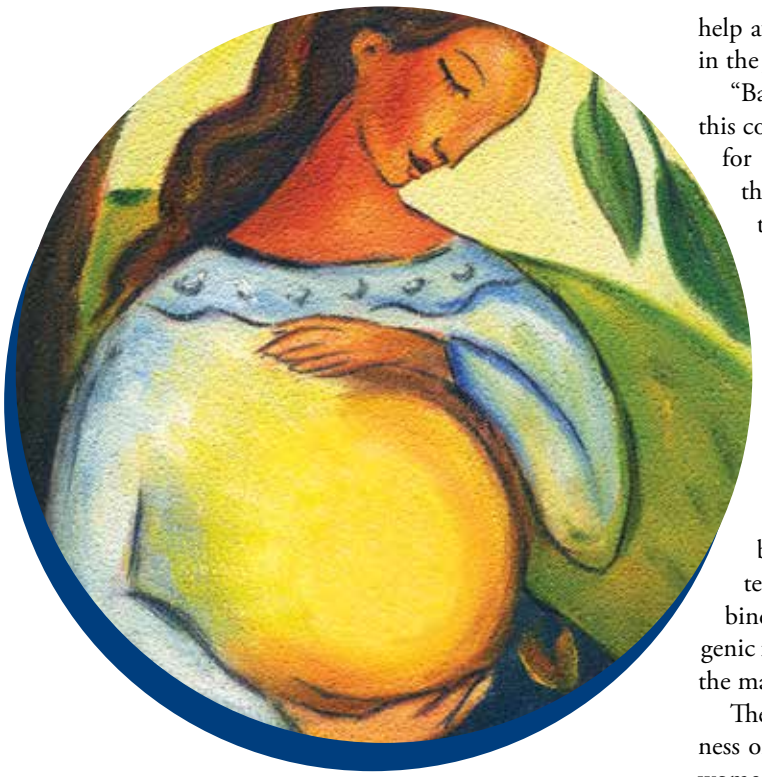
ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

KIDNEY WEEK EDITION

KidneyNews

October/November 2015 | Vol. 7, Numbers 10 & 11

Therapy May Cut Preterm Delivery from Preeclampsia



© Bull's Eye www.fotosearch.com

Preeclampsia during pregnancy can lead to serious health consequences for mother and baby, but preventive and therapeutic interventions have largely been unsuccessful, in part due to a limited understanding of the pathogenesis of the condition. In fact, the only way to cure preeclampsia is to deliver the baby. Recently, however, researchers proposed one of the first therapeutic interventions for preeclampsia that could help avoid preterm delivery. The results were published in the *Journal of the American Society of Nephrology.*

"Based on recent advances in the understanding of this condition, we and others are developing treatments for preeclampsia to allow women to safely prolong their pregnancy if they are suffering from very preterm preeclampsia," said lead author Ravi Thadhani, MD, MPH, Chief of Massachusetts General Hospital's Division of Nephrology. "Prolonging pregnancy allows the baby to mature, markedly reducing complications."

Dr. Thadhani is part of a collaborative team of scientists and clinicians from the United States and Germany that designed an open pilot study based on the knowledge that soluble FMS-like tyrosine kinase-1 (sFlt-1), which alters blood vessel growth, likely plays a role in the maternal signs and symptoms of preeclampsia. sFlt-1 binds and reduces free circulating levels of proangiogenic factors, thereby blocking their beneficial effects on the maternal endothelium.

The investigators evaluated the safety and effectiveness of removing sFlt-1 from the blood of 11 pregnant women with very preterm preeclampsia (23–32 weeks' gestation) through apheresis, which involves passing the patient's blood through a column lined with a material that binds to sFlt-1. sFlt-1 is retained while the rest of the blood is then returned to the body.

The 11 women received a total of 17 apheresis treatments (6 were treated once, 4 were treated twice, and 1 was treated 3 times). All participants experienced a reduction of sFlt-1, from an average pre-apheresis sFlt-1 concentration of 17,394 pg/mL to an average post-apheresis concentration of 14,265 pg/mL. The average percent reduction per treatment was 18% (range 7% to 28%) with concomitant reductions of 44% in protein/creatinine ratios. In addition to reducing proteinuria, apheresis transiently reduced women's blood pressure.

Pregnancy continued an average of 8 days for women treated once and 15 days for women treated multiple times. Pregnancy continued for only 3 days in 22 untreated women with preeclampsia. No major adverse effects of apheresis were observed as compared with infants born prematurely to untreated women with and without preeclampsia. Also, newborn babies of women in the apheresis group required fewer days of supplemental oxygen compared with those born to women in the preeclampsia control group, which suggests less pulmonary pathology.

"Our pilot study suggested we can safely prolong pregnancy when we target removal of sFlt-1 in women with severe preterm preeclampsia, and we hope this is confirmed in randomized trials," said Dr. Thadhani.

In an accompanying editorial, Thomas Easterling, MD, of the Maternal and Infant Care Clinic at the University of Washington Medical Center, in Seattle, noted that apheresis may be an important component of a broader intervention of synergistic agents, but he questioned whether the observed reduction in sFlt-1 concentration is clinically significant.

"Achieving an additional week of gestational age in a premature infant at the gestational ages studied is important and, given the cost of care in the neonatal intensive care unit, probably cost-effective," he wrote. He noted that approximately 20,000 women per year, 0.5%

Continued on page 6

Inside

KIDNEY WEEK SCIENTIFIC SESSIONS

THURSDAY

Measuring the Global Burden of Kidney Disease to Improve Public Health
State-of-the Art Lecture: Christopher J.L. Murray

Brave New World in Payment and Care Delivery
Christopher R. Blagg Endowed Lectureship: Shari M. Ling

Adaptive Trial Design for Acute Kidney Injury (AKI) Interventional Studies
Robert W. Schrier Endowed Lectureship: Ravi I. Thadhani

Approaches to Reduce FGF23 Levels in CKD Patients
Jack W. Coburn Endowed Lectureship: Isidro B. Salusky

FRIDAY

Genetics of Cardiovascular Disease: Getting to the Heart of the Matter
State-of-the-Art Lecture: Helen H. Hobbs

The Podocyte: From Periphery to Center Stage
Homer W. Smith Address: Dontscho Kerjaschki

SATURDAY

Cellular Mechanisms of Insulin Resistance: Implications for Obesity, Diabetes, and Metabolic Syndrome
State-of-the-Art Lecture: Gerald I. Shulman

Genomics of FSGS
Michelle P. Winn Endowed Lecture: Corinne Antignac

SUNDAY

Human Organs on Chips
State-of-the-Art Lecture: Donald E. Ingber

Novel Therapy for Diabetes Insipidus
Barry M. Brenner Endowed Lectureship: Jeff M. Sands

Renal Physiology is Key to Understand and Augment Nephron Repair
Young Investigator Award: Janos Peti-Peterdi

When fluid restriction is not enough for clinically significant hypervolemic and euvolemic hyponatremia *(serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction)*

Start SAMSCA® (tolvaptan)

Removing excess water with SAMSCA helps you manage hyponatremia while you are treating your patient's primary condition.

- **Too rapid correction of serum sodium can cause serious neurologic sequelae**
- Avoid fluid restriction during the first 24 hours of therapy

INDICATION and Important Limitations:

- SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)
- Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA. It has not been established that raising serum sodium with SAMSCA provides a symptomatic benefit to patients

IMPORTANT SAFETY INFORMATION:

SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely. Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable

Contraindications: Urgent need to raise serum sodium acutely, inability of the patient to sense or appropriately respond to thirst, hypovolemic hyponatremia, concomitant use of strong CYP 3A inhibitors, anuric patients, and hypersensitivity (e.g. anaphylactic shock, rash generalized) to tolvaptan or its components

Warnings and Precautions:

- Subjects with SIADH or very low baseline serum sodium concentrations may be at greater risk for too-rapid correction of serum sodium. In patients receiving SAMSCA who develop too rapid a rise in serum sodium or develop neurologic sequelae, discontinue or interrupt treatment with SAMSCA and consider administration of hypotonic fluid. Fluid restriction should generally be avoided during the first 24 hours
- SAMSCA can cause serious and potentially fatal liver injury. Avoid use in patients with underlying liver disease, including cirrhosis, because the ability to recover may be impaired. Limit duration of therapy with SAMSCA to 30 days. ***SAMSCA is not approved for use in ADPKD***
- Dehydration and hypovolemia can occur, especially in potentially volume-depleted patients receiving diuretics or those who are fluid restricted. In patients who develop medically significant signs or symptoms of hypovolemia, discontinuation is recommended
- Co-administration with hypertonic saline is not recommended
- Avoid concomitant use with: CYP 3A inhibitors and CYP 3A inducers. The dose of SAMSCA may have to be reduced if co-administered with P-gp inhibitors
- Monitor serum potassium levels in patients with a serum potassium >5 mEq/L and in patients receiving drugs known to increase serum potassium levels

Adverse Reactions: The most common adverse reactions (SAMSCA incidence ≥5% more than placebo, respectively): thirst (16% vs 5%), dry mouth (13% vs 4%), asthenia (9% vs 4%), constipation (7% vs 2%), pollakiuria or polyuria (11% vs 3%) and hyperglycemia (6% vs 1%)

Gastrointestinal Bleeding in Patients with Cirrhosis: In patients with cirrhosis in the hyponatremia trials, GI bleeding was reported in 10% of tolvaptan-treated patients vs 2% for placebo

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

Please see Brief Summary of FULL PRESCRIBING INFORMATION, including Boxed WARNING, on following pages.

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.
Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850.
SAMSCA is a registered trademark of Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.

Learn more at SAMSCA.com

Otsuka
Otsuka America Pharmaceutical, Inc.

Samsca® (tolvaptan) 15 mg 30 mg tablets

June 2015 07US15EBP0104

SELECTIVE. CORRECTIVE.

SAMSCA® (tolvaptan) tablets for oral use
Brief Summary of Prescribing Information. Please see Full Prescribing Information for complete product information.

WARNING: INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR SERUM SODIUM
SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely. Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.

INDICATIONS AND USAGE: SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).
Important Limitations: Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA. It has not been established that raising serum sodium with SAMSCA provides a symptomatic benefit to patients.
CONTRAINDICATIONS: SAMSCA is contraindicated in the following conditions:
Urgent need to raise serum sodium acutely: SAMSCA has not been studied in a setting of urgent need to raise serum sodium acutely.
Inability of the patient to sense or appropriately respond to thirst: Patients who are unable to auto-regulate fluid balance are at substantially increased risk of incurring an overly rapid correction of serum sodium, hypernatremia and hypovolemia.
Hypovolemic hyponatremia: Risks associated with worsening hypovolemia, including complications such as hypotension and renal failure, outweigh possible benefits.
Concomitant use of strong CYP 3A inhibitors: Ketoconazole 200 mg administered with tolvaptan increased tolvaptan exposure by 5-fold. Larger doses would be expected to produce larger increases in tolvaptan exposure. There is not adequate experience to define the dose adjustment that would be needed to allow safe use of tolvaptan with strong CYP 3A inhibitors such as clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, and telithromycin.
Anuric patients: In patients unable to make urine, no clinical benefit can be expected.
Hypersensitivity: SAMSCA is contraindicated in patients with hypersensitivity (e.g. anaphylactic shock, rash generalized) to tolvaptan or any component of the product *[see Adverse Reactions (6.2)]*.
WARNINGS AND PRECAUTIONS:
Too Rapid Correction of Serum Sodium Can Cause Serious Neurologic Sequelae (see BOXED WARNING): Osmotic demyelination syndrome is a risk associated with too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours). Osmotic demyelination results in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma or death. In susceptible patients including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable. In controlled clinical trials in which tolvaptan was administered in titrated doses starting at 15 mg once daily, 7% of tolvaptan-treated subjects with a serum sodium <130 mEq/L had an increase in serum sodium greater than 8 mEq/L at approximately 8 hours and 2% had an increase greater than 12 mEq/L at 24 hours. Approximately 1% of placebo-treated subjects with a serum sodium <130 mEq/L had a rise greater than 8 mEq/L at 8 hours and no patient had a rise greater than 12 mEq/L/24 hours. Osmotic demyelination syndrome has been reported in association with SAMSCA therapy *[see Adverse Reactions (6.2)]*. Patients treated with SAMSCA should be monitored to assess serum sodium concentrations and neurologic status, especially during initiation and after titration. Subjects with SIADH or very low baseline serum sodium concentrations may be at greater risk for too-rapid correction of serum sodium. In patients receiving SAMSCA who develop too rapid a rise in serum sodium, discontinue or interrupt treatment with SAMSCA and consider administration of hypotonic fluid. Fluid restriction during the first 24 hours of therapy with SAMSCA may increase the likelihood of overly-rapid correction of serum sodium, and should generally be avoided.
Liver Injury: SAMSCA can cause serious and potentially fatal liver injury. In a placebo-controlled and open label extension study of chronically administered tolvaptan in patients with autosomal dominant polycystic kidney disease, cases of serious liver injury attributed to tolvaptan were observed. An increased incidence of ALT greater than three times the upper limit of normal was associated with tolvaptan (42/958 or 4.4%) compared to placebo (5/484 or 1.0%). Cases of serious liver injury were generally observed starting 3 months after initiation of tolvaptan although elevations of ALT occurred prior to 3 months. Patients with symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine or jaundice should discontinue treatment with SAMSCA. Limit duration of therapy with SAMSCA to 30 days. Avoid use in patients with underlying liver disease, including cirrhosis, because the ability to recover from liver injury may be impaired. *[see Adverse Reactions (6.1)]*.
Dehydration and Hypovolemia: SAMSCA therapy induces copious aquaresis, which is normally partially offset by fluid intake. Dehydration and hypovolemia can occur, especially in potentially volume-depleted patients receiving diuretics or those who are fluid restricted. In multiple-dose, placebo-controlled trials in which 607 hyponatremic patients were treated with tolvaptan, the incidence of dehydration was 3.3% for tolvaptan and 1.5% for placebo-treated patients. In patients receiving SAMSCA who develop medically significant signs or symptoms of hypovolemia, interrupt or discontinue SAMSCA therapy and provide supportive care with careful management of vital signs, fluid balance and electrolytes. Fluid restriction during therapy with SAMSCA may increase the risk of dehydration and hypovolemia. Patients receiving SAMSCA should continue ingestion of fluid in response to thirst.
Co-administration with Hypertonic Saline: Concomitant use with hypertonic saline is not recommended.
Drug Interactions:
Other Drugs Affecting Exposure to Tolvaptan:
CYP 3A Inhibitors: Tolvaptan is a substrate of CYP 3A. CYP 3A inhibitors can lead to a marked increase in tolvaptan concentrations *[see Dosage and Administration (2.3), Drug Interactions (7.1)]*.
Do not use SAMSCA with strong inhibitors of CYP 3A *[see Contraindications (4.4)]* and avoid concomitant use with moderate CYP 3A inhibitors.
CYP 3A Inducers: Avoid co-administration of CYP 3A inducers (e.g., rifampin, rifabutin, rifapentin, barbiturates, phenytoin, carbamazepine, St. John's Wort) with SAMSCA, as this can lead to a reduction in the plasma concentration of tolvaptan and decreased effectiveness of SAMSCA treatment. If co-administered with CYP 3A inducers, the dose of SAMSCA may need to be increased *[see Dosage and Administration (2.3), Drug Interactions (7.1)]*.
P-gp Inhibitors: The dose of SAMSCA may have to be reduced when SAMSCA is co-administered with P-gp inhibitors, e.g., cyclosporine *[see Dosage and Administration (2.3), Drug Interactions (7.1)]*.
Hyperkalemia or Drugs that Increase Serum Potassium: Treatment with tolvaptan is associated with an acute reduction of the extracellular fluid volume which could result in increased serum potassium. Serum potassium levels should be monitored after initiation of tolvaptan treatment in patients with a serum potassium >5 mEq/L as well as those who are receiving drugs known to increase serum potassium levels.
ADVERSE REACTIONS:
Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse event information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates. In multiple-dose, placebo-controlled trials, 607 hyponatremic patients (serum sodium <135 mEq/L) were treated with SAMSCA. The mean age of these patients was 62 years; 70% of patients were male and 82% were Caucasian. One hundred eighty nine (189) tolvaptan-treated patients had a serum sodium <130 mEq/L, and 52 patients had a serum sodium <125 mEq/L. Hyponatremia was attributed to cirrhosis in 17% of patients, heart failure in 68% and SIADH/other in 16%. Of these patients, 223 were treated with the recommended dose titration (15 mg titrated to 60 mg as needed to raise serum sodium). Overall, over 4,000 patients have been treated with oral doses of tolvaptan in open-label or placebo-controlled clinical trials. Approximately 650 of these patients had hyponatremia; approximately 219 of these hyponatremic patients were treated with tolvaptan for 6 months or more. The most common adverse reactions (incidence ≥5% more than placebo) seen in two 30-day, double-blind, placebo-controlled hyponatremia trials in which tolvaptan was administered in titrated doses (15 mg to 60 mg once daily) were thirst, dry mouth, asthenia, constipation, pollakiuria or polyuria and hyperglycemia. In these trials, 10% (23/223) of tolvaptan-treated patients discontinued treatment because of an adverse event, compared to 12% (26/220) of placebo-treated patients; no adverse reaction resulting in discontinuation of trial medication occurred at an incidence of >1% in tolvaptan-treated patients.
Table 1 lists the adverse reactions reported in tolvaptan-treated patients with hyponatremia (serum sodium <135 mEq/L) and at a rate at least 2% greater than placebo-treated patients in two 30-day, double-blind, placebo-controlled trials. In these studies, 223 patients were exposed to tolvaptan (starting dose 15 mg, titrated to 30 and 60 mg as needed to raise serum sodium). Adverse events resulting in death in these trials were 6% in tolvaptan-treated-patients and 6% in placebo-treated patients.

