drug that has to be taken at least 1 hour before AURYXIA. Oral drugs that can be administered concomitantly with AURYXIA are: amlodipine, aspirin, atorvastatin, calcitriol, clopidogrel, digoxin, doxercalciferol, enalapril, fluvastatin, levofloxacin, metoprolol, pravastatin, propranolol, sitagliptin, and warfarin. There are no empirical data on avoiding drug interactions between AURYXIA and most concomitant oral drugs. For oral medications where a reduction in the bioavailability of that medication would have a clinically significant effect on its safety or efficacy, consider separation of the timing of the administration of the two drugs. The duration of separation depends upon the absorption characteristics of the medication concomitantly administered, such as the time to reach peak systemic levels and whether the drug is an immediate release or an extended release product. Consider monitoring clinical responses or blood levels of concomitant medications that have a narrow therapeutic range.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category B: There are no adequate and well-controlled studies in pregnant women. It is not known whether AURYXIA can cause fetal harm when administered to a pregnant woman. Animal reproduction studies have not been conducted.

The effect of AURYXIA on the absorption of vitamins and other nutrients has not been studied in pregnant women. Requirements for vitamins and other nutrients are increased in pregnancy. An overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes, and fetal malformation.

Labor and Delivery: The effects of AURYXIA on labor and delivery are unknown.

Nursing Mothers: Data from rat studies have shown the transfer of iron into milk by divalent metal transporter-1 (DMT-1) and ferroportin-1 (FPN-1). Hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

Pediatric Use: The safety and efficacy of AURYXIA have not been established in pediatric patients.

Geriatric Use: Clinical studies of AURYXIA included 106 subjects aged 65 years and older (33 subjects aged 75 years and older). Overall, the clinical study experience has not identified any obvious differences in responses between the elderly and younger patients in the tolerability or efficacy of AURYXIA.

OVERDOSAGE

No data are available regarding overdose of AURYXIA in patients. In patients with chronic kidney disease on dialysis, the maximum dose studied was 2,520 mg ferric iron (12 tablets of AURYXIA) per day. Iron absorption from AURYXIA may lead to excessive elevations in iron stores, especially when concomitant IV iron is used.

In clinical trials, one case of elevated iron in the liver as confirmed by biopsy was reported in a patient administered IV iron and AURYXIA.

PATIENT COUNSELING INFORMATION

Dosing Recommendations: Inform patients to take AURYXIA as directed with meals and adhere to their prescribed diets. Instruct patients on concomitant medications that should be dosed apart from AURYXIA.

Adverse Reactions: Advise patients that AURYXIA may cause discolored (dark) stools, but this staining of the stool is considered normal with oral medications containing iron.

AURYXIA may cause diarrhea, nausea, constipation, and vomiting. Advise patients to report severe or persistent gastrointestinal symptoms to their physician.



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Policy Update

21st Century Cures Draft Legislation Aims to Accelerate New Therapies

By Rachel Meyer

Building upon nearly a year of hearings, roundtables, and input from patient and other advocacy groups, the House Energy and Commerce Committee released a draft piece of legislation aimed at spurring the development of innovative new therapies and speeding their delivery to patients. Energy and Commerce Committee Chair Fred Upton (R-MI) and Rep. Diana DeGette (D-CO) launched this bipartisan effort—the 21st Century Cures Initiative—during the last Congress, and the committee floated a preliminary draft bill in January 2015.

ASN has been in conversation with committee staff and the offices heading up components of the draft legislation of potential relevance or benefit to patients with kidney disease—such as telehealth expansion in the Medicare program and the development of patient-reported outcomes measures for use in US Food and Drug Administration regulatory decision-making; the society’s input on the discussion draft is available at <https://www.asn-online.org/policy/>.

The nearly 400-page draft is chock-full of proposals—some new, some based on prior legislation—as well as a significant number of “placeholders” that will be fleshed out in the coming weeks and months. Broken down into five broad sections, the draft currently covers the following themes:

- TITLE I—Putting Patients First By Incorporating Their Perspectives into the Regulatory Process and Addressing Unmet Needs
- TITLE II—Building the Foundation for 21st

Century Medicine, Including Helping Young Scientists

- TITLE III—Modernizing Clinical Trials
- TITLE IV—Accelerating The Discovery, Development, and Delivery Cycle and Continuing 21st Century Innovation at NIH, FDA, CDC, and CMS
- TITLE V—Modernizing Medical Product Regulation

Despite the unobjectionable-sounding nature of these titles, the path to passage of the 21st Century Cures legislation will not be without controversy. Although the initiative began as a fully bipartisan effort, the January 2015 draft reflected considerably more partisan influence.

“As Chairman Upton and I begin to draft the bill itself, we look forward to receiving feedback on the issues identified in his draft document and other suggestions. While I don’t endorse the draft document, I know that with continued engagement, we can reach a bipartisan consensus to help advance biomedical research and cures,” said Rep. DeGette in a press release following the draft’s release.

Meanwhile, Senate Health, Education, Labor, and Pensions Committee Chair Lamar Alexander (R-TN) and Sen. Richard Burr (R-NC) chimed in to the conversation on discovery and development with the release in late January of the “Innovation for Healthier Americans” Report, a similar concept to the 21st Century Cures Initiative. “Getting more and better cures and treatments to patients more quickly is a goal shared by all,” Rep. Upton said. “I

applaud Senators Alexander and Burr for releasing this report today and encouraging further discussion to determine how best to keep America at the forefront of health care innovation.”

Although some in Washington have pointed out that the 21st Century Cures draft includes numerous and potentially questionable benefits for industry, it has also won praise for many patient-centered provisions and for its focus on integrating the patient voice into the regulatory process. “Keeping our work centered on the patient and understanding the patient perspective will bring much needed focus on results for patients who may lack adequate treatment options,” said Energy and Commerce Committee Health Subcommittee Chair Rep. Joe Pitts (R-PA). Besides discussions regarding the policy content, the cost of the legislation could be an issue for the budget-conscious on both sides of the aisle—and as of yet, no estimates of the cost of the draft legislation have been released.

The committee anticipates an aggressive schedule to introduce the 21st Century Cures legislation and send a bill to President Obama’s desk for signature by the end of 2015, thereby avoiding the snarl of 2016 presidential election politics to the extent possible. Although the draft is far from finalized and its future remains uncertain, the initial target for having the bill on the House floor may be as early as May 2015. ASN will continue working with Congress to provide input and help advance a patient-centered bill. Stay tuned for email notices regarding how you can help the society encourage Congress to move this and other important legislation forward in the coming months. ●

Top Five Kidney Policy Issues in 2015

By Mark Lukaszewski

These are the major policy issues affecting the kidney community in 2015.

National Institutes of Health (NIH) Funding

ASN requests that Congress allocate \$32 billion for the NIH and \$2.066 billion for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in fiscal year (FY) 2016. The society is also requesting additional NIDDK funding—\$150 million per year over the next 10 years—beyond current funding levels for kidney research to spur innovation.

President’s Proposed Budget

On February 2, 2015, President Barack Obama released his proposed federal budget for FY 2016 (see budget story). The president specifically calls on Congress to raise the 2016 spending caps for defense and non-defense programs (which includes medical research), which he proposes paying for by cutting spending to inefficient government programs and through tax reform.

Treatment Options for Patients with Dialysis-Requiring Acute Kidney Injury (AKI)

President Obama’s proposed FY 2016 budget expands the Part B scope of benefits to allow patients with dialysis-requiring AKI to receive treatment at a Medicare-certified End Stage Renal Disease (ESRD) facility. Currently, these patients face limited options for treatment, each of which comes with major challenges. If implemented correctly the plan could potentially afford significant improvements to overall care and quality of life.

Telehealth and the 21st Century Cures Legislation

ASN is collaborating with the U.S. Committee on Energy and Commerce on its 21st Century Cures legislation. The Committee is committed to accelerating discovery, development, and delivery of promising new treatments to patients and has solicited ASN’s insights on telehealth and other critical nephrology issues. Read the society’s comments to Congress at <http://asn.kdny.info/JA7L8>.