Table 1. Adverse Reactions (>2% more than placebo) in Tolvaptan-Treated Patients in Double-Blind, Placebo-Controlled Hyponatremia Trials

System Organ Class MedDRA Preferred Term	Tolvaptan 15 mg/day-60 mg/day (N = 223) n (%)	Placebo (N = 220) n (%)
Gastrointestinal Disorders		
Dry mouth	28 (13)	9 (4)
Constipation	16 (7)	4 (2)
General Disorders and Administration Site Conditions		
Thirst[a]	35 (16)	11 (5)
Asthenia	19 (9)	9 (4)
Pyrexia	9 (4)	2 (1)
Metabolism and Nutrition Disorders		
Hyperglycemia[b]	14 (6)	2 (1)
Anorexia[c]	8 (4)	2 (1)
Renal and Urinary Disorders		
Pollakiuria or polyuria[d]	25 (11)	7 (3)

The following terms are subsumed under the referenced ADR in Table 1:
[a]polydipsia; [b]diabetes mellitus; [c]decreased appetite; [d]urine output increased, micturition, urgency, nocturia
In a subgroup of patients with hyponatremia (N = 475, serum sodium <135 mEq/L) enrolled in a double-blind, placebo-controlled trial (mean duration of treatment was 9 months) of patients with worsening heart failure, the following adverse reactions occurred in tolvaptan-treated patients at a rate at least 2% greater than placebo: mortality (42% tolvaptan, 38% placebo), nausea (21% tolvaptan, 16% placebo), thirst (12% tolvaptan, 2% placebo), dry mouth (7% tolvaptan, 2% placebo) and polyuria or pollakiuria (4% tolvaptan, 1% placebo).
Gastrointestinal bleeding in patients with cirrhosis: In patients with cirrhosis treated with tolvaptan in the hyponatremia trials, gastrointestinal bleeding was reported in 6 out of 63 (10%) tolvaptan-treated patients and 1 out of 57 (2%) placebo treated patients.
The following adverse reactions occurred in <2% of hyponatremic patients treated with SAMSCA and at a rate greater than placebo in double-blind placebo-controlled trials (N = 607 tolvaptan; N = 518 placebo) or in <2% of patients in an uncontrolled trial of patients with hyponatremia (N = 111) and are not mentioned elsewhere in the label: *Blood and Lymphatic System Disorders: Disseminated intravascular coagulation; Cardiac Disorders: Intracardiac thrombus, ventricular fibrillation; Investigations: Prothrombin time prolonged; Gastrointestinal Disorders: Ischemic colitis; Metabolism and Nutrition Disorders: Diabetic ketoacidosis; Musculoskeletal and Connective Tissue Disorders: Rhabdomyolysis; Nervous System: Cerebrovascular accident; Renal and Urinary Disorders: Urethral hemorrhage; Reproductive System and Breast Disorders (female): Vaginal hemorrhage; Respiratory, Thoracic, and Mediastinal Disorders: Pulmonary embolism, respiratory failure; Vascular disorder: Deep vein thrombosis.*
Postmarketing Experience: The following adverse reactions have been identified during post-approval use of SAMSCA. Because these reactions are reported voluntarily from a population of an unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
Neurologic: Osmotic demyelination syndrome; *Investigations:* Hypernatremia. Removal of excess free body water increases serum osmolality and serum sodium concentrations. All patients treated with tolvaptan, especially those whose serum sodium levels become normal, should continue to be monitored to ensure serum sodium remains within normal limits. If hypernatremia is observed, management may include dose decreases or interruption of tolvaptan treatment, combined with modification of free-water intake or infusion. During clinical trials of hyponatremic patients, hypernatremia was reported as an adverse event in 0.7% of patients receiving tolvaptan vs. 0.6% of patients receiving placebo; analysis of laboratory values demonstrated an incidence of hypernatremia of 1.7% in patients receiving tolvaptan vs. 0.8% in patients receiving placebo. *Immune System Disorders:* Hypersensitivity reactions including anaphylactic shock and rash generalized *[see Contraindications (4.6)]*.
DRUG INTERACTIONS:
Effects of Drugs on Tolvaptan:
Ketoconazole and Other Strong CYP 3A Inhibitors: SAMSCA is metabolized primarily by CYP 3A. Ketoconazole is a strong inhibitor of CYP 3A and also an inhibitor of P-gp. Co-administration of SAMSCA and ketoconazole 200 mg daily results in a 5-fold increase in exposure to tolvaptan. Co-administration of SAMSCA with 400 mg ketoconazole daily or with other strong CYP 3A inhibitors (e.g., clarithromycin, itraconazole, telithromycin, saquinavir, nelfinavir, ritonavir and nefazodone) at the highest labeled dose would be expected to cause an even greater increase in tolvaptan exposure. Thus, SAMSCA and strong CYP 3A inhibitors should not be co-administered *[see Dosage and Administration (2.3) and Contraindications (4.4)]*.
Moderate CYP 3A Inhibitors: The impact of moderate CYP 3A inhibitors (e.g., erythromycin, fluconazole, aprepitant, diltiazem and verapamil) on the exposure to co-administered tolvaptan has not been assessed. A substantial increase in the exposure to tolvaptan would be expected when SAMSCA is co-administered with moderate CYP 3A inhibitors. Co-administration of SAMSCA with moderate CYP3A inhibitors should therefore generally be avoided *[see Dosage and Administration (2.3) and Warnings and Precautions (5.5)]*. **Grapefruit Juice:** Co-administration of grapefruit juice and SAMSCA results in a 1.8-fold increase in exposure to tolvaptan *[see Dose and Administration (2.3) and Warnings and Precautions (5.5)]*. **P-gp Inhibitors:** Reduction in the dose of SAMSCA may be required in patients concomitantly treated with P-gp inhibitors, such as e.g., cyclosporine, based on clinical response *[see Dose and Administration (2.3) and Warnings and Precautions (5.5)]*. **Rifampin and Other CYP 3A Inducers:** Rifampin is an inducer of CYP 3A and P-gp. Co-administration of rifampin and SAMSCA reduces exposure to tolvaptan by 85%. Therefore, the expected clinical effects of SAMSCA in the presence of rifampin and other inducers (e.g., rifabutin, rifapentin, barbiturates, phenytoin, carbamazepine and St. John's Wort) may not be observed at the usual dose levels of SAMSCA. The dose of SAMSCA may have to be increased *[Dosage and Administration (2.3) and Warnings and Precautions (5.5)]*. **Lovastatin, Digoxin, Furosemide, and Hydrochlorothiazide:** Co-administration of lovastatin, digoxin, furosemide, and hydrochlorothiazide with SAMSCA has no clinically relevant impact on the exposure to tolvaptan.
Effects of Tolvaptan on Other Drugs: Digoxin: Digoxin is a P-gp substrate. Co-administration of SAMSCA with digoxin increased digoxin AUC by 20% and Cmax by 30%. **Warfarin, Amiodarone, Furosemide, and Hydrochlorothiazide:** Co-administration of tolvaptan does not appear to alter the pharmacokinetics of warfarin, furosemide, hydrochlorothiazide, or amiodarone (or its active metabolite, desethylamiodarone) to a clinically significant degree. **Lovastatin:** SAMSCA is a weak inhibitor of CYP 3A. Co-administration of lovastatin and SAMSCA increases the exposure to lovastatin and its active metabolite lovastatin-β hydroxyacid by factors of 1.4 and 1.3, respectively. This is not a clinically relevant change.
Pharmacodynamic Interactions: Tolvaptan produces a greater 24 hour urine volume/excretion rate than does furosemide or hydrochlorothiazide. Concomitant administration of tolvaptan with furosemide or hydrochlorothiazide results in a 24 hour urine volume/excretion rate that is similar to the rate after tolvaptan administration alone. Although specific interaction studies were not performed, in clinical studies tolvaptan was used concomitantly with beta-blockers, angiotensin receptor blockers, angiotensin converting enzyme inhibitors and potassium sparing diuretics. Adverse reactions of hyperkalemia were approximately 1-2% higher when tolvaptan was administered with angiotensin receptor blockers, angiotensin converting enzyme inhibitors and potassium sparing diuretics compared to administration of these medications with placebo. Serum potassium levels should be monitored during concomitant drug therapy. As a V_2 receptor antagonist, tolvaptan may interfere with the V_2 agonist activity of desmopressin (dDAVP). In a male subject with mild Von Willebrand (vW) disease, intravenous infusion of dDAVP 2 hours after administration of oral tolvaptan did not produce the expected increases in vW Factor Antigen or Factor VIII activity. It is not recommended to administer SAMSCA with V_2 agonist.
USE IN SPECIFIC POPULATIONS: There is no need to adjust dose based on age, gender, race, or cardiac function *[see Clinical Pharmacology (12.3)]*.
Pregnancy: Pregnancy Category C. There are no adequate and well controlled studies of SAMSCA use in pregnant women. In animal studies, cleft palate, brachymelia, microphthalmia, skeletal malformations, decreased fetal weight, delayed fetal ossification, and embryo-fetal death occurred. SAMSCA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In embryo-fetal development studies, pregnant rats and rabbits received oral tolvaptan during organogenesis. Rats received 2 to 162 times the maximum recommended human dose (MRHD) of tolvaptan (on a body surface area basis). Reduced fetal weights and delayed fetal ossification occurred at 162 times the MRHD. Signs of maternal toxicity (reduction in body weight gain and food consumption) occurred at 16 and 162 times the MRHD. When pregnant rabbits received oral tolvaptan at 32 to 324 times the MRHD (on a body surface area basis), there were reductions in maternal body weight gain and food consumption at all doses, and increased abortions at the mid and high doses (about 97 and 324 times the MRHD). At 324 times the MRHD, there were increased rates of embryo-fetal death, fetal microphthalmia, open eyelids, cleft palate, brachymelia and skeletal malformations *[see Nonclinical Toxicology (13.3)]*.
Labor and Delivery: The effect of SAMSCA on labor and delivery in humans is unknown.
Nursing Mothers: It is not known whether SAMSCA is excreted into human milk. Tolvaptan is excreted into the milk of lactating rats. Because many drugs are excreted into human milk and because of the potential for serious adverse reactions in nursing infants from SAMSCA, a decision should be made to discontinue nursing or SAMSCA, taking into consideration the importance of SAMSCA to the mother.
Pediatric Use: Safety and effectiveness of SAMSCA in pediatric patients have not been established.
Geriatric Use: Of the total number of hyponatremic subjects treated with SAMSCA in clinical studies, 42% were 65 and over, while 19% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Increasing age has no effect on tolvaptan plasma concentrations.
Use in Patients with Hepatic Impairment: Moderate and severe hepatic impairment do not affect exposure to tolvaptan to a clinically relevant extent. No dose adjustment of tolvaptan is necessary. Avoid use of tolvaptan in patients with underlying liver disease.
Use in Patients with Renal Impairment: No dose adjustment is necessary based on renal function. There are no clinical trial data in patients with CrCl <10 mL/min, and, because drug effects on serum sodium levels are likely lost at very low levels of renal function, use in patients with a CrCl <10 mL/min is not recommended. No benefit can be expected in patients who are anuric *[see Contraindications 4.5) and Clinical Pharmacology (12.3)]*.
Use in Patients with Congestive Heart Failure: The exposure to tolvaptan in patients with congestive heart failure is not clinically relevantly increased. No dose adjustment is necessary.
OVERDOSAGE: Single oral doses up to 480 mg and multiple doses up to 300 mg once daily for 5 days have been well tolerated in studies in healthy subjects. There is no specific antidote for tolvaptan intoxication. The signs and symptoms of an acute overdose can be anticipated to be those of excessive pharmacologic effect: a rise in serum sodium concentration, polyuria, thirst, and dehydration/hypovolemia. The oral LD50 of tolvaptan in rats and dogs is >2000 mg/kg. No mortality was observed in rats or dogs following single oral doses of 2000 mg/kg (maximum feasible dose). A single oral dose of 2000 mg/kg was lethal in mice, and symptoms of toxicity in affected mice included decreased locomotor activity, staggering gait, tremor and hypothermia.
If overdose occurs, estimation of the severity of poisoning is an important first step. A thorough history and details of overdose should be obtained, and a physical examination should be performed. The possibility of multiple drug involvement should be considered. Treatment should involve symptomatic and supportive care, with respiratory, ECG and blood pressure monitoring and water/electrolyte supplements as needed. A profuse and prolonged aquaresis should be anticipated, which, if not matched by oral fluid ingestion, should be replaced with intravenous hypotonic fluids, while closely monitoring electrolytes and fluid balance.
ECG monitoring should begin immediately and continue until ECG parameters are within normal ranges. Dialysis may not be effective in removing tolvaptan because of its high binding affinity for human plasma protein (>99%). Close medical supervision and monitoring should continue until the patient recovers.
PATIENT COUNSELING INFORMATION: As a part of patient counseling, healthcare providers must review the SAMSCA Medication Guide with every patient *[see FDA-Approved Medication Guide (17.3)]*.
Concomitant Medication: Advise patients to inform their physician if they are taking or plan to take any prescription or over-the-counter drugs since there is a potential for interactions.**Strong and Moderate CYP 3A inhibitors and P-gp inhibitors:** Advise patients to inform their physician if they use strong (e.g., ketoconazole, itraconazole, clarithromycin, telithromycin, nelfinavir, saquinavir, indinavir, ritonavir) or moderate CYP 3A inhibitors (e.g., aprepitant, erythromycin, diltiazem, verapamil, fluconazol) or P-gp inhibitors (e.g., cyclosporine) *[see Dosage and Administration (2.3), Contraindications (4.4), Warnings and Precautions (5.5) and Drug Interactions (7.1)]*.
Nursing: Advise patients not to breastfeed an infant if they are taking SAMSCA *[see Use In Specific Populations (8.3)]*.
For more information about SAMSCA, call 1-877-726-7220 or go to www.samsca.com.
Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan
Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850
SAMSCA is a registered trademark of Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan

Otsuka
Otsuka America Pharmaceutical, Inc.

07US14L-0919B Rev. 02, 2014

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

KidneyNews

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

www.asn-online.org

Postmaster: Please send address changes to *ASN Kidney News*, c/o Customer Service, American Society of Nephrology 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.

ASN Kidney Week—New in 2015

Found in Translation: Connecting Research and Patient Care

Early Programs

ASN offers 13 Early Programs on Tuesday, November 3, and/or Wednesday, November 4, preceding the Annual Meeting (November 5–8). New Early Programs are:

- **Advances in Research Conference: Engineering Genomes to Model Disease, Target Mutations, and Personalize Therapy** covers the principles and practical application of this technology to disease modeling, human genetics, and, ultimately, new approaches to personalized therapy in kidney disease.
- **Curing Kidney Disease: At the Crossroads of Biology, Infrastructure, Patients, and Government** focuses on a multidisciplinary approach to "curing kidney disease" in four different modules: Drug and Device Discovery, Clinical Trial Design and Infrastructure, Patient-Centric Approaches to Kidney Disease, and the Regulatory Pathway.
- **Women's Renal Health across the Decades** is designed for all trainees and practicing nephrologists who care for women with kidney disease. It spans the life of a woman from adolescence to postmenopause and addresses the kidney concerns across these stages of life.

Translational Sessions

ASN introduces a new Annual Meeting session type to the program. Translational Sessions include scientific research that is intended to update and/or translate to clinical practice for the care of patients with kidney disease. This year's topics include CKD and nutrition, graft injury, drug repurposing, glomerular genomics, diabetes, HIV, kidney tumors, iron metabolism, transport physiology and electrolyte disorders, potassium and blood pressure, as well as clinical trials and organ transplantation.

Board Certification Forum and Recertification Forum

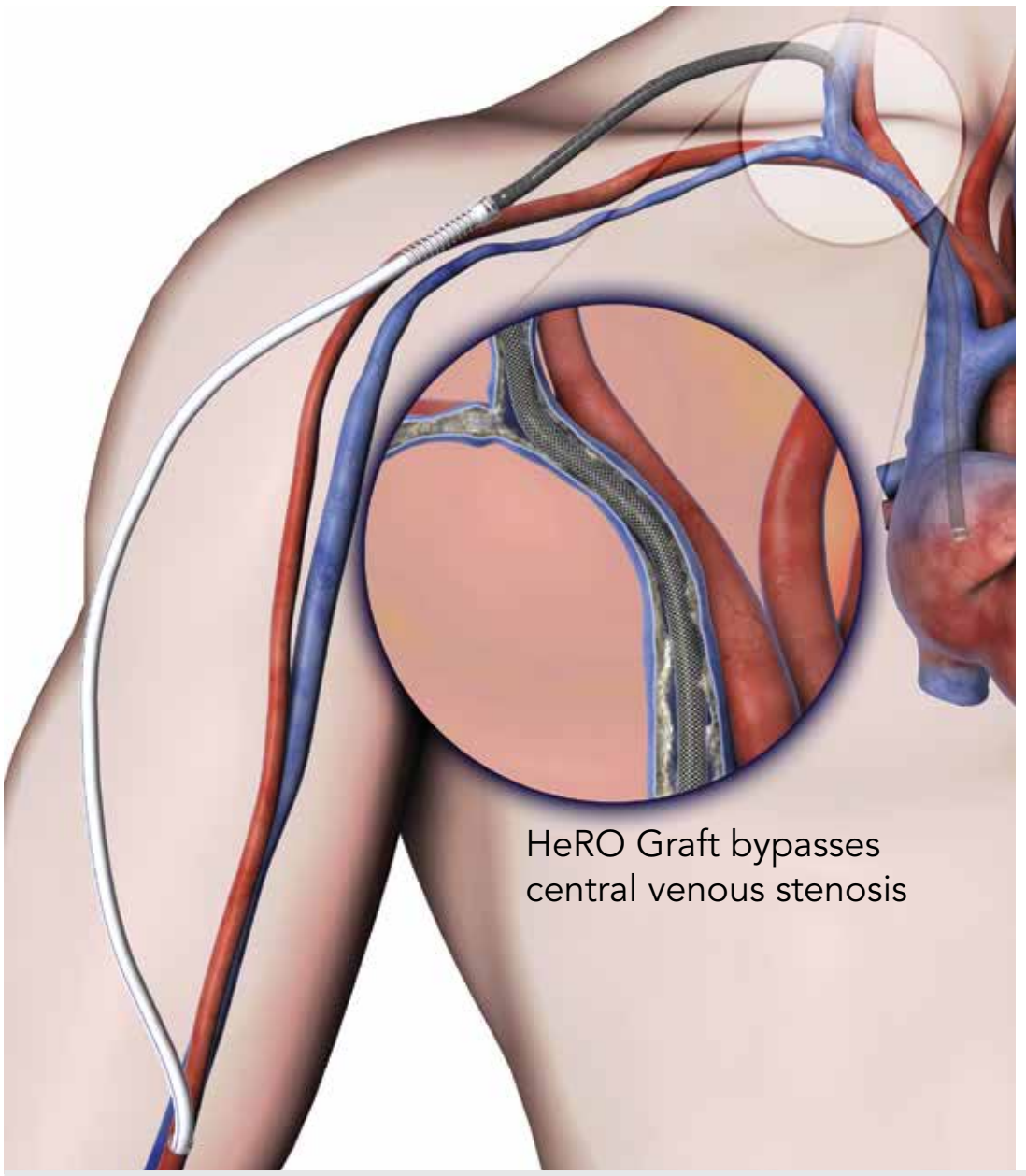
A special forum has been added to the Kidney Week schedule to offer ASN members an opportunity to voice their concerns and opinions about the controversies in board certification and recertification. The forum will be chaired by ASN leadership and will be held on Friday, November 6, at 10:30 am.

Meet-the-Experts Roundtables

ASN introduces an opportunity for small group interaction with several distinguished Kidney Week faculty. On Friday, November 6, and Saturday, November 7, from 12:45 pm to 1:45 pm in the Scientific Exposition hall, annual meeting participants can share a table with an expert faculty. Tickets ($35 USD) will be available each morning to reserve a seat at one of the roundtables where you will share a box lunch and conversation with colleagues and an expert faculty. Tickets are sold on a first-come, first-served basis. All sales are final, no refunds or exchanges.

Extended Poster Hours

Poster viewing will be extended to the time period from 9:30 am to 4:30 pm in the exhibit hall on Thursday, November 5; Friday, November 6; and Saturday, November 7.



HeRO Graft bypasses central venous stenosis

HeRO (Hemodialysis Reliable OutFlow) Graft is the **ONLY** fully subcutaneous AV access solution clinically proven to maintain long-term access for hemodialysis patients with **central venous stenosis.**

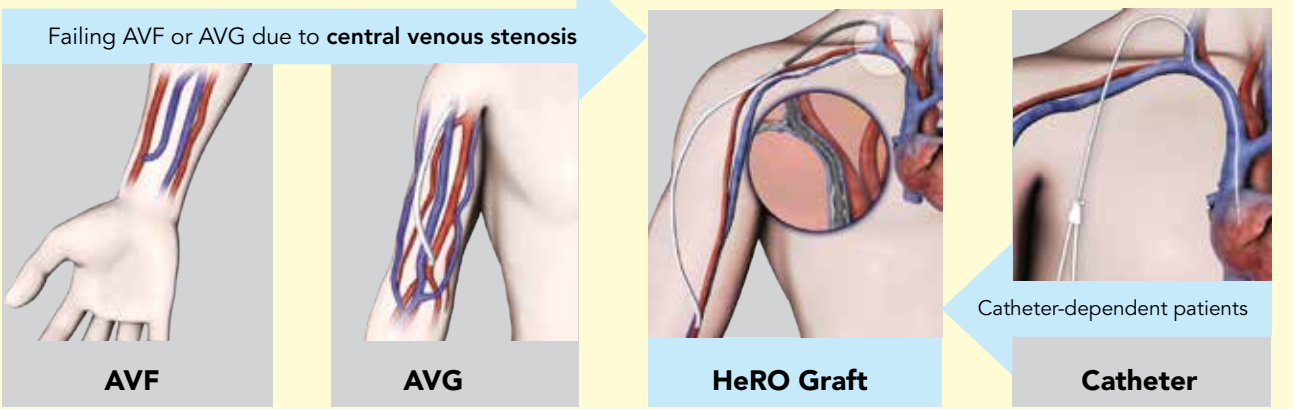
- **Fewer Infections:** 69% reduced infection rate compared with catheters[1]
- **Superior Dialysis Adequacy:** 1.7 Kt/V, a 16% to 32% improvement compared with catheters[1]
- **High Patency Rates:** Up to 87% cumulative patency at 2 years[1, 2]
- **Cost Savings:** A 23% average savings per year compared with catheters[3]

Reducing Catheter Dependency

HeRO Graft Candidates

- Catheter-dependent or approaching catheter-dependency
- Failing AVF or AVG due to central venous stenosis

Treatment Algorithm



Learn more at **www.herograft.com**
Order at: **888.427.9654**

References:
1) Katzman et al., J Vasc Surg 2009. 2) Gage et al., EJVES 2012. 3) Dageforde et al., JSR 2012.

Indications for Use: The HeRO Graft is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. See Instructions for Use for full indication, contraindication and caution statements. Rx only.

HeRO Graft is classified by the FDA as a vascular graft prosthesis.

1. Download the App
2. Scan the code with your mobile device to watch video

Get the free mobile app at
http://gettag.mobi

1655 Roberts Boulevard, NW • Kennesaw, Georgia 30144 • Phone (888) 427-9654 • (770) 419-3355

CryoLife®
Life Restoring Technologies®

Preeclampsia Intervention

Continued from page 1

of 4 million births in the United States, develop preeclampsia before 34 weeks gestation. Dr. Easterling agreed with the study's authors that a randomized trial is needed, but designing and carrying one out will be challenging.

Other experts in the field also welcomed the results and look forward to additional research on the strategy. "The study by Thadhani *et al*. is fascinating. As a physician scientist working in this field, I am thrilled to see this study whereby a molecule that is pathologically linked to preeclampsia and associated with adverse outcomes was used to identify a patient population for directed therapy but was also used to monitor response to therapy," said Sarosh Rana, MD, Section Chief of Maternal Fetal Medicine at the University of Chicago. "This is science at its very best, and I am happy that it is happening to benefit our pregnant moms and their babies."

Study co-authors include Henning Hagmann, MD, Wiebke Schaarschmidt, MD, Bernhard Roth, MD, Tuelay Cingoez, MD, S. Ananth Karumanchi, MD, Julia Wenger, MPH, Kathryn Lucchesi, PhD, RPh, Hector Tamez, MD, MPH, Tom Lindner, MD, Alexander Fridman, MD, Ulrich Thome, MD, Angela Kribs, MD, Marco Danner, Stefanie Hamacher, MSc, Peter Mallmann, MD, Holger Stepan, MD, and Thomas Benzing, MD.

Disclosures: Ravi Thadhani, Grant support from Kaneka Corporation, consultant to Thermofisher Scientific, financial interest in Aggamin LLC and patents on diagnostics for preeclampsia; Henning Hagmann, Grant support from Kaneka Corporation; S. Ananth Karumanchi, Co-inventor on patents on preeclampsia markers and therapies, grant support from Thermofisher Scientific, financial interest in Aggamin LLC and Consultant to Siemens and Roche Diagnostics; Thomas Benzing, support from the German Research Foundation.

The article, entitled "Removal of sFlt-1 by Dextran Sulfate Apheresis in Preeclampsia," is available at http://jasn.asnjournals.org/

The editorial, entitled "Apheresis to Treat Preeclampsia: Insights, Opportunities and Challenges," is available at http://jasn.asnjournals.org/

TRIFERIC®
ferric pyrophosphate citrate

Replaces Iron and Maintains Hemoglobin without Increasing Iron Stores

- Hemodialysis patients lose 5-7 milligrams of iron every dialysis treatment.[1]
- Triferic replaces that 5-7 milligram iron loss every dialysis treatment.[2]
- Triferic is added to liquid bicarbonate on-site at the clinic. Via dialysate, Triferic crosses the dialyzer membrane and enters the blood, immediately binding to transferrin for direct incorporation into hemoglobin.[2]
- Triferic's unique binding action enables it to bypass the RE block, and overcome the Functional Iron Deficiency that occurs with intravenous iron products.[2]
- Triferic is true iron maintenance therapy.[2]

Iron Delivered via Dialysate

Clinically proven to replace iron and maintain hemoglobin in adult hemodialysis patients.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions. Hypersensitivity reactions have been reported in 1 (0.3%) of 292 patients receiving Triferic in two randomized clinical trials.

Iron status should be determined on pre-dialysis blood samples. Post dialysis serum iron parameters may overestimate serum iron and transferrin saturation.

Adverse Reactions

The most common adverse reactions (≥3% and at least 1% greater than placebo) in controlled clinical studies include: procedural hypotension (21.6%), muscle spasms (9.6%), headache (9.2%), pain in extremity (6.8%), peripheral edema (6.8%), dyspnea (5.8%), back pain (4.5%), pyrexia (4.5%), urinary tract infection (4.5%), asthenia (4.1%), fatigue (3.8%), arteriovenous (AV) fistula thrombosis (3.4%), and AV fistula site hemorrhage (3.4%).

References: 1. Rao M, Muirhead N, Klarenbach S, Moist L, Lindsay RM. Management of Anemia With Quotidian Hemodialysis. American Journal of Kidney Diseases, Vol 42, No 1, Suppl 1 (July), 2003: pp S18-S23. 2. Triferic™ [Package Insert]. Rockwell Medical, Wixom, MI, January 2015.

Possibly the Most Significant Advancement in Dialysis in 25 Years

ROCKWELL MEDICAL

TRIFERIC® (FERRIC PYROPHOSPHATE CITRATE) SOLUTION, FOR ADDITION TO BICARBONATE CONCENTRATE

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE: Triferic is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). **Limitation of Use.** Triferic is not intended for use in patients receiving peritoneal dialysis. Triferic has not been studied in patients receiving home hemodialysis.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS: Hypersensitivity Reactions. Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions *[see Adverse Reactions].* Hypersensitivity reactions have been reported in 1 (0.3%) of 292 patients receiving Triferic in two randomized clinical trials. **Iron Laboratory Testing.** Iron status should be determined on pre-dialysis blood samples. Post dialysis serum iron parameters may overestimate serum iron and transferrin saturation.

ADVERSE REACTIONS: The following adverse reactions are described below and elsewhere in the labeling: Hypersensitivity Reactions *[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 a drug may not reflect the rates observed in practice. In two randomized, placebo-controlled clinical trials, a total of 292 patients were administered Triferic for periods of up to 1 year *[see Clinical Studies in the Full Prescribing Information].* The mean total exposure in the randomized treatment period was 5 months. A total of 296 patients received placebo treatment for a similar time period. In the two studies, 64% were male and 54% were Caucasian. The median age of patients was 60 years (range, 20 to 89 years). Adverse events occurring in 3% or greater of patients treated with Triferic in the randomized clinical trials are listed in Table 1.

Table 1: Adverse Reactions Reported in Two Clinical Trials in at Least 3% of Patients Receiving Triferic and at an Incidence at least 1% Greater than Placebo

System organ class Preferred term	**Triferic N=292 n (%)**	**Placebo N=296 n (%)**
Number of patients with at least one adverse reaction	229 (78.4)	223 (75.3)
General Disorders and Administration Site Conditions		
Peripheral edema	20 (6.8)	11 (3.7)
Pyrexia	13 (4.5)	9 (3.0)
Asthenia	12 (4.1)	9 (3.0)
Fatigue	11 (3.8)	6 (2.0)
Infections and Infestations		
Urinary tract infection	13 (4.5)	4 (1.4)
Injury, Poisoning, and Procedural Complications		
Procedural hypotension	63 (21.6)	57 (19.3)
Arteriovenous fistula thrombosis	10 (3.4)	6 (2.0)
Arteriovenous fistula site hemorrhage	10 (3.4)	5 (1.7)
Musculoskeletal and Connective Tissue Disorders		
Muscle spasms	28 (9.6)	24 (8.1)
Pain in extremity	20 (6.8)	17 (5.7)
Back pain	13 (4.5)	10 (3.4)
Nervous System Disorders		
Headache	27 (9.2)	16 (5.4)
Respiratory, Thoracic and Mediastinal Disorders		
Dyspnea	17 (5.8)	13 (4.4)

Adverse Reactions Leading to Treatment Discontinuation. In clinical trials, adverse reactions leading to treatment discontinuation included headache, asthenia, dizziness, constipation, nausea, hypersensitivity reactions, intradialytic hypotension, pruritus, and pyrexia. Adverse reactions reported in the treatment extension period were similar to those observed in the randomized clinical studies.

USE IN SPECIFIC POPULATIONS: Pregnancy. Pregnancy Category C. *Risk Summary:* There are no adequate and well-controlled studies of Triferic in pregnant women. In pregnant rats and rabbits, ferric pyrophosphate citrate caused developmental toxicity at maternally toxic dose levels that were higher than the maximum theoretical amount of iron transferred to patients from Triferic. The incidence of major malformations in human pregnancies has not been established for Triferic. However, all pregnancies regardless of exposure to any drug have a background rate of 2 to 4% for major malformations, and 15 to 20% for pregnancy loss. Use Triferic during pregnancy only if the potential benefit justifies the potential risk to the fetus. *Animal Data:* In a fertility and early embryonic development study in female rats, the maternally toxic ferric pyrophosphate citrate dose of 40 mg/kg administered three times per week by intravenous (IV) infusion was not toxic to the developing embryo. In embryo-fetal developmental toxicity studies, ferric pyrophosphate citrate was administered during the period of organogenesis as a one-hour IV infusion to pregnant rats and rabbits. No maternal or developmental toxicity was observed at doses up to 30 mg/kg/day in rats and 20 mg/kg/day in rabbits. Maternally toxic doses affected embryo-fetal development, resulting in post-implantation loss due to early resorptions, abnormal placentae, decreased fetal body weight and fetal head and vertebral malformations at 90 mg/kg/day in rats and vertebral malformations at 40 mg/kg/day in rabbits. A pre-and post-natal development study was conducted in pregnant rats with intravenous doses of ferric pyrophosphate citrate up to 90 mg/kg/day. The maternally toxic dose of 90 mg/kg/day resulted in reductions in the number of live offspring and lower offspring body weights. There were no adverse effects on survival of offspring at doses up to 30 mg/kg/day, or on behavior, sexual maturation or reproductive parameters of offspring at any dose level. **Nursing Mothers.** It is not known if ferric pyrophosphate citrate is present in human milk. Because many drugs are excreted in human milk and because of the potential for adverse events in nursing infants, a decision should be made whether to discontinue nursing or to avoid Triferic, taking into account the importance of iron to the mother and the known benefits of nursing. **Pediatric Use.** Safety and effectiveness have not been established in pediatric patients. **Geriatric Use.** In controlled clinical trials, 99 (28.6%) patients ≥ 65 years of age were treated with Triferic. No overall differences in safety and efficacy were observed between older and younger patients in these trials *[see Clinical Studies in the Full Prescribing Information].*

OVERDOSAGE: No data are available regarding overdosage of Triferic in humans.

NONCLINICAL TOXICOLOGY: Carcinogenesis, Mutagenesis, Impairment of Fertility. Studies examining the carcinogenic potential of ferric pyrophosphate citrate have not been conducted. Ferric pyrophosphate citrate was clastogenic in the in vitro chromosomal aberration assay in CHO cells in the presence of metabolic activation. Ferric pyrophosphate citrate was not mutagenic in the in vitro bacterial reverse mutation (Ames) test or clastogenic in the in vitro chromosomal aberration assay in CHO cells in the absence of metabolic activation or in the in vivo mouse micronucleus assay. In a combined male and female fertility study in rats, ferric pyrophosphate citrate was administered intravenously over one hour three times per week at doses of up to 40 mg/kg. No adverse effects on fertility or reproduction were noted.

Manufactured for
Rockwell Medical, Inc.
Wixom, MI 48393

Version: 09/2015

ROCKWELL MEDICAL

ASN Finalizes New Strategic Plan

The society must continuously engage our diverse, vibrant membership to ensure that we are nimble enough to respond quickly to the pace of change in … a dynamic health care environment.

–Jonathan Himmelfarb, MD, FASN, ASN President

ASN recently finalized a new strategic plan that expands the society's leadership role in supporting transformative research targeting prevention, treatment, and cures for kidney diseases. ASN has also committed to articulating a vision for nephrology practice in the future as part of the strategic plan.

Responding to changes in nephrology, medicine, health care, and science—as well as the evolution of not-for-profit organizations—ASN produced strategic plans in 2003 and 2010. These plans resulted in ASN's focus on education, communications and publications, policy and advocacy, grants and travel support, and workforce.

"To lead the society to the next level, the ASN Council initiated a new strategic planning process in July 2014," said ASN Past President Sharon M. Moe, MD, FASN. The society held a series of listening sessions with ASN members during Kidney Week 2014 in Philadelphia, PA. "Combined with input from ASN's committees, advisory groups, and former councilors, the feedback from the listening sessions helped the leadership finalize a new strategic plan" during the past year, Dr. Moe added.

"The new strategic plan will shape the society through 2020," explained ASN President Jonathan Himmelfarb, MD, FASN. "Focused on helping nephrology overcome current challenges and building the profession, the new strategic plan leverages the success of ASN, the ASN Foundation for Kidney Research, and the Kidney Health Initiative to continue to broaden outreach to future professionals, support those already working in nephrology, and assert the value of nephrology," Dr. Himmelfarb said.

"The next five years are crucial to the future of nephrology," Dr. Himmelfarb noted. "Interest in careers in nephrology is at an all-time low, while nephrology is among the least-popular specialties for graduates of US medical schools." Kidney research "has generated the lowest number of randomized controlled trials and produced few new approved safe and effective drugs, devices, and biologics." As a result, according to Dr. Himmelfarb, "It's not surprising that the public, press, politicians, policymakers, and primary care providers exhibit less awareness of kidney diseases than many other prevalent diseases."

"The society must continuously engage our diverse, vibrant membership to ensure that we are nimble enough to respond quickly to the pace of change in such a dynamic health care environment," Dr. Himmelfarb said.

During Kidney Week 2015 in San Diego, CA, ASN leaders will hold a second round of listening sessions "to seek the membership's advice on how to move from broad goals to an implementation plan," explained ASN President-Elect Raymond C. Harris, MD, FASN. These discussions will help the leadership identify short-, medium-, and long-term objectives ASN must meet during the next five years (2016–2020) to accomplish its new strategic plan.

To discuss the new ASN Strategic Plan, please email ASN Executive Director Tod Ibrahim at tibrahim@asn-online.org.

ASN's vision, mission, and goals (2016–2020)

1. **Vision:** To prevent, treat, and cure kidney diseases.

2. **Mission:** ASN leads the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge, and advocating for the highest quality care for patients.

3. **Goals:** To accomplish this vision and mission, ASN will:
   - **a. Lead the kidney community by focusing on education, communications, policy, and collaboration**
     - i. Educate health professionals and scientists by creating innovative tools and platforms, expanding to new settings, and increasing audiences.
     - ii. Communicate new knowledge effectively, rapidly, and extensively.
     - iii. Advocate for policies that promote the highest quality patient care, increased funding for research, and a commitment to medical education.
     - iv. Collaborate with patient, health and science professional, and other organizations to advance mutually shared goals, including greater awareness of kidney diseases.
   - **b. Transform kidney research through discovery and innovation to prevent, treat, and cure kidney diseases**
     - i. Galvanize the kidney community to advance research that enhances the lives of patients.
     - ii. Include patients, families, and caregivers as stakeholders in the design and implementation of kidney research.
     - iii. Engage new partners and facilitate collaboration among health professionals, scientists, and other stakeholders.
     - iv. Leverage breakthroughs to increase awareness of kidney diseases and to promote interest in careers in nephrology.
     - v. Ensure the continued success of the Kidney Health Initiative and the ASN Foundation for Kidney Research.
   - **c. Encourage every kidney health professional in the world to contribute to, and benefit from, ASN**
     - i. Expand membership to include the interprofessional kidney health care team, including physicians, scientists, doctors of pharmacy, pharmacists, advanced practice providers, nurses, dieticians, and social workers.
     - ii. Extend the society's voting privilege(s) to every ASN member.
     - iii. Promote diversity and inclusiveness within ASN to enrich the nephrology profession and kidney community as well as the lives of people with kidney diseases.
   - **d. Foster career development for current and future kidney health professionals**
     - i. Continue to strengthen the pipeline of health professionals, scientists, and educators in nephrology.
     - ii. Develop resources for career development for each ASN member at every stage in professional life.
     - iii. Empower ASN members to become leaders in health care practice, research, and education as well as administration and management.
   - **e. Assert the value of nephrology to health and science professionals, health care systems, and other stakeholders to ensure high-quality care for patients**
     - i. Define the scope of nephrology practice and articulate a vision for nephrology in the future (Nephrology 2020).
     - ii. Facilitate improvements in patient care, research, and education by using all available data sources to produce recurring reports about the state of nephrology.
     - iii. Highlight the specialty of nephrology as a leader in health care delivery and quality improvement.