ESRD Seamless Care Organization (ESCO)

The Centers for Medicare & Medicaid Services (CMS) developed the first-ever disease-specific accountable care organization for dialysis providers, with the goal of reducing costs to the Medicare part D system. Designed to reduce duplicative services and expenditures, ESCOs would consolidate all aspects of care for patients with ESRD. The ESCO program has been riddled with problems since its conception. Over the past 2 years the Centers for Medicare and Medicaid Innovations (CMMI) has extended the request for applications three times, and now has pushed back its launch to July 2015. ASN is hopeful that CMS and CMMI have made much-needed changes to the program to ensure it saves costs and promotes improved patient care.

Follow @ASNAdvocacy on Twitter and visit <http://www.asn-online.org/policy/> to learn how you can take action on important issues affecting the kidney community. ●

President Proposes Modest 2016 Budget Increases for NIH and NIDDK

By Grant Olan

On February 2, 2015, President Barack Obama released his proposed federal budget for Fiscal Year 2016 (October 1, 2015, to September 30, 2016), the starting point of the congressional budget-making process.

In his State of the Union address, the president made the case that the US has turned the corner on the economy and is now in a stable position. As such, the president is now asking Congress to make investments in government services—including research—that have been underfunded since Congress instituted deficit reduction measures earlier in the decade.

The president is specifically calling on Congress to raise the 2016 spending caps for defense and non-defense programs and to pay for the increases by cutting spending for inefficient government programs and reforming the tax code. As federal budget experts in Washington, DC, continue to observe, since all discretionary programs (defense and non-defense combined) constitute less than one-third of total federal spending, these programs are not the driver of U.S. debt.

Nonetheless, due to the deficit reduction measures, funding for discretionary programs as a percentage of the GDP is at a near record low and annual budgets for federal research agencies have not kept pace with increases in inflation. As a result, the National Institutes of Health’s (NIH) purchasing power is shrinking, grant application success rates are at record lows, and the average age a first-time investigator gets their first research project grant (nearly 45 years of age) is a record high.

ASN is especially concerned about the funding environment for kidney research, which has been underfunded compared to other areas of research. And the trend continues: in his budget proposal, the president is

requesting a 2.95% increase in the overall NIH budget, but just a 2.59% increase for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—the largest funder of kidney research in the world (Table 1).

“Considering that Medicare spends more on the cost of care for patients with end stage renal disease than the entire NIH budget (\$35 billion vs. \$30 billion in 2014), ASN believes more investments are needed in kidney research to slow or prevent the progression of kidney disease and develop better therapies to improve patient care and health, which could yield significant saving to Medicare, the federal government, and taxpayers,” ASN Research Advocacy Chair Frank “Chip” Brosius said. “Total federal investments in kidney research are less than 1% of what it spends on the total cost of kidney care (about \$650 million vs. \$80 billion).”

“ASN is working with the research advocacy community (including Friends of NIDDK) in urging the president and Congress to raise the spending levels for discretionary programs and ensure parity between increases for defense and non-defense programs,” continued ASN Public Policy Board Chair John R. Sedor, MD, FASN. “The society is specifically calling on Congress to provide NIH \$32 billion and NIDDK \$2.066 billion in 2016, as well as provide NIDDK an additional \$150 million per year over the next 10 years on top of the current funding level for kidney research to spur innovation in this field, which has lagged far behind other areas.”

Congress is currently working on a budget resolution instructing the House and Senate Appropriations Committees how much they can allocate for discretionary programs for 2016. Follow ASNAdvocacy on Twitter or check back here for updates.

Table 1
NIH and NIDDK Funding

	2015 Actual	President’s 2016 Budget Request	% Change Over 2015 Actual
Millions of Dollars			
NIH	\$29,446	\$29,446	2.95%
NIDDK	\$1,889	\$1,889	2.59%

	2015 Actual	ASN’s 2016 Budget Requests	% Change Over 2015 Actual
Millions of Dollars			
NIH	\$29,446	\$32,000	8.67%
NIDDK	\$1,889	\$2,066	9.37%

Industry Spotlight

New Drug for Type 1 and 2 Diabetes

The US Food and Drug Administration has approved Sanofi’s new diabetes drug formulation Toujeo (insulin glargine injection, 300 U/mL). The drug, which may be used by patients with either type 1 or type 2 diabetes, is a once-daily long-acting basal insulin.