ASN from A to Z:

An Alphabetical Look at ASN's Activities since Kidney Week 2014

A **ASN Strategic Plan That Will Lead the Society to the Next Level by 2020.** The ASN leadership held a series of "listening sessions" with the society's members during Kidney Week 2014. This valuable feedback—as well as input from ASN's committees, advisory groups, and other panels—helped the leadership finalize a new strategic plan during the past year. Focused on building the profession, the new strategic plan will shape the society through 2020.

B **Blue Ribbon Panel on Career Development.** Starting with a retreat in February, this panel is evaluating current professional development programs within and outside of nephrology to help ASN address key gaps to better support kidney professionals at all career stages.

C **Commendation.** The Accreditation Council for Continuing Medical Education (ACCME) in December awarded ASN Accreditation with Commendation, signifying that ASN is now among the top 16% of ACCME-accredited organizations providing continuing medical education.

D **Dialogue on Transforming Kidney Research through Discovery and Innovation**. In September, ASN convened a summit to help shape the society's efforts to galvanize the kidney community to advance research that enhances the lives of patients; include patients, families, and caregivers as stakeholders in the design and implementation of kidney research; engage new partners and facilitate collaboration among health professionals, scientists, and other stakeholders; and leverage breakthroughs to increase awareness of kidney diseases and to promote interest in careers in nephrology.

E **Endowment of Ben J. Lipps Research Fellowship Program.** In four years, the ASN Foundation for Kidney Research fully endowed the Ben J. Lipps Research Fellowship Program at $20,000,000, guaranteeing that 20 nephrology fellows will receive annual funding in perpetuity.

F **Fellows in Nephrology: Building a Better Match.** Working on a very short timeline, the ASN Match Task Force addressed the viability, integrity, and process of the nephrology match. As a result of the task force's efforts, nephrology was the first specialty in the National Resident Matching Program's Specialties Matching Service to adopt an "all-in" policy.

G **Giving Voice to the Kidney Community.** ASN advocates for legislative and regulatory action to promote the highest quality patient care, increase funding for research, and to maintain the commitment to medical education. In 2015, this effort included working with the Senate Finance Committee's Chronic Conditions Workgroup, crafting a bill with the US House of Representatives to expand telehealth options that advance patient safety and access to care, and advocating for the CKD Improvement in Research and Treatment Act to strengthen research funding and reduce health disparities.

H **Harold Amos Medical Faculty Development Program Award.** ASN partnered with the Robert Wood Johnson Foundation in February to support the career development of kidney scholars and future health care leaders from historically disadvantaged backgrounds.

I **Innovations in Kidney Education Contest.** ASN received 40 submissions for the inaugural contest intended to recognize innovative tools—including apps, videos, smart board talks, and games—focused on educating medical and graduate students in key concepts of nephrology.

J **Journals.** *JASN* continues to maintain the highest impact factor among

nephrology journals, while *CJASN* published three successful series (Renal Immunology for the Clinician, Renal Physiology for the Clinician, and the Role of the Medical Director).

K **Kidney Self-Assessment Program (KSAP).** In March, ASN launched KSAP, a continuing medical education and recertification product that reviews the essentials of nephrology for fellows preparing for initial certification, practicing nephrologists preparing for recertification, and practitioners looking to refresh their understanding of the core elements of nephrology.

L **Lafayette.** On January 1, 2015, Richard A. Lafayette, MD, became the second Editor-in-Chief of *ASN Kidney News*, succeeding Pascale H. Lane, MD, FASN. *Kidney News* remains the most widely distributed newsmagazine.

M **Membership.** With more than 15,500 physicians, scientists, and other health professionals, ASN membership has grown 21% since 2010.

N **Network of Minority Health Research Investigators (NMRI) and Student National Medical Association (SNMA).** For the first time this year, ASN exhibited at the SNMA Annual Meeting and provided travel support for 15 participants to attend the NMRI Workshop, a network of current and potential investigators and technical personnel interested in minority health research, including individuals from traditionally underserved communities.

O **Online Products.** ASN continues to expand distance learning opportunities, including the Board Review Course and Update Online, Dialysis Practice Improvement Module, Dialysis "Virtual Mentor" Curriculum, Ebola and Dialysis: Resources for Nephrology Health Professionals, Educational Symposia, Early Programs, Geriatric Nephrology Curriculum, Kidney Transplantation Practice Improvement Module, Kidney Week On-Demand, and Transplant Nephrology Core Curriculum (with the American Society of Transplantation).

P **Patient and Family Partnership Council of the Kidney Health Initiative (KHI).** With more than 70 member organizations, KHI—ASN's landmark collaboration with the US Food and Drug Administration—completed several more projects this year and established the Patient and Family Partnership Council to guarantee that the patient's voice, experience, and involvement are meaningful and effective.

Q **Quality Metrics Task Force.** Through a series of regulatory efforts and dialogue with the Centers for Medicare & Medicaid Services, as well as engagement in the National Quality Forum endorsement process, ASN improved how the Medicare program evaluates the quality of patient care in the ESRD Quality Incentive Program. In its quality advocacy, ASN focuses on the importance of transparency, the use of measures based in rigorous evidence, and need to maintain flexibility for nephrologists to deliver individualized patient care.

R **Recertification.** ASN continued to raise concerns about maintenance of certification with the leadership of the American Board of Internal Medicine (ABIM). Throughout the year (in February, March, April, July, and September), the society also provided regular updates to its members about ABIM, MOC, recertification, and related issues. Additionally, ASN conducted a podcast interview in June with Paul S. Teirstein, MD, President of the National Board of Physicians and Surgeons.

S **Strategic Plan for Patient Care Advocacy.** In February, ASN finalized a strategy for advancing legislative and regulatory policies to improve patient access to transplantation, expand telehealth, reduce health disparities, and reinforce the nephrology care team's role in delivering patients the highest quality care.

T **Twitter Chats.** Once a month, ASN participated in Twitter chats organized by Matthew A. Sparks, MD, FASN, and Joel Topf, MD. During the past year, these chats have focused on Ask the ASN President with Jonathan Himmelfarb, MD, FASN; ASN Kidney Week 2015 with Lloyd G. Cantley, MD, FASN; and Kidney Health Advocacy Day with Crystal A. Gadegbeku, MD, and Michelle A. Josephson, MD.

U **Unifier.** During Kidney Community Advocacy Day 2015, ASN brought together more than 100 representatives from 16 kidney organizations to visit over 120 congressional offices representing more than 30 states. These advocates joined forces on Capitol Hill and urged Congress to increase funding for kidney research and to cosponsor legislation supporting living donors.

V **Vulcan Mind Meld.** Kidney STARS and TREKS are committed to ensuring that nephrology will "live long and prosper," with more than 250 total medical students, residents, graduate students, and other trainees participating in both programs in 2015.

W **Workforce.** Working with researchers from George Washington University, ASN released four reports about the nephrology workforce since last year's meeting: *The US Nephrology Workforce: Developments and Trends* (November), *The 2015 NRMP SMS Nephrology Match—ASN Brief Analysis* (December), *Findings from the 2014 Survey of Nephrology Fellows* (January), and *Analysis of the NRMP-SMS Nephrology Match for the 2015–2016 Appointment Year* (March). *Graphic Design USA* recognized *The US Nephrology Workforce: Developments and Trends* with a 2015 "American Health +Wellness Award."

X **XPRIZE.** ASN is working with the XPRIZE Foundation to research a prize competition that could potentially address kidney disease.

Y **Yamagata**, Japan. More than 35% of ASN members are from outside the United States, representing nearly 115 countries and including six members in Yamagata. As illustrated in **Table 1**, ASN is a global organization.

Z **Zenith** (Coming Soon!): Establishing communities to serve as platforms for discussion, networking, and communication among ASN members with shared interests in nephrology; reinventing the *ASN Kidney News* website as a dynamic resource for real-time news and context on the latest advances in kidney health and insights into kidney policy; holding ASN Kidney Week 2016 in Chicago, IL; and celebrating ASN's 50th Anniversary (1966–2016).

Table 1

ASN activity	From outside the United States
Kidney Week participants	45%
Kidney Week abstract submissions	57%
JASN submissions	62%
CJASN submissions	67%
Facebook followers	56%
Twitter followers	51%

Austerity Shortchanges Cure for Kidney Diseases and Other Chronic Conditions

Prominent Kidney Researcher Loses Lab, and with it, Job and Discoveries

By Frank C. Brosius, MD

Budget austerity measures are imperiling funding for NIH research. This concerns me a great deal as a physician-scientist focused on providing the 20 million Americans with kidney disease the best care possible. Kidney disease is a devastating disease, and it's costing taxpayers a fortune. When patients progress to kidney failure, otherwise known as end stage renal disease (ESRD), they require dialysis or a transplant. Although transplant is the optimal form of treatment for most patients, there aren't enough donated kidneys for everyone who needs one, so most patients with ESRD (nearly 650,000) are stuck on dialysis.

I say stuck because most patients receive in-center dialysis treatment three times a week for three to four hours for each treatment. And because kidney disease causes other chronic diseases, such as diabetes, high blood pressure, and heart disease (80% of patients with ESRD have three comorbidities), patients are often shuttling between many doctor appointments and visits. Not surprisingly, only 1 in 5 patients on dialysis works, and many draw Social Security Disability Insurance (SSDI) benefits.

Here's the kicker, ESRD—the only health condition that Medicare automatically covers regardless of age or disability—represents 7% of Medicare's cost but less than 1% of the patient population. At $35 billion annually, the Medicare ESRD Program costs more than NIH's entire budget, and for a treatment with grim outcomes. Fifty percent of patients with ESRD die within three years of initiating dialysis, and the leading cause of death of patients with ESRD is heart disease.

If we can prevent the progression of kidney disease or improve the care of patients with ESRD, that would reduce heart disease and other chronic conditions and yield significant Medicare and SSDI savings. But that requires sustained and steady increases for NIH, particularly for groundbreaking basic research, the building block for new treatments and cures. Instead we are moving backward.

For example, Benjamin Margolis, MD, a colleague at the University of Michigan Medical School, in Ann Arbor, is one of the leading investigators in the basic science of cells in the kidney tubules. His discoveries and research program have been critical for understanding how these cells are organized in order to maintain a normal balance of water, acid, calcium, potassium, protein (and many other substances) in all animals from flies to humans.

Dr. Margolis was an investigator in the Howard Hughes Medical Institute for 10 years, has been first or senior author on some of the most highly cited papers in understanding kidney cell biology, is internationally recognized for his research, has won an American Society of Nephrology-American Heart Association Young Investigator Award, and has presented over 100 invited lectures worldwide.

Dr. Margolis has continued to publish critical new research in top-ranked journals. His research has direct applicability to our understanding of polycystic kidney disease, one form of which is one of the most frequent genetic diseases in the world, affecting an estimated 12.5 million people worldwide. His research has been recognized by the Polycystic Kidney Disease Foundation (http://www.pkdcure.org/learn/multimedia/videos).

Unfortunately, Dr. Margolis' research has not been funded in the past year. Although he was able to get some research support from the university, this highly productive investigator and his research program were shut down owing to lack of funds. Two highly promising young faculty researchers who were mentored by Dr. Margolis lost the opportunity to continue their research, despite having their own career development awards from NIH. Other highly productive members of his laboratory were also suddenly without a job.

This scenario is not uncommon. Highly productive senior investigators like Dr. Margolis are being forced to end their research careers because of research funding cuts. While disruptive and discouraging to senior investigators, the impact on junior investigators is barely imaginable. They see their mentors, who are often leaders in their fields, being forced to end productive research programs.

The takeaway for them is that careers in fundamental biomedical research are impossible. After all, when their heroes can't succeed, how can they imagine success? The greatest tragedy is not that Dr. Margolis had to lock the door to his research laboratory, but that current and future trainees will now not even try to open the door to a biomedical research career.

I urge Congress to increase the budget caps and provide NIH steady and sustained increases year after year. That is absolutely essential for attracting the best and brightest minds to science, maintaining America's position as the world leader in medical innovation, and curing our biggest healthcare challenges, including kidney disease.

Frank C. Brosius, MD, is affiliated with the University of Michigan Hospital in Ann Arbor, MI. Dr. Brosius is chair of the American Society of Nephrology Research Advocacy Committee.

TINY CRYSTALS.
BIG PROBLEM.

Gout preys on more than just bones and joints— monosodium urate (MSU) crystals can deposit in the kidneys, spine, and soft tissues, including ligaments or tendons.[1,2] Even when patients are not flaring, these crystals can be associated with chronic inflammation, bone erosion, organ damage, and other systemic diseases.[2-6]

Keeping uric acid levels consistently <6 mg/dL—below the MSU saturation point—can dissolve existing crystals and prevent new crystal formation.[7-10]

Take a deeper look at TheRealGout.com

AstraZeneca

References:

1. Paparo F, Zampogna G, Fabbro E, et al. Imaging of tophi with an extremity-dedicated MRI system. *Clin Exp Rheumatol.* 2011;29(3):519-526. **2.** Taylor JW, Grainger R. Clinical features of gout. In: Terkeltaub R, ed. *Gout and Other Crystal Arthropathies.* 1st ed. Philadelphia, PA: Elsevier Saunders; 2012:105-120. **3.** Dalbeth N, Stamp L. Hyperuricaemia and gout: time for a new staging system? *Ann Rheum Dis.* 2014;73(9):1598-1600. **4.** Schumacher HR Jr. The pathogenesis of gout. *Cleve Clin J Med.* 2008;75(suppl 5):S2-S4. **5.** Terkeltaub R, Edwards NL. Disease definition and overview of pathogenesis of hyperuricemia and gouty inflammation. In: Terkeltaub R, Edwards NL, eds. *Gout: Diagnosis and Management of Gouty Arthritis and Hyperuricemia.* 3rd ed. Durant, OK: Professional Communications, Inc; 2013:19-47. **6.** Terkeltaub R, Edwards NL. Clinical features and natural course. In: Terkeltaub R, Edwards NL, eds. *Gout: Diagnosis and Management of Gouty Arthritis and Hyperuricemia.* 3rd ed. Durant, OK: Professional Communications, Inc; 2013:69-84. **7.** Zhang W, Doherty M, Bardin T, et al. EULAR evidence based recommendations for gout. Part II: management. Report of a task force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). *Ann Rheum Dis.* 2006;65(10):1312-1324. **8.** Jordan KM, Cameron JS, Snaith M, et al. British Society for Rheumatology and British Health Professionals in Rheumatology guideline for the management of gout. *Rheumatology* (Oxford). 2007;46(8):1372-1374. **9.** Khanna D, Fitzgerald JD, Khanna PP, et al; 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. *Arthritis Care Res* (Hoboken). 2012;64(10): 1431-1446. **10.** Sivera F, Andres M, Carmona L, et al. Multinational evidence-based recommendations for the diagnosis and management of gout: integrating systematic literature review and expert opinion of a broad panel of rheumatologists in the 3e initiative. *Ann Rheum Dis.* 2014;73(2):328-335.

Health Literacy: Enhancing Patient Engagement

ASN Kidney News gratefully acknowledges the editor of this special section, *Kidney News* Editorial Board member Glenda Payne, MS, RN, CNN, for her contributions to the issue.

Health Literacy: A Critical First Step in a Collective Effort to Improve the Care of Individuals with CKD/ESRD

By Barry H. Smith, Pamela Hoyt-Hudson, Jennifer Melendez, and Molly Phillips

Proficiency in health literacy is a critical ingredient in the outcomes of both the prevention and the treatment of kidney disease. Unfortunately, according to a US Department of Education report, only 12 percent of Americans are proficient in health literacy (1). Given that health literacy is all about communication and understanding among patients, families, and health care professionals, the fact that health literacy skills are also suboptimal among nephrologists, nephrology nurses, technicians, and other health care staff can only mean that the results of our treatment efforts are far less than they could be. This is simply unacceptable.

With the conviction that in this era of health care reform, the health literacy problem requires urgent attention focused on improving the quality of care we provide, the Rogosin Institute hosted a roundtable entitled Health Literacy and Renal Disease: Promoting Prevention and Achieving Improved Outcomes in Chronic Kidney Disease (CKD) and ESRD on March 9, 2015, at its Jack J. Dreyfus Center for Health Action and Policy in New York City. The goal of the roundtable was to generate concrete ideas and proposals and to launch pilot programs to improve health literacy among both patients and professionals to ensure better care and outcomes for CKD and ESRD patients in New York City and elsewhere.

The participants included individuals with kidney disease and a diverse team of health literacy experts from across the United States with backgrounds in medicine, nursing, nutrition, social work, health information technology, and public policy. Cindy Brach, senior health policy researcher at the Agency for Healthcare Research and Quality, provided the keynote for this roundtable meeting.

In preparation for the roundtable, members of the Rogosin staff conducted interviews with 41 patients at seven different facilities (six dialysis facilities and one CKD clinic) to ensure that patients' voices were incorporated into this discussion. The patients were asked about their understanding of their diagnosis, health care experiences, understanding of health-related communications of various types, and what tools they wish they had to help them understand their treatment and be better partners in their care. The participants ranged in age from 24 to 88, were split fairly evenly between men and women (54 percent men, 46 percent women), and had diverse racial and ethnic backgrounds. The ESRD interviewees had been receiving dialysis for as little as 2 months and as long as 15 years.

Key themes that emerged from the interviews included the need for more support from families, peers, caregivers, and the care team for the patients themselves and for their care partners; the importance of tailoring education to the specific needs of the individual patient; and the need for education materials of all types in different languages. The participants shared that simply receiving information about their health did not necessarily lead to behavior changes. When asked about how they would like to learn about their health care, 84 percent of the Rogosin patients interviewed stated that they considered videos to be valuable educational tools and wished that these were available to them.

With these data and the participants' experience and expertise available in the room, discussion at the roundtable was spirited. The driving force of the discussion was the recognition of suboptimal health literacy skills among both kidney patients and the staff caring for them, and the urgent need to achieve better health and quality of life outcomes for patients with both CKD and ESRD. Throughout the discussion, common themes included the need to recognize the totality of the complex, difficult, and varied challenges facing CKD and ESRD patients; to promote a sense of hope among patients and their families; to address mental and emotional health issues; and to actively engage patients and staff in true care partnerships.

The group defined the following specific problems as needing high-priority action:

- Fragmentation of the care of CKD and ESRD patients, most of whom have complex multiple comorbidities
- Lack of patient support systems
- Limited staff skills in health literacy techniques and tools
- Suboptimal appreciation of the importance of health literacy among patients and staff
- Limited distribution of already available educational and training information and tools to improve health literacy levels

To address these issues, actionable project ideas were developed by the roundtable participants for pilot implementation at Rogosin, with the ultimate goal of collaborative replication at other sites. The project action plans currently in various stages of implementation at Rogosin include the following:

- *Care coordination*: Rogosin is working on multiple initiatives to increase collaboration and coordination of care of CKD and ESRD patients. For example, a renal management clinic was recently launched, whereby an interdisciplinary team works with stage 4 and 5 CKD patients to help educate them about their condition and their treatment options, and to prepare them for dialysis or transplantation if their kidney function continues to deteriorate.
- *Patient support:* Patient participants shared that they often learned best from other patients and felt that fostering peer support was critical. While building support group opportunities and peer mentorship programs more generally at each of the Rogosin CKD facilities, a series of peer-to-peer learning videos will be developed and made available through the Rogosin iTunes University site. The videos will also be available on iPads for patients to view during their dialysis treatments.
- *Staff training:* All current and future staff members, from front-desk administrators to technicians to physicians, will be trained in the importance of health literacy skills and the basic techniques required, including the "teach-back" method (see box). Health Literacy Champions at each dialysis unit will be appointed from within the staff to move this initiative forward and sustain it.
- *Dissemination of health literacy information:* Participants at the roundtable are currently working on articles related to health literacy and renal disease intended to be published in both academic journals and practice-based publications to increase awareness among professionals about the importance of health literacy. The articles in this issue of *Kidney News* mark the launch of this effort. In addition, Rogosin staff, with the assistance of the other roundtable participants, will develop a catalog of available health literacy materials (both general and kidney-specific) for broad dissemination for the benefit of both patients and staff.

Recognizing that the improvement of health literacy skills must involve an ongoing commitment and program, Rogosin health literacy roundtable participants will reconvene in the next 6 to 12 months to report pilot project progress and to discuss collaborative plans for replication in other sites. We welcome all who are interested in the improvement of health literacy levels to contact us and join with the roundtable participants to bring nephrology health professionals to the forefront of what we hope will be a national effort to improve health outcomes and quality of life for all kidney patients and their families. Please join this effort. We can achieve much more together.

References

1. National Center for Education Statistics, U.S. Department of Education, 2010.
2. Schillinger D, et al. Closing the loop: physician communication with diabetic patients who have low health literacy. *Arch Intern Med* 2003; 163:83-90.

Barry H. Smith, MD, PhD, is president and CEO of the Rogosin Institute and director of its Dreyfus Health Foundation division, professor of clinical surgery at Weill-Cornell Medical College, and attending physician at the NewYork-Presbyterian Weill-Cornell Medical Center, New York. Pamela Hoyt-Hudson is vice president for health action and policy and director of the center for health action and policy; Jennifer Melendez is director of community engagement and research; and Molly Phillips is manager of health promotion programs and policy of the Rogisin Institute. The Rogosin Institute is an independent not-for-profit treatment and research center that has been providing care to patients for over five decades. Rogosin is affiliated with New York-Presbyterian Hospital and Weill Cornell Medical College and is a member of New York-Presbyterian Healthcare System. Rogosin provides patient-centered care for individuals with chronic diseases, including kidney disease, diabetes, hypertension, lipid disorders, and cancer.

What is teach-back?

- A method for ensuring understanding in a nonshaming way.
- Asking patients to explain in their own words what they need to know or do.
- An indication of how well you communicated the information, not a "test" of the patient.
- A chance to check for understanding and, if necessary, repeat the explanation and check again.
- An evidence-based approach to improving patient–provider communication and patient health outcomes (2).

Universal Precautions for Health Literacy

By Cindy Brach

This month, *KN* Editorial Board member and special section editor Glenda Payne interviewed Cindy Brach, MPP, lead for health literacy at the Agency for Healthcare Research and Quality, about ways nephrology professionals can recognize issues in health literacy and more effectively bridge communication gaps.

Why the interest in health literacy, and why now? Current buzzwords such as "patient-centered," "patient engagement," and "improved experience of care" depend on clear communication. Miscommunication happens frequently, due to a mismatch in the health literacy of the members of the health care team (provider or patient). According to Richard Carmona, the former US Surgeon General, "Health literacy is the currency for success in everything we do in health, wellness, and prevention." How can nephrology professionals recognize issues in health literacy and more effectively bridge communication gaps?

What is health literacy? How is this different from literacy or reading grade level?

Health literacy has traditionally been defined as an individual's capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. A person's health literacy depends on how complicated health information is, and how complex health-related tasks are. A national survey revealed that only 12% of adults in the United States are able to understand and use all the types of health information that are currently being distributed (1). Many people who read well have limited health literacy. They have difficulty understanding written medicine instructions, finding information in complex documents, and extracting information from graphs and charts. Additionally, health literacy includes the ability to verbally communicate—both listening and speaking, the ability to understand and use numbers, and the ability to navigate the health care system.

How can patients or families with limited health literacy be identified?

There is no evidence that identifying patients and families with limited health literacy is effective (2). Health literacy is dynamic. At one visit an individual may be able to absorb and follow up on health information; at another time the same individual may be tired, scared, or feeling sick and not be able to understand or act on information as easily.

Patients should, however, be asked about their literacy, and the health care team should be prepared to refer them to reading and math resources in the local community. The Agency for Healthcare Research and Quality (AHRQ) Health Literacy Universal Precautions Toolkit (Tool 20) describes the DIRECT approach to see whether patients would like to improve their reading skills (3).

What is meant by "universal precautions" for health literacy, and why is this recommended?

Health literacy universal precautions structure the delivery system as though everyone may have limited health literacy. It's just like blood safety: where everyone's blood is treated as if it could be infected. When an organization has implemented health literacy universal precautions, it becomes easier for patients and families to understand what to do to take care of their health, and easier for them to navigate the health system. Health literacy universal precautions include a wide range of activities, such as making way-finding signage clear, offering help with forms, reviewing written materials together, confirming understanding at multiple points in every encounter, making referrals easy, and proactively following up.

Continued on page 16

Universal Precautions

Continued from page 15

What patient benefits are possible if the health care team routinely uses educational techniques that recognize and address health literacy barriers?

When health care teams use techniques like encouraging questions and communicating clearly (e.g., using plain nonmedical language and visual aids, and limiting the amount of information provided at any one time), patients are more likely to become engaged in their health care. They're likely to be less frustrated, feel that their health care team cares for them, and be able to make health care decisions collaboratively.

Are there potential benefits for the health care team if they deploy educational techniques that recognize and address health literacy barriers?

Absolutely. Health care providers often mistake misunderstanding for noncompliance and then resent patients' failure to take responsibility for their health. If they use health literacy techniques, they should see patients become empowered and better able to manage their conditions. This may lead to fewer calls for clarification, fewer medicine errors, and quicker progress toward health goals.

Individuals with kidney failure are more likely to be older, to belong to a racial or ethnic minority, and to have lower socioeconomic status and lower educational levels. How would using techniques that recognize and address health literacy barriers make the care of patients with kidney failure more effective?

This is a population that is at high risk for limited health literacy. Using the teach-back method (see previous page) to confirm understanding is especially important. When health care professionals use this method, they ask patients to teach back information in their own words. If patients are unable to teach back, or simply parrot back what was said to them, the health care professional reteaches the information and checks again for comprehension. Using teach-back helps catch the misunderstandings before they create problems. An online course, Always Use Teach-back! Training Toolkit, is available for free (4).

Recently *Nephrology News & Issues* referenced an article by Dr. Veena Joshi in the *World Journal of Nephrology*. Joshi reviewed the scientific literature from 1990 to 2014 on quality of life in people with chronic kidney disease. His review found that most of what treatment teams typically focus on (e.g., laboratory results, Kt/V, electrolyte status, hemoglobin) was found to have "little or no association with quality of life." Joshi found that self-efficacy, influence on dialysis care practice, treatment satisfaction, and different types of counseling and rehabilitation interventions had a positive association with quality of life. How could health literacy universal precautions potentially improve patients' quality of life?

The demands on people with chronic kidney disease are great. They struggle to understand their disease, make lifestyle changes, choose from among treatment options, take their medicines, make and keep appointments, and handle insurance. Health care organizations that adopt health literacy universal precautions can potentially increase patients' quality of life by reducing the demands on them and by providing more effective assistance in dealing with this chronic disease. In addition to the interpersonal techniques mentioned above (e.g., communicating clearly, encouraging questions, and confirming understanding), health care organizations can use these techniques:

1. Design telephone systems so patients don't get frustrated and hang up.
2. Select and review with patients written materials that are easy to understand and act on, and make alternative audiovisual materials available.
3. Follow up with patients proactively.
4. Provide language assistance and be culturally competent.
5. Reconcile medicines, check that patients and families know when and how much to take, and help them establish reminder systems.
6. Refer patients to community resources.
7. Help patients with insurance and medicine discounts.
8. Secure referral appointments and exchange information directly.
9. Get and respond to feedback from patients and families about what would make things better for them.

References

1. Kutner M, et al. *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy.* Washington, DC, National Center for Educational Statistics, 2006.
2. Paasche-Orlow MK, Wolf MS. Evidence does not support clinical screening of literacy. *J Gen Intern Med* 2008; 23:100–102.
3. Brega A, et al. *AHRQ Health Literacy Universal Precautions Toolkit,* 2nd Ed. Rockville, MD, Agency for Healthcare Research and Quality, 2015. http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2.html. Accessed July 2, 2015.
4. Always Use Teach-back! training toolkit. 2015. http://www.teachbacktraining.org/. Accessed July 2, 2015.

Health Literacy Research to Improve Kidney Disease Care

By Kerri Cavanaugh

Health literacy research over the past 2 decades has shaped its definition, determined how it is assessed, and provided us with an initial understanding about how this concept significantly contributes to the connections among patients, families, health care providers, and health systems. We all strive to apply the most rigorous and contemporary evidence in the care of patients, and this is no different for practices related to health literacy.

The US Department of Health and Human Services National Action Plan to Improve Health Literacy gives seven recommendations to act on now for better health. One recommendation calls for additional "basic research and the development, implementation, and evaluation of practices and interventions to improve health literacy" (1). Most reported health literacy research has been about people without kidney disease, but that is changing. Our team and others have shown that lower health literacy is common in individuals who require dialysis and may be as high as 50 percent. This estimate is somewhat lower for those who receive a kidney transplant, but it escalates to nearly 90 percent for patients with kidney disease who do not speak English as a first language. Individuals with kidney disease who require dialysis and have lower health literacy have been shown to have higher risks for hospitalization (2) and mortality (3).

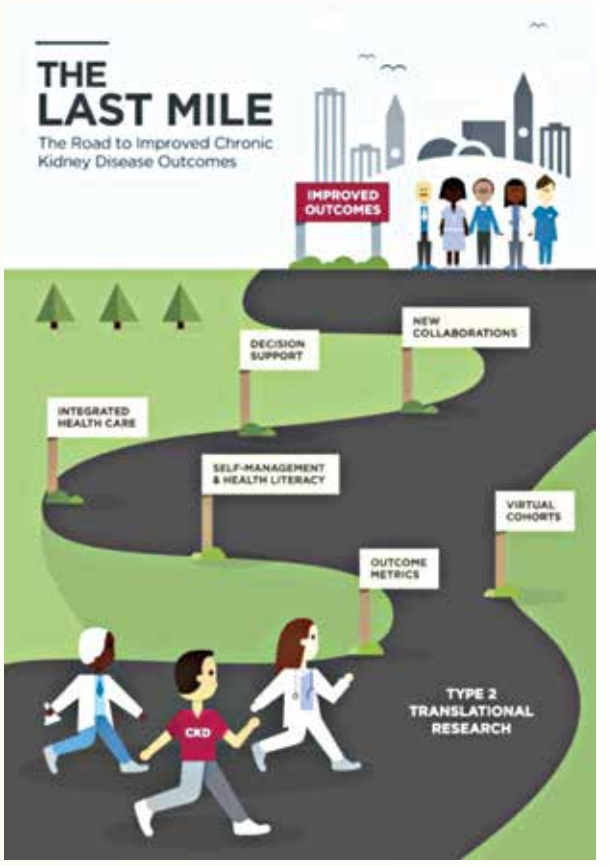
A common misconception is that health literacy is defined primarily by a person's reading skills. The Institute of Medicine asserts that the concept of literacy, not specific to health literacy, is broad and in addition to reading and writing includes speaking, listening, quantitative skills, knowledge, and the influence of culture on each of these components (4). Skills in health literacy affect how effectively patients obtain, process, and use health care information. Research leaders have identified health literacy as a key area to advance translational research and improved outcomes in kidney disease care (Figure 1).

Although several tools may be used to evaluate an individual's health literacy skills (5), there are concerns that these assessments may not fully capture the broad range of activities and skills that health literacy defines. It is critical to recognize that health literacy is not exclusively "about them" but is in fact "about us": our skills as health care providers in delivering information. Recognition and acceptance of the responsibility for clear communication is called organizational health literacy. A recent Institute of Medicine white paper provides an overview of existing measures that health systems may use to determine their current level of health literacy and identify specific areas where improvements can be made (6).

This growing recognition of the role of health literacy in kidney disease has contributed to its inclusion in interventions to improve kidney disease education. Efforts include promotion of patient-centered dialogue and shared decision-making in choosing renal replacement therapy options and in facilitating navigation of the transplantation evaluation process. Compliance with complex treatment plans requires an understanding of what is expected. The information burden for successful navigation of kidney disease is high. As care providers we must ensure that this information is delivered in a way that all people can receive and use effectively. This includes creating written educational materials that use formatting, use visual aids, and avoid complex text (7) and developing complementary programs for multidisciplinary teams of kidney care providers to deliver congruent information and instructions. Practices can incorporate health literacy strategies now into their existing quality improvement programs and contribute to our understanding of its impact. The Agency for Healthcare Research and Quality Health Literacy Universal Precautions Toolkit includes 21 brief, research-based tools with instructions for implementation (8).

Now is the time for commitment by the kidney community to address health literacy and improve care, promote kidney health, and potentially slow the progression or even prevent the development of kidney disease. Learn about health literacy, recognize its potential for positive impact, and align your actions with strategies to close any gaps in your own health literacy skills. The investment will be worth it.

Figure 1. Health literacy as a key research component to improve kidney disease care



Courtesy Tuot DS, et al. *Clin J Am Soc Nephrol* 2014; 9:1802–1805

References

1. U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National Action Plan to Improve Health Literacy. Washington, DC, U.S. Department of Health and Human Services, 2010.
2. Green JA, et al. Associations of health literacy with dialysis adherence and health resource utilization in patients receiving maintenance hemodialysis. *Am J Kidney Dis* 2013; 62:73–80.
3. Cavanaugh KL, et al. Low health literacy associates with increased mortality in ESRD. *J Am Soc Nephrol* 2010; 21:1979–1985.
4. Nielsoen-Bohlman L, et al, editors. *Health Literacy: A Prescription to End Confusion*. Washington, DC, National Academies Press, 2004.
5. Dageforde LA, Cavanaugh KL. Health literacy: emerging evidence and applications in kidney disease care. *Adv Chronic Kidney Dis* 2013; 20:311–319.
6. Vanderbilt Center for Effective Health Communication. Measures to assess a health-literate organization. http://iom.nationalacademies.org/Activities/PublicHealth/HealthLiteracy/~/media/Files/Activity%20Files/PublicHealth/HealthLiteracy/Commissioned-Papers/Measures_Assess_HLO.pdf.
7. Tuot DS, Cavanaugh KL. Evaluating the merits of CKD patient educational materials: readability is necessary but not sufficient. *Am J Kidney Dis* 2015; 65:814–816.
8. AHRQ Health Literacy Universal Precautions Toolkit. http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/.

Kerri Cavanaugh, MD, MHS, is affiliated with the Vanderbilt Center for Kidney Disease in Nashville, TN.

Hope: An Essential Prerequisite for Health Literacy in Chronic Kidney Disease

By Dori Schatell

Hope Abides

Hope abides; therefore I abide.
Countless frustrations have not cowed me.
I am still alive, vibrant with life.
The black cloud will disappear,
The morning sun will appear once again
In all its supernal glory.

—by Sri Chinmoy Ghose

Have you ever sat in your examination room with a patient and the patient's care partner and explained the progression of chronic kidney disease (CKD) and the ESRD treatment options for a second, third, or fourth visit in a row, watching your patient's eyes glaze over when you say "dialysis," while the partner's eyes widen with fear? Does it feel as if your words aren't getting through? You're right. Your patients are shell-shocked: devastated by emotions, panicked, and feeling hopeless about their futures. We call it denial.

Terrified patients can't learn. Education researchers have noted, "Humans act emotionally before the conscious awareness of emotion can occur; we react before we know we are reacting. 'A traumatized person in a state of alarm is less capable of concentrating, more anxious, and more attentive to nonverbal cues such as tone of voice, body posture, and facial expressions'" (1).

The good news is that you can help your patients through their fears—by starting with hope.

The value of hope

The literature on hope offers some useful hints as to how we can help patients adapt, including setting and moving toward personal goals:

- A meta-analysis of studies of hope in family members of people with chronic illnesses (2) found that a key hope

Continued on page 18

Essential Prerequisite

Continued from page 17

was "transitional refocusing" from a difficult present to a positive future. The sources for hope shift as the patient's circumstances change and the timelines shrink. If a patient worsens, the focus might become hope for a good day versus a bad one.

- Among patients with chronic illness, a qualitative study (3) found that hope encompassed three types of dynamic work: 1) shifting perceptions of mortality from horror toward peaceful acceptance, 2) replacing uncertainty with recognition and reconciliation (i.e., knowledge conquers fear), and 3) establishing a go-ahead-spirit identity versus resignation.
- The only CKD-specific study of hope enrolled 103 dialysis patients in the United Kingdom (4), finding that those who self-reported higher hope levels on the trait hope scale were less anxious and depressed, felt less burdened by CKD and its treatment, and had better mental functioning on the Kidney Disease Quality of Life-36, which predicts reduced morbidity and mortality (5). This suggests that hope is literally a matter of life and death.

How to address the emotion and implement hope

In a perfect world, you as a clinician convey a vital self-care message to your patients. They must care for themselves: take multiple medications, eat differently, get a dialysis access, choose a modality, or identify a living donor for preemptive transplantation. Ideally, the patient agrees and takes on the positive actions that only he or she can do.

This ideal scenario does not tend to occur, unfortunately. All too often, these well-intentioned conversations (the hardest part of being a nephrologist, we learned in an unpublished interview study), focus on the medical and clinical nature of the disease—symptoms, lab test results, medication adjustments—and don't address patients' fears. Some typical concerns of people with CKD include these:

- Am I going to die?
- Will I be able to keep my job?
- Will I be a burden on my loved ones?
- Will my partner leave me?
- How will I pay for this?
- Will life "on a machine" even be worth living?

Consider using this list of examples to reassure your patients. For example:

- "People often worry that when their kidneys fail, they will die. Fortunately, we have treatments that can help you live, and you can still have a good life."
- "If you are working, you can choose a treatment option that can let you keep your job." (Social Security Disability Insurance usually replaces only about 30 percent of a work salary; that is not an optimal solution.)
- "Fortunately, Medicare can help you pay for kidney failure treatment at any age, if you are a US citizen and have worked enough to qualify."