The new drug is a triple dose of the insulin glargine found in Sanofi’s existing diabetes drug Lantus (100 U/mL). Designed to release insulin more slowly, Toujeo was better at modulating nighttime hypoglycemia than Lantus, according to results from the EDITION clinical trial

program. The EDITION trial evaluated the efficacy and safety of Toujeo compared to Lantus in more than 3500 adults with type 1 or type 2 diabetes, all with uncontrolled diabetes on their current therapy.

Toujeo is expected to be available in the United States in early April. In February, Lantus was to lose its patent protection. Analysts say that Sanofi, however, may have to work very hard to persuade Lantus users to make the switch to Toujeo.

Toujeo’s clinical advantages are not found on US labeling,

according to Fierce Biotech analyst Tim Anderson. Europe’s different labeling rules allow the advantages to be noted.

In addition, Novo Nordisk’s long-acting diabetes drug Tresiba is approved for use in Europe, creating a crowded marketplace for big diabetes drug companies, Reuters noted. While the FDA rejected a Novo bid for approval in February 2013 with a directive for more testing, Novo said it would submit interim results with an eye toward a potential launch in 2016.

Rockwell Wins Approval for Triferic

Rockwell Medical has won drug approval by the US Food and Drug Administration (FDA) for a new anemia drug, Triferic (soluble ferric pyrophosphate or SFP).

The results from two phase 3 clinical studies demonstrated that Triferic was effective in maintaining “hemoglobin during the treatment period in iron-replete patients with hemodialysis-dependent chronic kidney disease in the studies as conducted,” according to FDA documents.

The drug could reduce the need for erythropoiesis-stimulating agents (ESAs). Motley Fool financial website highlighted data that showed a reduction of 30 to 37 percent in the need for ESAs when Triferic was used. “The impact of this on dialysis providers is enormous,” Motley Fool wrote, and estimated that a 35 percent reduction in the \$2 billion spent on ESAs annually would be about \$700 million in savings.

Several industry analysts expect Triferic to change the way

iron replacement therapy is given in dialysis patients. Triferic so far is the only iron replacement therapy that can be delivered through the dialysate solution. Triferic also is slowly infused and taken up by the body in a manner similar to dietary absorption, Seeking Alpha noted, qualities that may be bad news for earlier FDA-approved intravenous iron products for the treatment of iron deficiency anemia that require patient monitoring after administration.

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Practice Pointers

Continued from page 13

nal tract for sodium and hydrogen, and the OPAL-HK trial that evaluated Patiromer, a non-absorbed polymer that binds potassium in exchange for calcium, show effective alternatives that will hopefully be available in the near future. (18,19) ●

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David J. R. Steele, MD, is affiliated with the Nephrology Division of the Massachusetts General Hospital.

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MOC Changes' Impact on ASN Programs; Nephrology Board Formed

By Jeffrey S. Berns, MD, Chair, ABIM Nephrology Board

As you have likely heard, the American Board of Internal Medicine (ABIM) recently took action to address many concerns from the community regarding the Maintenance of Certification (MOC) program.

On February 3, 2015, ABIM president Richard J. Baron, MD, MACP, apologized for the mistakes that were made with the previous changes to MOC and announced significant and immediate changes to the program via e-mail to all ABIM Board-Certified physicians (Table 1).

Table 2 presents a brief look at the impact of ABIM changes on ASN member activities for MOC.

In addition to the changes to the MOC program, ABIM is also changing the way it operates through recent changes to its governance structure (see below) and by taking significant steps to engage the physician community in a dialogue on the MOC program to help design a program that reflects the shared values of the medical community, and provides a better framework for physicians to demonstrate that they are keeping up with the changes in their disciplines.

To ensure that ABIM is meeting the needs of the medical community, ABIM plans to gather feedback through the changes to its governance as well as by asking physicians directly about their vision for their specialties, the MOC program, and their opinions about what it means to be a doctor today. ABIM has also created "Transforming ABIM," a Google+ Community that you can join, to ask questions and share ideas, and a blog.

In addition, ABIM has posted information about "Where the Money Goes" and many of its financial reports on its website.