A second approach is to ask your patients what is going through their minds when you give them this news. What do they worry about? What matters most to them? You can get to know your patients and then fine-tune your messages so they feel heard and reassured simultaneously. If you chose nephrology because of the opportunities for long-term relationships with patients, learning their motivations can be rewarding for both you and them. Consider pointing your patients to the nonprofit Medical Education Institute's free online decision aid at www.mydialysischoice.org. This tool can show you their values and help you assess which dialysis options offer them the best fit and realistic hope for a good life after kidney failure.

References

1. Shuck B, Albornoz C, Winberg M. Emotions and their effect on adult learning: a constructivist perspective. In: *Proceedings of the Sixth Annual College of Education Research Conference: Urban and International Education Section*, edited by Nielsen SM, Plakhotnik MS. Miami, Florida International University, pp108–113. http://coeweb.fiu.edu/research_conference/
2. Duggleby W, et al. Metasynthesis of the hope experience of family caregivers of persons with chronic illness. *Qual Health Res* 2010; 20:148–158.
3. Schaufel MA, Nordrehaug JE, Malterud K. Hope in action—facing cardiac death: a qualitative study of patients with life-threatening disease. *Int J Qual Stud Health Well-being*. 2011;6. doi: 10.3402/qhw.v6i1.5917.
4. Billington E, et al. Does hope predict adjustment to end-stage renal failure and consequent dialysis? *Br J Health Psychol* 2008; 13:683–699.
5. Mapes DL, et al. Health-related quality of life as a predictor of mortality and hospitalization: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney Int* 2003; 64:339–349.

Dori Schatell, MS, is executive director of the Medical Education Institute, Inc., in Madison, WI.

Peer Mentoring and Health Literacy: A Shift in Information Sharing

By Leanne Peace and Jaime A. Roy

In the ever-changing climate of health care, providers eagerly seek innovative approaches to actively engage patients and their families in their care. The Center for Advancing Health defines engagement as "actions individuals must take to obtain the greatest benefit from the health care services available to them."

As providers, the next logical question is, how do we encourage individuals to take these actions toward engagement? Perhaps the question isn't how but rather who does the encouraging? Many health care organizations have determined that the patient population contains infinite potential and resources that can be activated through peer mentoring programs.

Although approaches may vary, peer mentoring programs are generally designed to match a more experienced patient with an individual (a peer) who has a new diagnosis or faces challenges in dealing with a chronic condition. Peer mentors do not provide medical advice; rather, they serve as a companion who can share experiences and help legitimize and relieve feelings of fear, anger, grief, and anxiety. Most important, by positively modeling active engagement, peer mentors can provide hope and encouragement, aid in problem solving, promote self-care management, and reinforce communication between patients and their health care providers.

Mary Wu, a two-time kidney transplant recipient and patient advocate, responds: "Peer mentorship is an excellent means of providing [the] support [needed] to endure [the complexity of your] health journey… [it is] commendable that peer mentorship is coming into the forefront and playing an active role in the ever-changing health care system."

The National Kidney Foundation of Michigan (NKFM) has successfully led an effective peer mentoring program since the 1980s and has trained more than 8000 chronic kidney disease (CKD) peer mentors. Erica Perry, MSW, has worked with NKFM since the inception of that organization's peer mentoring program and has now retired. Perry says that peer mentoring gives patients an opportunity to learn in a safe and empowering environment where questions are encouraged and answers are explained in ways that are useful, practical, and without complex medical terminology.

The peer-to-peer learning environment in these programs can also provide a more holistic approach to ensuring health literacy. "Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions and services needed to prevent or treat illness," according to the US Department of Health and Human Services, Health Resources and Services Administration.

The vision of the NKFM peer mentoring program addresses the need for health literacy to play an integral role in a CKD patient's life and the peer-to-mentor relationship. "As a valuable part of the health care team, peer mentors empower patients to move forward with their lives after being diagnosed with kidney disease. [Peer mentors] are a bridge for better communication with medical staff, which assures that staff understand patient concerns, issues, and priorities. Peer mentors show patients that controlling and managing their health will allow them to live longer, happier lives," according to the NKFM.

Julia Herzog, MSW, a kidney transplant recipient, currently oversees the NKFM peer mentoring program. She explains that the NKFM peer mentoring program includes training in communication and teaches mentors to focus on important topics and to effectively communicate to peers what resources are available that can help them make health care decisions. This approach can have a meaningful impact on clinics that want to focus on important educational topics, such as treatment modality options, infection prevention, access options, self-care, and more, because patients tend to be more receptive to receiving information that comes from a peer.

Mentors are able to break down communication barriers by building trusting relationships with their peers. They can share experiences of overcoming concerns and are able to relate as empathetic and friendly helpers rather than medical experts. Mentors should be trained in how to empower their peers through information sharing and also how to strengthen communications between peers and their health care team for answers to any and all medical questions.

Individuals interested in becoming peer mentors with the NKFM peer mentoring program are screened to ensure that they exemplify the traits of good communicators and empathic listeners, valuing confidentiality and finding excitement in helping empower others. Additionally, peer mentors should be successful in modeling self-management, working with their health care team to make decisions, and having the time and energy for training, retraining, and visits with patients.

It is not uncommon for providers to express concerns regarding patient confidentiality and objectivity, becoming overinvolved, or giving erroneous medical information. These concerns may create barriers in the successful launch of a peer mentoring program. Intentional trainings that explain the role and boundaries of a peer mentor and the effective methods that can help providers and patients work together to improve the quality of life and care of individuals with CKD are key to effective peer mentoring programs.

Both Perry and Herzog indicate that training and frequent in-service programs for peer mentors are key to developing a successful program and earning the confidence of the health care providers who implement these programs. "It [peer mentorship] is a two-way street and an all-win situation!" said transplant recipient and patient advocate Mary Wu.

Resources

- Center for Advancing Health: http://www.cfah.org/file/CFAH_Engagement_Behavior_Framework_current.pdf.
- HRSA: http://www.hrsa.gov/publichealth/healthliteracy/healthlitabout.html.
- NKFM: http://www.nkfm.org/sites/default/files/documents/pages/peer_mentoring_brochure.pdf.
- NKF of Michigan, Julie Herzog, MSW, Program Coordinator, jherzog@nkfm.org.
- Erica Perry, MSW, eperry@umich.edu.

Leanne Peace, MSW, MHA, is director of the Missouri Kidney Program in Columbia, MO. Jaime A. Roy, MPA, is associated with the ESRD National Coordinating Center in Lake Success, NY.

Awareness Survey Helps Quantify Patient Understanding of Health Terminology

By Linda McCann

With all this talk about health literacy (HL), do people even know what the term means? After the Health Literacy Roundtable in March 2015, a short questionnaire was administered to 22 patients and six staff members in an effort to determine what patients and staff know about HL. The patients and staff were first asked if they had heard the term "health literacy." If they responded "yes," they were asked to describe the term in their own words. If they responded that they had not heard the term, the following definition was provided: "Health literacy is the degree to which you can receive and understand basic health information and services to the point where you feel you can help make decisions about your health care and treatments."

The six staff members interviewed included registered nurses and certified hemodialysis technicians. Although only one, a registered nurse, had heard the term "health literacy," all of the staff interviewed had some understanding of the meaning.

Twenty-two patients were chosen as a convenience sample based on their availability and willingness to participate. All of the patients were undergoing dialysis in one of five facilities in California. Their ages ranged from 56 to 91; 14 of the participants were women, and eight were men. English was the primary language of all but two of the participants. Those two reported that English was their second language; both spoke English and self-reported a good understanding of English. Only three of the patient participants, all women, remembered hearing the term "health literacy." Each could state the definition in her own words. Two other patients had not heard the term but demonstrated a general understanding of HL.

After providing the definition of HL to the patients, we asked for a yes-or-no response to the following statements:

- I understood/understand enough to be able to answer questions about my disease and dialysis when friends and family ask questions.
- I understood/understand enough to follow instructions for taking my medications.
- I understood/understand that I have to come to dialysis at least three times per week for the rest of my life unless I can have a transplant.
- I understood/understand the choices I have for dialysis treatment (peritoneal dialysis, hemodialysis, in-center, home).
- I understood/understand that my blood work can show how I am doing on dialysis.
- I received simple explanations about what I should eat and drink and am able to determine what changes I need to make in my diet.
- I felt/feel overwhelmed by the information and words used to describe my disease and treatment.

Table 1 presents the results of this survey.

Findings

The majority of participants admitted to being overwhelmed by the terminology used by dialysis staff and nephrologists. Several participants indicated that they were given too much information too soon after starting dialysis. One participant complained that she had difficulty understanding the education because it was provided by registered nurses who spoke English as a second language. One participant had been undergoing dialysis for more than 5 years but felt that the education should be reviewed periodically to maintain understanding. She did not remember receiving simple or adequate information when she started dialysis. Another felt that information about emergencies and disasters needed to be clearer. One participant, who is blind

Continued on page 20

Awareness Survey

Continued from page 19

and had somewhat limited English, felt that she was totally on her own and that no accommodation was made for her limitations, which included limited usefulness of audio teaching. Although almost all patients felt they had adequate information to modify their diet as needed, a review of their clinical records and conversations with their nutritionists found that many had significant nutrition issues (e.g., hyperphosphatemia, hypoalbuminemia, excessive fluid weight gain). Participants who had been closely followed up during their earlier stages of chronic kidney disease and had been educated by a practitioner were less likely to be overwhelmed by the complexity of the information provided at the initiation of dialysis.

Conclusion

If patients are to be successfully engaged as partners in their care, simple, repetitive health information must be provided in small segments and tailored to the individual. Validating that the information is received and understood by the patient and family, by the use of methods such as "teach-back," which is discussed elsewhere in this issue, is an integral part of this process.

Linda McCann, RD, RCN, is associated with Satellite Dialysis in San Jose, CA, and is a member of the KN Editorial Board.

Table 1. Health literacy survey results

Question/Statement	All Patients		Male		Female	
	Yes	No	Yes	No	Yes	No
Had heard the term "health literacy"	3	19	0	8	3	11
Understood/understand enough to answer questions from friends/family	16	6	7	1	9	5
Understood/understand instructions on how to take medications	19	3	8	0	11	3
Understood/understand dialysis as lifelong unless transplantation is possible	21	1	8	0	13	1
Understood/understand dialysis options (hemodialysis, peritoneal dialysis, home, in-center)	17	5	7	1	10	4
Understood/understand that blood work indicates progress/issues	17	5	7	1	10	4
Received simple explanations of diet (eat/drink)	21	1	8	0	13	1
Overwhelmed by language (potassium, dialysate, phosphorus)	15	7	5	3	10	4

Can We Talk ... about Health Literacy Strategies?

By Terri Ann Parnell

Chronic kidney disease (CKD) is a complex medical condition that requires multiple self-management strategies including the ability to understand, implement, and maintain clinical recommendations and self-care treatment strategies (1). Heart disease, diabetes mellitus, and nephropathies are among the top 10 causes of death, with rankings of 1, 7, and 9, respectively (2). CKD affects approximately 26 million American adults in the United States, whereas millions of others are at increased risk (3).

Understanding and managing CKD requires the ability to "obtain, process, understand, and communicate about health-related information needed to make informed health decisions" (4). Low health literacy is associated with poor management of chronic illness and has a negative impact on an individual's ability to optimize his or her health outcomes (5). Although reports from national data in 2010 showed that in the United States, nearly nine out of 10 adults were below the proficient level in health literacy, and more than 75 million adults had basic or below basic health literacy (6), the health literacy burden should not be placed solely on the individual. Enhancing health literacy must be a collaborative partnership between the health care professional, who provides information and care, the individual receiving care and information, and the health care system.

Enhancing health literacy and person-centered care

Addressing health literacy is a cross-cutting priority that is vital to providing safe, effective, person-centered care. Each member of the health care team must participate in spearheading the implementation of health literacy strategies into practice, with the ultimate goal of advancing health through the delivery of safe, high-quality health care. In an effort to lessen the complex demands that are currently being placed on persons managing chronic disease, health literacy efforts require changes in both organizational and professional practices.

In 2012, the Institute of Medicine published 10 attributes that can assist organizations in creating an environment that enables and empowers all health care consumers to access and benefit from their health care services (7).

The attributes of "health-literate organizations" begin with leadership setting the health literacy mission and vision, preparing the workforce to be health literate in an effort to meet the needs of all populations being served, and including members of the community in the planning and evaluating of health services. Health literacy strategies are integrated throughout all communications, including the assessment of patient understanding. Best practices are implemented and fully integrated throughout the organization to enhance culturally and linguistically appropriate communication and ultimately patient safety. To foster sustainability, organizations can develop patient education and health literacy committees that promote, sustain, and advance an environment that supports principles of equity, diversity, and health literacy (8). A health-literate organization creates a culture and expectation that requires all professionals to engage in the promotion of health-literate strategies and that ultimately prioritizes health literacy as a core organizational value (7).

Health care professionals have many responsibilities across an organization and therefore have a vital role in enhancing health literacy and the delivery of safe, effective, person-centered care. The culture of a health-literate organization fosters the use by all professionals of a "universal precautions approach" to health literacy rather than assuming an individual's health literacy level. This approach will enable all persons to easily access, navigate, and use information and health care services.

Some specific strategies for enhancing health literacy

- Always ask at the initial point of contact about a patient's preferred language to discuss health care, and obtain appropriate interpretation services when necessary.
- Begin where the patient is by asking what the patient already knows about his or her chronic disease. This approach may also help identify opportunities to enhance self-management skills.
- Learn about and always use "plain language" in each patient–provider interaction to promote clear communication.
- Incorporate the use of "teach-back" or "show-me" to ascertain understanding.
  - The use of teach-back should not be a question-and-answer session or quiz for the patient, but rather an opportunity to assess how well the professional did in explaining information using everyday language.
  - Teach-back also assists in identifying areas that require reinforcement or areas where barriers to learning may exist.
- Review and reinforce key action steps numerous times, possibly in several different ways, to foster learning.
- Summarize action steps, and end with "What questions do you have for me?" to provide a comfortable, shame-free environment. Phrasing the question in this fashion implies that you encourage and even expect questions and helps empower the patient to ask them when necessary.

Health literacy efforts must focus on enhancing communication and health maintenance skills so that patients can make informed health-related decisions and enhance adherence to their medical regimens (9). This is an important focus for patients managing chronic disease, where the aim is to improve overall adherence to medication and treatment regimens and ultimately enhance lifestyle behaviors. Health care professionals and health care organizations that prioritize health literacy as an essential component of care will provide person-centered care that will enhance patient safety, patient satisfaction, and ultimately patient outcomes.

References

1. Dageforde LA, Cavanaugh KL. Health literacy: emerging evidence and applications in kidney disease care. *Adv Chronic Kidney Dis* 2013; 20:311–319.
2. Elliott RW. Educating older adults with chronic kidney disease. *Nephrol Nurs J* 2014; 41:522–525.
3. The National Kidney Foundation. About chronic kidney disease. https://www.kidney.org/kidneydisease/aboutckd.
4. Berkman ND, Davis TC, McCormack L. Health literacy: what is it? *J Health Comm* 2010; 15(Suppl 2):9–19.
5. Edwards M, et al. The development of health literacy in patients with a long-term health condition: the health literacy pathway model. *BMC Public Health* 2012; Feb 14:130.
6. U.S. Department of Education, Institute of Education Sciences, National Center for Education Statistics. 2003 National Assessment of Adult Literacy (NAAL). 2010. http://nces.ed.gov/naal/.
7. Brach C, et al. Attributes of a health literate organization. Institute of Medicine Discussion Paper. Washington, DC, National Academies Press, 2012.
8. Parnell TA, et al. Health literacy as an essential component to achieving excellent patient outcomes. Institute of Medicine Discussion Paper. Washington, DC, National Academies Press, 2014.
9. Freedman DA, et al. Public health literacy defined. *Am J Prev Med* 2009; 36:446–450.

Terri Ann Parnell, MA, DNP, RN, is principal and founder of Health Literacy Partners, LLC.

Health Literacy: Critical for Success in Integrated Care

By Doug Johnson

During the past 3 years, we at Dialysis Clinic, Inc., have focused on providing care for all patients with kidney disease with the goal to reach out to them, wherever they are, and work with them to empower them to live the life they want to live, without allowing kidney disease to get in the way of their life dreams. For most patients with kidney disease, the best way to have optimal quality of life is to avoid dialysis. Therefore, our primary goal for treating patients with chronic kidney disease (CKD) is to avoid dialysis or delay its start.

Nationwide, there is a clear knowledge gap about CKD. Among individuals with stage 3 CKD, 93 percent do not know they have kidney disease. Even among those with stage 4 CKD, 47 percent are unaware that they have kidney disease (1).

We are learning that health literacy is much more than making handouts easier to read. To us, the key to determining health literacy, and improving health literacy skills, is to sit down with a patient one on one and spend whatever time is necessary to help the patient learn about kidney disease and, most important, about how to make it less likely that kidney disease will keep the patient from having the life she wants. As we talk with the patient, we can identify areas where our language is not clear and revise our discussion of these topics. We have modified our approach based on feedback from our patients, and we will continue to modify this program as our patients point out our gaps in communication and effective education.

We currently treat 3100 patients with all stages of CKD in 26 locations. Our CKD program is our fastest growing program; a year ago, we treated only 1570 patients. At the patient's first visit, a care coordinator, a registered nurse, spends 1 to 1.5 hours talking with the patient. Unlike a 15-minute physician's visit, this extended time allows the patient to express his or her life goals and the care coordinator to provide vital information about kidney disease and its treatment. Most important, this longer personal discussion allows the care coordinator to evaluate the patient's understanding of kidney disease and to tailor the discussion to meet the needs of that specific patient.

In some of our locations, patients have the opportunity to choose "RoundingWell" patient check-ins. These patients receive a RoundingWell text or e-mail several times each week. The messages, which are written at the 4th grade to 6th grade reading level, both evaluate a patient's current knowledge about a topic and provide additional information to strengthen a patient's health literacy skills. The care coordinator receives an electronic update on the patient's response and is able to tailor future topics for discussion to best meet the needs of that patient.

One topic in which evaluation and strengthening of health literacy skills is critical is medical management without dialysis. Many patients, and their families, believe that dialysis will solve all of their health problems. It is critical to clearly explain that dialysis only treats kidney disease; the patient who also has a weak heart will still struggle from having a weak heart even after starting dialysis. Many patients, especially elderly patients with multiple comorbidities, will do just as well with medical management without dialysis and can thus avoid the stress and disruption of their lives that dialysis brings.

If a patient selects medical management without dialysis, the care coordinator meets with the patient's family, evaluates their health literacy skills, and tailors the explanation to the family to facilitate their understanding that medical management without dialysis is a reasonable choice. This explanation emphasizes that we will continue close follow-up of the patient with the nephrologist or primary care physician and will add palliative care and hospice services when the patient is eligible if the patient requests it. We have found that this process has empowered many patients to choose medical management without dialysis. In Spartanburg, SC, site of our strongest program, more than 10 percent of patients have selected medical management without dialysis. Although each patient knows that this decision can be changed at any time, very few do so.