ABIM has altered its governance structure in some important ways. Perhaps most notable is the formation of new specialty boards. In the past, the only specialty-specific committees were the test writing committees, which were charged primarily with developing new exam questions. Due to the amount of time and effort involved in this process, test writing committee members had little time to consider specialty-specific issues related to initial certification or MOC. Recognizing that there was a need for ABIM to adapt its MOC program to more closely align with the needs and specific practice patterns of its diplomates within each specialty and to also examine requirements for taking initial certifying exams, ABIM established these specialty boards to:

- Define, refine and set standards for certification and MOC in the discipline;
- Perform oversight/review of performance assessments in the discipline; and
- Build partnerships with societies and other organizational stakeholders.

The secure examination will continue to be developed by a separate, dedicated group of physicians, but will now be referred to as exam committees, i.e., the Nephrology Board Exam Committee. The Exam Committee has been charged with maintaining exam "blueprints" that appropriately mirror the specialty's scope of knowledge and practice for both initial certification and MOC test takers.

As chair of the ABIM's Nephrology Board, I am excited to have this opportunity to introduce the role of this newly formed Nephrology Specialty Board and its members.

The ABIM Nephrology Board, along with nine other specialty Boards, held their inaugural meetings in fall 2014. Each of the specialty boards is comprised of practicing ABIM Board-Certified physicians, an intra-professional team member, and a patient representative. Members of the ABIM Nephrology Board include:

Jeffrey S. Berns, MD, Chair, Philadelphia, PA

I am a board certified internist and nephrologist and Professor of Medicine and Pediatrics at the Perelman School of Medicine at the University of Pennsylvania, where I am Associate Dean for Graduate Medical Education, Associate Chief of the Renal, Electrolyte, and Hypertension Division, and Director of the Nephrology Fellowship Training Program.

Laura Greenberg, RN, Cherry Hill, NJ

Laura Greenberg, the board's intra-professional member, is a Clinical Nurse at Penn Medicine's Renal, Electrolyte, and Hypertension Clinic and the Lead Clinical Nurse overseeing Penn Medicine's combined Renal and Rheumatology Ambulatory Practice.

Edward R. Jones, MD, Philadelphia, PA

Dr. Jones, a board-certified internist and nephrologist, is a practicing nephrologist in Philadelphia and a Chairman of Kidney Care Partners. He also is a Counselor to the Renal Physician Association (RPA).

Kevin Longino, MBA, Greenwich, CT

Kevin Longino, our patient representative, was diagnosed with an inherited kidney disease in 2000 and received a transplanted kidney in 2004. He continues to enjoy excellent health and has become a passionate advocate for kidney health and organ donor registration.

Andrew S. Narva, MD, Bethesda, MD

Dr. Narva, a board-certified internist and nephrologist, is the Director of the National Kidney Disease Education Program (NKDEP) at the National Institutes of Health and previously served as Director of the Kidney Disease Program for the Indian Health Service.

Jerry Yee, MD, Detroit, MI

Dr. Yee, a board certified internist and nephrologist, is the Division Head of the Henry Ford Hospital's Division of Nephrology and Hypertension and Clinical Professor of Internal Medicine, Wayne State University.

Rudolph A. Rodriguez, MD, Seattle, WA

Dr. Rodriguez, a board certified internist and nephrologist, is the Director of the Hospital & Specialty Medicine Service Line at the VA Puget Sound Health Care System and a Professor and Vice Chair of the Department of Medicine at the University of Washington.

Suzanne G. Watnick, MD, Portland, OR

Dr. Watnick, a board certified nephrologist, is a Professor of Medicine at Oregon Health and Science University (OHSU) and the Medical Director of the Portland VA Medical Center Dialysis Unit in Portland, OR. She also serves as the training program director for the Nephrology Fellowship at OHSU.

I am honored to lead such a diverse group of professionals from across the spectrum of nephrology and

look forward to sharing updates with you as we embark on our work of ensuring the importance and value of board certification in Nephrology and the relevancy of MOC to nephrologists across the country.

Further information about ABIM's new governance structure may be found via the ABIM website: <http://www.abim.org/about/governance>.

Jeffrey S. Berns, MD, is chair of the ABIM Nephrology Board. He is an internist and nephrologist and Professor of Medicine and Pediatrics at the Perelman School of Medicine at the University of Pennsylvania.

Table 1

Changes to ABIM MOC Program

- Effective immediately, ABIM is **suspending the Practice Assessment, Patient Voice, and Patient Safety requirements for at least two years**. This means that no nephrologist will have his or her certification status changed for not having completed activities in these areas for at least the next two years. Diplomates who are currently not certified but who have satisfied all requirements for Maintenance of Certification except for the Practice Assessment requirement will be issued a new certificate this year.
- Within the next six months, ABIM will change the language used to publicly report a diplomate's MOC status on its website from "meeting MOC requirements" to **"participating in MOC."**
- ABIM is updating the Internal Medicine MOC exam. The update will focus on making the exam more reflective of what physicians in practice are doing, **with any changes to be incorporated beginning fall 2015**, with more subspecialties to follow.
- **MOC enrollment fees will remain at or below** the 2014 levels through at least 2017.
- **By the end of 2015, ABIM will assure new and more flexible ways for internists to demonstrate self-assessment of medical knowledge** by recognizing most forms of ACCME-approved Continuing Medical Education.

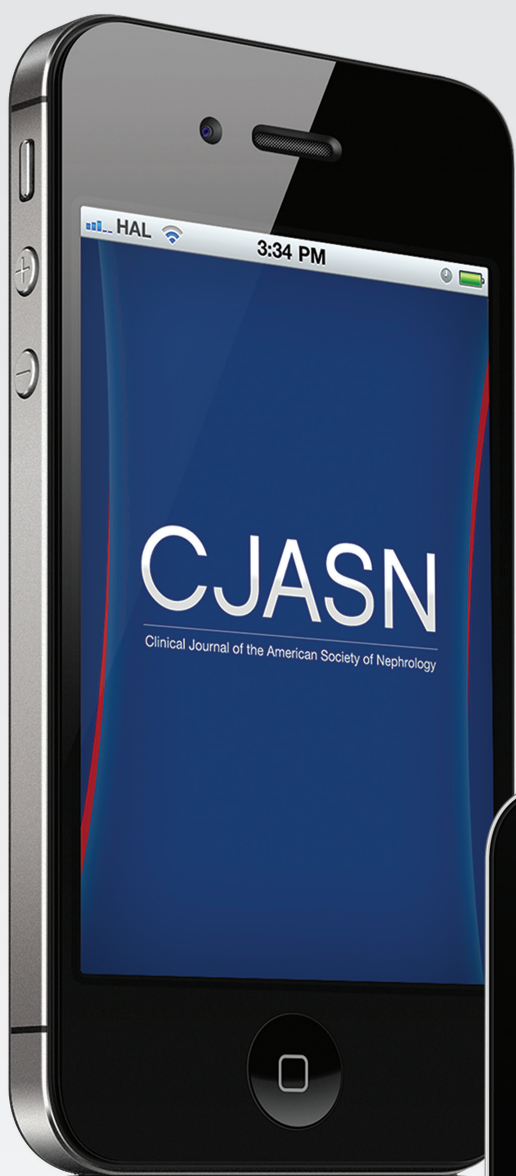
Table 2
Impact of ABIM changes on ASN member activities for Maintenance of Certification (MOC)