When a patient chooses dialysis, we evaluate the patient's understanding of the benefits of dialyzing with a fistula and of dialyzing at home. We have found that once patients have the opportunity to fully learn about their choices in care, they are more likely to choose to dialyze at home, or dialyze in-center with a fistula. In our Spartanburg location, of patients who received CKD care coordination and started dialysis in 2014, 29 percent started dialysis at home (compared with a national average of less than 9 percent) (1), and 73 percent of patients who started dialysis in-center started with a fistula and never had a catheter (compared with a national average of 20 percent starting with a fistula) (1).

We are beginning to implement a more formal program for care coordination for patients using dialysis. We plan to treat about 1500 patients in this program. From our initial experience, we are learning that patients who have the opportunity to work with a care coordinator and receive RoundingWell check-ins become more engaged in their care. We anticipate that the outcomes for these patients will improve and that hospitalizations and costs of care will decrease. In a limited trial, we found that the number of in-hospital dialysis treatments decreased by 20 percent in 2014 in one hospital where we partnered with the hospital to educate and engage patients using dialysis who were likely to receive their hospital care at that location.

A key area in which we are working to improve health literacy is transplantation. We believe transplantation is the ideal treatment for a patient with kidney failure because those who undergo successful transplantation can more easily continue to work and do not need to have their lives interrupted with dialysis treatments. However, nationwide, only 2.6 percent of patients receive a preemptive transplant (1). We are seeing that as we more effectively educate patients about the option of transplantation and the steps they would need to take to receive a transplant, they have more hope of a possible future life without dialysis.

We have also learned that it is critical to educate patients about the possible benefits of palliative care and hospice to improve their quality of life and ease the transition to end of life. In Nashville, TN, our care coordinators approach patients when it seems that the burden of dialysis outweighs its benefits and talk with them about the potential benefits of palliative and hospice care. Of 60 patients approached, 13 selected hospice care and 31 selected palliative care, with 8 of those patients later transitioning to hospice.

As we work with patients to improve their lives, we are learning that it is essential to work one on one to learn about and help them meet their own life goals. We find that by tailoring our work to the goals of each patient, we are able to evaluate their understanding of health issues, fill any educational gaps, improve their health literacy skills, and work with each patient to have the life he wants to live, without allowing kidney disease to get in the way.

Reference

1. Saran R, Li Y, Robinson B, et al. US Renal Data System 2014 annual data report: epidemiology of kidney disease in the United States. *Am J Kidney Dis* 2015; 66(1)(suppl 1):S1-S306.

The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.

Doug Johnson, MD, is vice chair of Dialysis Clinic, Inc.

Kidney Week 2015
Corporate Supporters

ABSTRACTS2VIEW™ CD-ROM

SANOFI RENAL

CELL PHONE CHARGING STATIONS

Genentech
A Member of the Roche Group

COLUMN WRAPS

OPKO Renal

CONVENTION CENTER BANNERS

AMGEN

FRESENIUS MEDICAL CARE
RENAL THERAPIES GROUP

Hospira

Mallinckrodt Pharmaceuticals

relypsa

ROCKWELL MEDICAL

ZS Pharma

CYBER CENTER, COMPLIMENTARY WI-FI, AND POWER STATIONS

Shire

ESCALATOR CLINGS

OPKO Renal

relypsa

ZS Pharma

EXHIBIT HALL AISLE BANNERS

KERYX BIOPHARMACEUTICALS, INC

EXHIBIT HALL ATTENDEE LOUNGES

relypsa

EXHIBIT HALL REFRESHMENT BREAKS

FRESENIUS MEDICAL CARE
RENAL THERAPIES GROUP

EXHIBITOR SPOTLIGHTS

ALEXION

AMGEN

Baxter

BTG

FRESENIUS MEDICAL CARE
RENAL THERAPIES GROUP

genzyme
A SANOFI COMPANY

Genentech
A Member of the Roche Group

Hospira

relypsa

GUIDE TO EDUCATIONAL SYMPOSIA

Hospira

as of September 4, 2015

ASN gratefully acknowledges the following companies for their support of ASN Kidney Week 2015.

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

HOTEL KEY CARDS

AMGEN

HOTEL ROOM DROPS

FRESENIUS MEDICAL CARE
RENAL THERAPIES GROUP

KERYX BIOPHARMACEUTICALS, INC

Mallinckrodt Pharmaceuticals

KIDNEY WEEK *ON-DEMAND™*

ALEXION

KERYX BIOPHARMACEUTICALS, INC

Mallinckrodt Pharmaceuticals

relypsa

KIDNEY WEEK PODCASTS

OPKO Renal

LANYARDS

UNC HEALTH CARE KIDNEY CENTER

LIGHT BOXES

Akebia™ THERAPEUTICS

Hospira

relypsa

MEETING BAGS

VANDERBILT CENTER FOR KIDNEY DISEASE
www.vckd.org

MOBILE APP

AMGEN

ONLINE *ABSTRACTS2VIEW™* WITH PROGRAM BUILDER

OPKO Renal

ONSITE PROGRAM

Mallinckrodt Pharmaceuticals

PRELIMINARY PROGRAM

FRESENIUS MEDICAL CARE
RENAL THERAPIES GROUP

PRESIDENT'S RECEPTION AND DINNER

relypsa

SHUTTLE BUSES

Baxter

Continuing Education Supporters

EARLY PROGRAM SUPPORT

"Diagnosis and Management of Disorders of Acid-Base, Fluid, and Electrolyte Balance: Challenging Issues for the Clinician"
Supported by an independent educational grant from **ZS Pharma.**

LEARNING PATHWAY SUPPORT

Bone and Mineral Metabolism
Supported by an independent educational grant from **OPKO Renal.**

Chronic Kidney Disease
Supported by an independent educational grant from **AstraZeneca and FibroGen.**

PLENARY SESSION SUPPORT

Supported by an independent educational grant from **Akebia Therapeutics, Inc.**

Educational symposia support is recognized on page 38.

Policy Update

Kidney Community Unites to Raise Awareness on Capitol Hill

By Mark Lukaszewski

On September 10, 2015, more than 100 kidney patients and health professional advocates gathered in Washington, DC, for Kidney Community Advocacy Day (KCAD). Since 2010, ASN has organized an annual congressional advocacy day to raise awareness about kidney disease. This year, representatives from 16 organizations met with more than 120 congressional offices to promote kidney research funding and increase awareness of, and support legislation to encourage, living kidney donation (Table 1).

Introduced in 1972, the Medicare End-Stage Renal Disease (ESRD) program remains the only Medicare program that, by law, requires coverage for patients regardless of age or disability. Despite advances in access, equipment, and modality choice, there has been little transformative innovation in the quality and cost-effectiveness of care for Americans with kidney disease. Currently, the ESRD program covers less than 1 percent of Medicare patients yet accounts for more than 7 percent of Medicare costs—$35 billion annually, more than the entire annual National Institutes of Health (NIH) budget.

Increasing kidney research funding

Overall, kidney diseases cost Medicare $80 billion annually and affect more than 20 million Americans. However, federal investments in kidney research amount to less than 1 percent of Medicare expenditures for kidney care. With the clock running out for Congress to pass a federal budget for FY 2016, ASN along with 15 KCAD partner organizations urged Congress to strike a budget deal that would address the lack of adequate funding for NIH kidney research.

Despite the current fiscal climate, bipartisan support for increasing the NIH budget has swelled this year. Proposed 2016 budgets in both houses provide increases for NIH funding, including between $22 and $76 million for the National Institute of Diabetes and Digestive and Kidney Diseases. Unfortunately, because the budget caps limit the total dollar amount Congress can spend on discretionary programs, NIH increases would come at the expense of other public health and research programs.

However, the only way to attract the best and brightest minds for kidney research is to give NIH steady and sustained increases year after year. ASN and its partners will continue to advocate for adequate funding to ensure breakthroughs for kidney patients are as common as those for patients with cancer, heart disease, and HIV/AIDs.

Living Donor Act—promoting living organ donation

Not only does transplantation improve patient quality of life, it reduces Medicare expenditures. Increasing living donation by just 10 percent and transplanting patients before they even enter the Medicare ESRD program is estimated to save Medicare between $559,498,000 and $1,190,078,000 over 10 years.

"Kidney transplants are the best treatment option for most patients with kidney failure, yet there aren't enough donated kidneys for everyone who needs them," said ASN Secretary-Treasurer and Public Policy Board Chair John R. Sedor, MD, FASN. "More than 100,000 people are on the waiting list for a kidney transplant. Congress can help them by enacting commonsense legislation that promotes organ donations by ensuring insurance coverage and job security for donors."

The Living Donor Act would increase the number of kidney transplants by eliminating obvious and unnecessary barriers to donation by:

- Prohibiting insurance companies from denying or limiting coverage or charging higher premiums for living organ donors for life, disability, and long-term care plans: Eleven percent of living organ donors experience difficulty securing or paying for insurance after their procedures because of discriminatory practices.
- Clarifying that living organ donors can use "time off" protected by the Family and Medical Leave Act to recover from donation surgery and maintain job security: Post-donation hospitalizations average 3 to 7 days and most donors don't return to work earlier than 4 weeks after the operation.
- Directing the Secretary of Health and Human Services to create educational materials reflecting important changes outlined above. Raising awareness is imperative since the number of kidney transplants performed in the US is equal to less than 1 percent of the number of patients on dialysis annually.

Banning discriminatory behavior, eliminating unnecessary hurdles, and increasing education about living donation are critical for those considering donating a kidney to a friend, loved one, or deserving American. ASN and its KCAD partners underscored this legislation's importance by reminding members of Congress that 12 Americans die every day waiting for a kidney transplant.

Research funding and living organ donation are crucial for eradicating kidney disease. ASN will continue to work with others in the community to fight for the best legislation and increased research dollars. To learn more about ASN advocacy and public policy and to take action, please visit https://www.asn-online.org/policy/.

Table 1. Kidney Community Advocacy Day 2015 Participating Organizations

- Alport Syndrome Foundation
- American Association of Kidney Patients
- American Kidney Fund
- American Nephrology Nurses Association
- American Society of Nephrology
- American Society of Pediatric Nephrology
- American Society of Transplant Surgeons
- American Society of Transplantation
- Home Dialyzors United
- IGA Nephropathy Foundation of America
- National Kidney Foundation
- National Renal Administrators Association
- NephCure Kidney International
- Oxalosis and Hyperoxaluria Foundation
- Polycystic Kidney Disease Foundation
- Society for Transplant Social Workers

ASN Fights Federal Budget Cuts

By Grant Olan

Owing to federal austerity measures Congress implemented starting in 2011, federal spending for non-defense discretionary (NDD) programs—ranging from medical research to public health, to natural resources and veterans services—is at the lowest level since the 1950s as a percent of GDP. These measures set caps on spending for both defense and non-defense discretionary spending programs through 2021. As a result, the National Institutes of Health (NIH) has lost nearly 25 percent of its purchasing power since 2003.

In response, 3200 organizations, including ASN, banded together in 2012 in support of NDD United, an advocacy coalition seeking to restore funding for NDD programs to keep America competitive, safe, and secure. NDD United has organized advocacy days in Washington, DC, as well as letter-writing and media campaigns, to raise awareness about the impact austerity has had on important programs like medical research. For example, ASN co-sponsored a NDD United awareness effort on September 10, 2015, to deliver hundreds of baseball hats to congressional offices during an advocacy day called "Raise the Caps" that encouraged Congress to raise the budget caps.

Due in part to NDD United's efforts, Congress raised the spending caps for 2014 and 2015 and President Barack Obama has threatened to veto budget bills that lock spending caps in place for 2016. Unless Congress passes and President Obama signs a budget for 2016 by December 11, essential government services will shut down.

The last shutdown in 2013 lasted 16 days. Non-mandatory federal programs funded by Congress through the annual appropriations process, such as medical research, were affected. NIH, for instance, was unable to fund new grants and contracts during that time. ASN and NDD United are both urging lawmakers to come to agreement, support medical research and other important NDD programs, and avert a government shutdown.

"Better and more cost-efficient treatments and therapies are desperately needed to slow or prevent progression of kidney disease and improve care," commented ASN Research Advocacy Committee Chair Frank "Chip" Brosius, MD. "ASN urges Congress to raise the budget caps for 2016 and to increase investments for kidney research, which would reduce the significant burden of kidney disease on patients and the Medicare program."

Be a part of something innovative, influential, and dynamic.

Be a part of ASN.

ASN members enjoy an ever-expanding array of benefits, including:

World-class publications

ASN members receive subscriptions to CJASN, JASN, and Kidney News, and online access to NephSAP.

Distance learning discounts

ASN members receive discounts on distance learning, and can access cutting-edge resources anywhere.

Career resources

Whether you're searching for your first job or an advanced position, the Career Center has the resources you need.

Live meeting discounts

Enjoy reduced rates on ASN's live educational programs, including Kidney Week and BRCU.

Grant eligibility

The ASN Foundation provides grant support to members at various stages in their careers.

Travel support

Many travel support opportunities are available to help ASN members attend Kidney Week.

To learn more and join or renew today, visit the ASN Member Services Booth (Booth 929) in the Exhibit Hall or go to www.asn-online.org/membership.

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Plenary Session

State-of-the-Art Lecture

Lecturer to Explore Global Burden of Kidney Disease

Christopher J.L. Murray

A seminal figure in developing the approach to quantifying the magnitude of health losses known as the "global burden of disease" will deliver a state-of-the-art lecture on its applicability to kidney disease. Christopher J.L. Murray, MD, DPhil, will speak on "Measuring the Global Burden of Kidney Disease to Improve Public Health" on Thursday, Nov. 5.

Dr. Murray is professor of global health and director of the Institute for Health Metrics and Evaluation (IHME) at the University of Washington in Seattle. A physician and health economist, he has developed a range of new methods to strengthen the basis for population health measurement, measure the performance of public health and medical care systems, and assess the cost-effectiveness of health technologies. IHME is focused on the challenges of measurement and evaluation in the areas of health outcomes; health services; financial and human resources; evaluations of policies, programs, and systems; and decision analytics.

Dr. Murray is a founder of the global burden of disease concept, a systematic effort to quantify the comparative magnitude of health loss due to diseases, injuries, and risk factors by age, sex, and geography over time. He led the collaboration of almost 500 researchers from 50 countries that produced the Global Burden of Diseases, Injuries, and Risk Factors Study 2010. This effort generated nearly 1 billion estimates of health outcomes for 187 countries and 21 regions and was published in *The Lancet* in December 2012.

In his earlier work, Dr. Murray and his team focused on tuberculosis control and the development of the global burden of disease methods and applications. As part of this work, they developed a new metric to compare death and disability from various diseases and the contribution of risk factors to the overall burden of disease in developing and developed countries. This pioneering effort has been hailed as a major landmark in public health and an important foundation for policy formulation and priority setting.

From 1998 to 2003, Dr. Murray worked at the World Health Organization (WHO) where he was executive director of the Evidence and Information for Policy Cluster. From 2003 to 2007, he was director of the Harvard University Initiative for Global Health and the Harvard Center for Population and Development Studies, as well as the Richard Saltonstall Professor of Public Policy at the Harvard School of Public Health.

Dr. Murray has authored or edited 14 books, many book chapters, and 200 journal articles. He holds a BA from Harvard University, a DPhil in international health economics from Oxford University, and a medical degree from Harvard Medical School.

CMS Official to Address Payment and Care Issues

Shari M. Ling

A federal government leader will discuss the "Brave New World in Payment and Care Delivery" in the Christopher R. Blagg, MD, Lectureship in Renal Disease and Public Policy on Thursday, Nov. 5.

The speaker, Shari M. Ling, MD, is the deputy chief medical officer for the Centers for Medicare & Medicaid Services (CMS) and a medical officer in the Center for Clinical Standards and Quality (CCSQ).

Dr. Ling's focus is on the achievement of meaningful health outcomes through delivery of high-quality, person-centered care, with special interests in reducing health disparities and in the care of persons with dementia, multiple chronic conditions, and functional limitations.

Dr. Ling served as the lead coordinator and facilitator of the CCSQ National Quality Measures Forum. She represents CMS on the multiple chronic conditions workgroup of the Department of Health and Human Services (DHHS). She also serves as the clinical subgroup lead for the DHHS National Alzheimer's Project Act.

Dr. Ling serves as a part-time faculty member in the division of geriatric medicine and gerontology at Johns Hopkins University School of Medicine and as a volunteer faculty member in the division of rheumatology, allergy, and clinical immunology at the University of Maryland. She continues to see patients at the Veterans Administration Medical Center in Baltimore.

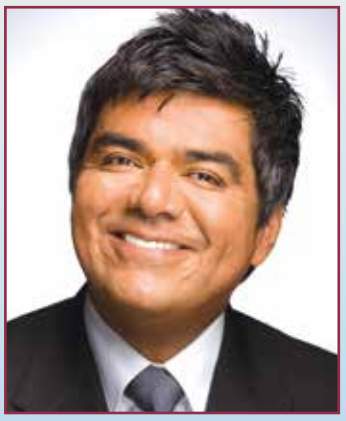
She worked for eight years at the National Institute on Aging as a clinician studying human aging and age-associated chronic diseases with attention to musculoskeletal conditions and morbidity function.

She served as associate editor of the *Journal of Gerontology* and has published more than 71 articles and book chapters.

Dr. Ling received her medical training at Georgetown University School of Medicine. She received her clinical training in internal medicine and rheumatology at Georgetown University Medical Center. She completed geriatric medicine training at Johns Hopkins University, where she served on the faculty. She also received training in direct service from the Ethel Percy Andrus Gerontology Center at the University of Southern California, where she served as the clinical services co-director of the Andrus Older Adult Counseling Center.

ASN gratefully acknowledges the Northwest Kidney Centers and its contributors for support of the Christopher R. Blagg, MD, Lectureship in Renal Disease and Public Policy. ASN thanks its Public Policy Board and the Renal Physicians Association for assistance with this session.

Award-Winning Actor and Comedian George Lopez Will Receive President's Medal during Kidney Week



George Lopez

Since receiving a kidney transplant in 2005, actor and comedian George Lopez has channeled his charitable energy into improving and saving the lives of people confronting the challenges of chronic kidney conditions. He is co-founder and president of the George Lopez Foundation, which is dedicated to bettering the lives of underprivileged children, adults, and military families confronting challenges in education and health, as well as increasing community awareness about kidney disease and organ donation.

His multi-faceted career encompasses television, film, standup comedy, and late-night television. He co-created, wrote, produced, and starred in the groundbreaking hit sitcom *George Lopez*, which ran for six seasons on ABC. For two seasons, he hosted *Lopez Tonight*, a late-night talk show on TBS. One of the entertainment industry's premier comedic talents, he is the founder of Travieso Productions, a film and television production company.

Talk to Explore the Importance of Trial Design for Interventional Studies

Ravi I. Thadhani

Adaptive Trial Design for Acute Kidney Injury (AKI) Interventional Studies" is the title of the Robert W. Schrier, MD, Endowed Lectureship on Thursday, Nov. 5.