ABIM 2014 MOC Requirements	ABIM 2015 MOC Changes	ASN Activities
Verification of Credentials <ul style="list-style-type: none">Valid, unrestricted, and unchallenged medical license.	Unchanged.	N/A
Enroll in MOC <ul style="list-style-type: none">Required.Pay annual or 10-year fees.Reported as “meeting MOC requirements.”	Enroll in MOC <ul style="list-style-type: none">Required.Pay annual or 10-year fees. Change—fees remain at or below 2014 levels through (at least) 2017.Reported as “meeting MOC requirements.” Change—publicly report status as “participating in MOC” in the next 6 months.	N/A
Earn MOC Points <ul style="list-style-type: none">Complete an MOC activity every 2 years.Earn 100 MOC points every 5 years (at least 20 points in medical knowledge).Earn points through:<ul style="list-style-type: none">Medical knowledge activities.Practice assessment activities.Patient safety activities.Patient Voice activities.	Earn MOC Points <ul style="list-style-type: none">Complete an MOC activity every two years.Earn 100 MOC points every 5 years (at least 20 points in medical knowledge).Earn points through:<ul style="list-style-type: none">Medical knowledge activities.Practice assessment activities. Change—requirement suspended for at least 2 years.Patient safety activities. Change—requirement suspended for at least 2 years.Patient Voice activities. Change—requirement suspended for at least 2 years	Medical knowledge activities: <ul style="list-style-type: none">NephSAP (Nephrology Self-Assessment Program): 10 points/issue.KSAP (Kidney Self-Assessment Program): 25 points per module.ASN Highlights 2015 Self-Assessment: 8 MOC points.“Maintenance of Certification: NephSAP Review and ABIM Modules”<ul style="list-style-type: none">Kidney Week early program.50 MOC points.Awards CME credit. Practice assessment activities: ¹ <ul style="list-style-type: none">Dialysis Practice Improvement Module: 20 MOC points.Kidney Transplantation Practice Improvement Module: 20 MOC points. Patient safety activities: <ul style="list-style-type: none">None currently available from ASN. Patient Voice activities: <ul style="list-style-type: none">None currently available from ASN.
Pass the MOC exam	Pass the MOC exam Change—Internal Medicine exam updated with focus on making exam more reflective of what physicians in practice are doing, beginning fall 2015. More subspecialty exams to follow.	Board Review Course and Update—Live. <ul style="list-style-type: none">Offered annually.Awards CME credits.MOC points prohibited. Board Review Course and Update—Online. <ul style="list-style-type: none">ASN Learning Center.Presented in topic modules.Awards CME credits.MOC points

¹Although “suspended” (not needed to fulfill MOC requirements for recertification), MOC points will continue to be awarded for completed practice improvement modules.

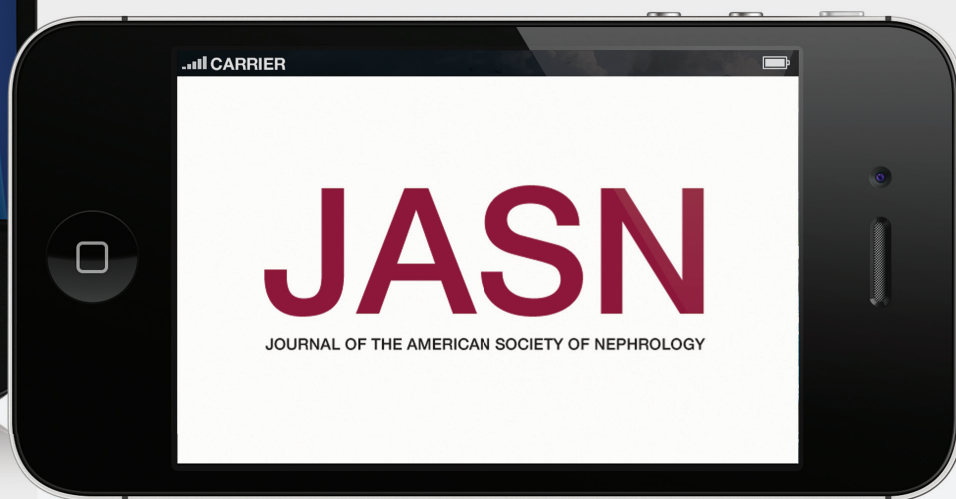
New Award Supports Kidney Research Scholar from Historically Disadvantaged Background

ASN recently announced the society is partnering with the Harold Amos Medical Faculty Development Program (AMFDP) of the Robert Wood Johnson Foundation to support the career development of a kidney research scholar from a historically disadvantaged background. The AMFPD awards 4-year post-residency grants to support the research and career development of physicians and dentists from disadvantaged backgrounds. The program, a long-running initiative of the Robert Wood Johnson Foundation, is designed to increase the number of faculty who achieve senior rank in academic medicine and dentistry and to foster the development of succeeding classes of such physicians and dentists. You may apply at <http://asn.kdny.info/IKdZJ>. ●



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To learn more and join or renew today, go to www.asn-online.org/membership.

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Time out.

Let's take a moment to look at the current state of the lab industry.

These days, a lot of labs are stripping away all of their value-added services and support to bring you that “unbelievably low” price. **At Spectra we believe the best price is one that doesn't come at a sacrifice to the quality of your results, efficiency of your staff, or the care of your patients.** We offer everything for one fair price—customer service, education and training, couriers, and medically necessary testing with no arbitrary limitations.

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