The speaker, Ravi I. Thadhani, MD, MPH, is chief of the renal unit and director of clinical research in nephrology at Massachusetts General Hospital in Boston and a professor of medicine at Harvard Medical School.

Dr. Thadhani has two major areas of research interest: medical complications of pregnancy and dialysis mortality. His main focus in the study of kidney disease is the cardiovascular and infectious consequences of defective vitamin D signaling in individuals with renal failure. His team has performed several hypothesis-generating observational studies suggesting that therapy with activated vitamin D sterols is associated with improved survival among patients with renal failure. He has collaborated with basic scientists to move these hypotheses forward, and is currently performing randomized trials to formally test the hypotheses in humans.

His research has led to the publication of more than 150 peer-reviewed articles, eight book chapters, and many review articles and invited commentaries. Dr. Thadhani has also mentored several fellows and junior faculty members, who have a strong track record of publications and grant support and earned many faculty appointments at leading institutions around the country.

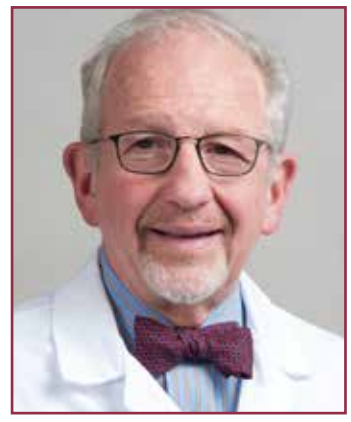
He has served ASN in a variety of capacities, including as a member of the clinical science committee and the annual meeting program committee as well as co-chair of the late-breaking clinical trials committee. For the National Kidney Foundation, he has chaired the clinical research committee and served on the annual meeting planning committee.

He has been on the editorial boards of the *Journal of the American Society of Nephrology, Kidney International, and Nephrology Dialysis Transplantation*. He was associate editor of the *American Journal of Kidney Diseases* and has been a guest editor of the *Journal of the American Society of Nephrology*.

Dr. Thadhani received his medical degree from the University of Pennsylvania and his MPH from the Harvard School of Public Health.

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

Bone and Mineral Metabolism Expert to Describe FGF23 Research



Isidro B. Salusky

Isidro B. Salusky, MD, will share the results of his current research into the role of fibroblast growth factor 23 (FGF23) in the pathogenesis of chronic kidney disease (CKD) mineral and bone disorder as well as the impact of therapies to treat the disorder on FGF23 production.

He will deliver the Jack W. Coburn, MD, Endowed Lectureship, entitled "Approaches to Reduce FGF23 Levels in CKD Patients," on Thursday, Nov. 5.

Dr. Salusky is distinguished professor of pediatrics, chief of the division of pediatric nephrology, director of the Clinical and Translational Research Center, and associate dean for clinical research at the David Geffen School of Medicine at UCLA.

Dr. Salusky is a clinical-translational research scientist in the subspecialty field of bone and mineral metabolism in children with CKD working to advance our understanding of the mechanisms of disordered mineral metabolism in these patients. As a result of continuous funding from the National Institutes of Health, his research group has characterized the features of bone diseases across the spectrum of CKD. The group has examined the effects of renal transplantation as well as the skeletal effects of therapy with active vitamin D sterols and phosphate binders. The group has also provided significant groundwork on the relationship between abnormalities of bone and mineral metabolism and vascular calcifications.

Dr. Salusky's service positions include chairing several committees for the National Kidney Foundation of Southern California, chairing the dialysis outcomes quality initiative of the National Kidney Foundation, and participating in many committees of the American Society of Pediatric Nephrology.

He has served on the editorial boards of many journals, including the *Journal of the American Society of Nephrology, American Journal of Kidney Diseases*, and *Advances in Renal Replacement Therapy*.

Among his many awards and recognitions, he has received the president's award from the National Kidney Foundation. He has published more than 140 peer-reviewed research papers, three books, 60 book chapters, and 290 abstracts.

Dr. Salusky received his medical degree from the National University of Buenos Aires in Argentina and completed a fellowship in pediatric nephrology at the Hopital des Enfants Malades in Paris. He joined the staff at UCLA with an advanced research fellowship in 1979 and has been there ever since.

ASN gratefully acknowledges Amgen for support of the Jack W. Coburn Endowed Lectureship.

Time Magazine has recognized Lopez as one of the 25 most influential Hispanics in America, and his entertainment industry work was recognized with a star on the Hollywood Walk of Fame in 2006, the ADCOLOR Industry Coalition's All-Star Award, and the 2015 Best Actor Imagen Award. For his charitable work, Harvard University honored him with its Artist of the Year and Humanitarian Award, and People for the American Way bestowed its Spirit of Liberty Award.

Lopez was most recently seen in the Lionsgate inspirational drama, *Spare Parts*, based on a true story about four undocumented Mexican-American teenagers from Phoenix who build an underwater robot that wins a national robotics competition. In 2014, he starred in the ensemble comedy *Saint George* on FX, which he co-created.

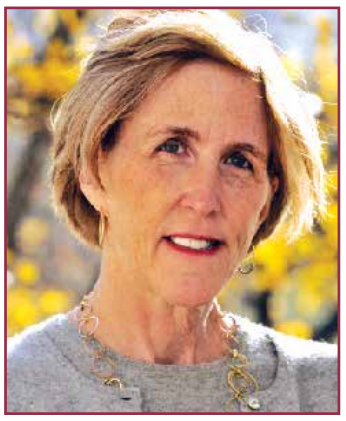
He also voiced characters in a string of animated blockbuster films including Rafael in *Rio* and *Rio 2*, Thurman in *Escape from Planet Earth*, Grouchy Smurf in *The Smurfs 1 and 2*, and Papi in *Beverly Hills Chihuahua 1, 2, and 3*. Other recent film credits include *Valentine's Day, Swing Vote, Henry Poole Is Here*, and *Balls of Fury*.

Lopez has had three HBO Comedy Specials: *It's Not Me, It's You*, in 2012; *Tall, Dark and Chicano*, in 2009 (nominated for a Best Comedy Album Grammy Award); and *America's Mexican*, in 2007. His autobiography, *Why You Crying?* was a *New York Times* bestseller in 2004, and he released his second memoir, *I'm Not Gonna Lie And Other Lies You Tell When You Turn 50*, in 2013.

Plenary Session

State-of-the-Art Lecture

Expert to Describe Contribution of Genetics to Cardiovascular Disease



Helen H. Hobbs

An internationally known genetics researcher will deliver a state-of-the-art lecture on "Genetics of Cardiovascular Disease: Getting to the Heart of the Matter" on Friday, Nov. 6.

Helen H. Hobbs, MD, is professor of internal medicine and molecular genetics, as well as director of the McDermott Center for Human Growth and Development, at the University of Texas Southwestern Medical Center Dallas.

Since 2002, she has been an investigator of the Howard Hughes Medical Institute. In partnership with Jonathan Cohen, she has identified genes and sequence variations contributing to metabolic and cardiovascular disorders with a focus on lipids and lipoproteins. Together they showed that rare genetic variations contribute to complex traits in the general population. By concentrating on alleles of low frequency and large phenotypic effect, they have discovered new therapeutic targets for the prevention and treatment of heart disease.

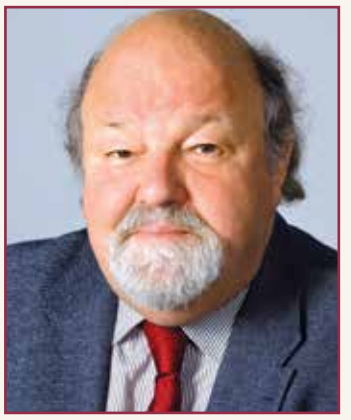
Recently, they identified genetic variants that contribute to the full spectrum of fatty liver disease, extending from hepatic steatosis to cirrhosis.

She holds five patents and has published more than 160 journal articles and book chapters. She serves as a consulting editor of the *Journal of Clinical Investigation* and is on the editorial boards of *Cell Metabolism* and *eLife*.

Among many awards, she has received the Alfred S. Maschke Award for Excellence in the Art and Practice of Medicine and a distinguished alumnus award from Case Western Reserve University School of Medicine, the Heinrich Wieland Prize, a clinical research prize and a distinguished scientist award from the American Heart Association, the Glorney-Raisbeck Award from the New York Academy of Medicine, the International Society of Atherosclerosis Prize, the Pasarow Foundation Award in Cardiovascular Research, and the Pearl Meister Greengard Prize from the Rockefeller University. Dr. Hobbs was elected to the Institute of Medicine, American Academy of Arts and Sciences, and the National Academy of Sciences.

She received her undergraduate degree from Stanford University, her medical degree from Case Western Reserve University School of Medicine, and her clinical and post-doctoral training at Columbia-Presbyterian Hospital and University of Texas Southwestern Medical Center Dallas.

Researcher to Receive Homer W. Smith Award



Dontscho Kerjaschki

Acclaimed researcher Dontscho Kerjaschki, MD, will receive the Homer W. Smith Award and deliver an address on "The Podocyte: From Periphery to Center Stage." Dr. Kerjaschki chairs the department of pathology at the Medical University of Vienna.

The Smith Award recognizes those who have made outstanding contributions to understanding how kidneys function in normal and diseased states. Dr. Kerjaschki's research has contributed in several ways, mainly focusing on the biology and pathology of kidney glomerular diseases and on lymphatic vessel biology and pathology. He discovered and defined the roles of the renal glomerulus and lymphatic endothelium in glomerular immune complex diseases, glomerular damage, and proteinuria. A leading expert in the nascent field of human lymphatic biology and pathology, he discovered the first reliable marker for lymphatic endothelial cells. This discovery has opened new avenues of investigation in pathology, ranging from renal transplant rejection to cancer metastasis.

Dr. Kerjaschki has received several major awards and was elected a fellow of the Royal College of Physicians and a member of the German National Academy of Sciences. He served as president of the German Society of Pathology.

He has served on the editorial boards of several journals, including the *Journal of the American Society of Nephrology* and *Journal of Clinical Investigation*. He was associate editor of the *American Journal of Pathology*. His own publications currently number 245.

Dr. Kerjaschki received his medical degree and his license for pathology and cytology from the University of Vienna in the 1970s. As an associate professor at the University of Vienna he specialized in renal pathology. During the 1980s, he was a visiting professor in the departments of cell biology at Yale University and the University of California, San Diego.

Homer W. Smith

Homer W. Smith was chairman of physiology at the University of Virginia before moving in 1928 to New York University (NYU). As director of the Physiology Laboratories at NYU, he developed and refined the concepts of glomerular filtration and tubular absorption and secretion of solutes.

The clarity of Dr. Smith's logic and the skill with which he explained his ideas transformed them into vivid and powerful concepts that are the cornerstones of our present understanding of normal and abnormal renal function. He attracted the best and brightest to the field, to NYU, and to the Mount Desert Island Biological Laboratory, where he spent many summers studying renal physiology in fish.

The Homer W. Smith award recognizes individuals who contribute to our basic understanding of how the kidneys function in health and disease.

ASN Scientific Exposition

Thursday, November 5 – Saturday, November 7

Exhibits

Halls B/C • 9:30 a.m. – 2:30 p.m.

Posters

Halls A/B • 9:30 a.m. – 4:30 p.m.

Highlights Include:

- Over 160 Exhibiting Companies
- ASN Services
  - General Information, KHI, Membership Services, Publications, Foundation, and Web Services
- Career Fair
- Complimentary Refreshment Breaks
- Cyber Center
- Exhibitor Spotlights
- "Locate Me" Kiosks – Posters/Exhibitors
- Meet the Experts
- Poster Sessions
- Wi-Fi

Exhibitor Spotlights

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

All presentations include breakfast or lunch.

Schedule

Thursday, November 5

10:00 a.m. – 11:00 a.m. • Theater 1

Management of Secondary Hyperparathyroidism (HPT) in Adult Patients on Dialysis: The Role of Sensipar® (cinacalcet)

Supported by AMGEN

11:00 a.m. – 12:00 p.m • Theater 2

Practical Implications of the Landmark OPAL-HK Study for Hyperkalemia Patients

Supported by relypsa

12:00 p.m. – 1:00 p.m. • Theater 1

Velphoro: A Potent, Non-Calcium, Iron-Based Phosphate Binder with a Low Pill Burden

Supported by FRESENIUS MEDICAL CARE RENAL THERAPIES GROUP

1:00 p.m. – 2:00 p.m. • Theater 2

Anticipate, Assess, Act: When Impaired Renal Function Delays Methotrexate Clearance

Supported by BTG

Friday, November 6

10:00 a.m. – 11:00 a.m. • Theater 1

Follow My Lead: The Amia Automated PD System with Sharesource Connectivity Platform

Supported by Baxter

11:00 a.m. – 12:00 p.m. • Theater 2

The Science of Biosimilars

Supported by Hospira

12:00 p.m. – 1:00 p.m. • Theater 1

Fabry Disease in the Hemodialysis Setting – Not as "Rare" as We Think

Supported by genzyme A SANOFI COMPANY

1:00 p.m. – 2:00 p.m. • Theater 2

Distinguishing Atypical Hemolytic Uremic Syndrome (aHUS) from Other Thrombotic Microangiopathies (TMAs): A Case Based Approach

Supported by ALEXION

Saturday, November 7

10:00 a.m. – 11:00 a.m. • Theater 1

Practical Implications of the Landmark OPAL-HK Study for Hyperkalemia Patients

Supported by relypsa

1:00 p.m. – 2:00 p.m. • Theater 2

ANCA-Associated Vasculitis: Clinical Manifestations and Immunopathogenesis

Supported by Genentech A Member of the Roche Group

EXCHANGE THE TWO VOUCHERS IN YOUR MEETING BAG FOR KIDNEY WEEK PROGRAM CONTENT AND NEVER MISS A SESSION AT KIDNEY WEEK!

Kidney Week *On-Demand*™

Kidney Week *On-Demand*™ provides over 200 hours* of presentations from Kidney Week 2015 annual meeting sessions. Exchange the voucher in your meeting bag for an electronic access code and experience Kidney Week anytime, anywhere.

**Final hours available subject to speaker permission.*

Personalized access codes may be obtained at any one of these booths:

- ALEXION – **Booth 902**
- KERYX BIOPHARMACEUTICALS, INC – **Booth 913**
- Mallinckrodt Pharmaceuticals – **Booth 1129**
- relypsa – **Booth 1119**

Abstracts2View™ CD-ROM

The *Abstracts2View*™ CD-ROM offers a concise and effective way to view and archive the 2015 abstracts and the program. Exchange the voucher in your meeting bag for a complimentary CD while supplies last at

SANOFI RENAL

Booth 429

Plenary Session

State-of-the-Art Lecture

Diabetes Expert to Speak on Cellular Mechanisms of Insulin Resistance

Gerald I. Shulman

A leading diabetes researcher will speak on "Cellular Mechanisms of Insulin Resistance: Implications for Obesity, Diabetes, and Metabolic Syndrome" at a state-of-the-art lecture on Saturday, Nov. 7.

Gerald I. Shulman, MD, PhD, is the George R. Cowgill Professor of Physiological Chemistry, Medicine, and Cellular and Molecular Physiology at Yale University, associate director of the Yale Diabetes Endocrine Research Center, and associate director of the Yale Medical Scientist Program. He is also an investigator of the Howard Hughes Medical Institute.

Dr. Shulman is an internationally recognized diabetes researcher and a leading authority on the cellular mechanisms of insulin resistance, the role of the liver and muscle in the pathogenesis of type 2 diabetes, and the benefits of exercise in the management of diabetes. Dr. Shulman pioneered the use of magnetic resonance spectroscopy to noninvasively examine intracellular glucose and fat metabolism in humans that has led to several paradigm shifts in our understanding of type 2 diabetes.

Dr. Shulman has received numerous awards, including the Outstanding Scientific Achievement Award and the Distinguished Clinical Scientist Award from the American Diabetes Association, the Diabetes Care Research Award from Boehringer-Mannheim/Juvenile Diabetes Foundation, and the Stanley Korsmeyer Award from the American Society for Clinical Investigation. He is a fellow of the American Association for the Advancement of Science and has been elected to the American Society for Clinical Investigation, Association of American Physicians, Institute of Medicine, and National Academy of Sciences.

Dr. Shulman completed his undergraduate studies in biophysics at the University of Michigan and received his MD and PhD degrees from Wayne State University. Following an internship and residency at Duke University Medical Center, he did an endocrinology fellowship at the Massachusetts General Hospital/Harvard Medical School and additional postdoctoral work in molecular biophysics and biochemistry at Yale. He joined the faculty at Harvard Medical School before being recruited back to Yale.

Genetics Researcher to Provide Insights into FSGS

Corinne Antignac

The genomics of focal segmental glomerulosclerosis (FSGS) will be the subject of the Michelle P. Winn, MD, Endowed Lectureship on Saturday, Nov. 7. The internationally recognized investigator Corinne Antignac, MD, PhD, will be the speaker.

Dr. Antignac is professor of genetics at University Paris Descartes and director of the INSERM (French Institute of Health and Medical Research) Laboratory of Hereditary Kidney Diseases at the newly established Imagine Institute, an interdisciplinary research center on rare genetic diseases at the Necker Enfants-Malades University Hospital in Paris.

Her research focuses on identifying and characterizing genes responsible for inherited renal disorders. Dr. Antignac has made seminal contributions to our understanding of the genetic basis of several renal diseases. Her group used positional cloning to identify gene mutations causing nephronophthisis, cystinosis, and steroid-resistant nephrotic syndrome. They have also used candidate gene approaches and phenotype/genotype correlation to identify genes in other hereditary renal disorders, such as Bartter syndrome, Alport syndrome, and renal tubular dysgenesis.

Dr. Antignac's main contribution has been to understanding the genetic bases of monogenic glomerular diseases. In 2001, Dr. Antignac identified the NPHS2 gene encoding podocin, one of the most frequently mutated genes in steroid-resistant nephrotic syndrome. Podocin turned out to be a crucial protein for the development and maintenance of the glomerular filtration barrier; this and other pioneering work led researchers to focus on the podocyte as a major player in the development and diseases of the glomerulus.

Dr. Antignac has since cloned many other genes involved in steroid-resistant nephrotic syndrome, including her recent discovery of an unexpected role for intraflagellar transport proteins in podocyte function.

Among her many contributions to her profession, she has served on the scientific committee of the French Medical Research Foundation and chaired the scientific review board of the Cystinosis Research Foundation. She served as associate editor of the *Journal of the American Society of Nephrology* and is currently on its editorial board, as well as the board of *Kidney International*.

Dr. Antignac has been awarded the Medical Research Prize from the French Medical Research Foundation, the Eloi Collery Prize from the French National Academy of Medicine, the Prize of the French Association of Patients with Nephrotic Syndrome, and the Lilian Jean Kaplan International Prize for Advancement in the Understanding of Polycystic Kidney Disease.

She received her MD and her PhD (in human genetics) from Paris 6 University and trained as a pediatric nephrologist.

Mark L. Zeidel to Be Given Robert G. Narins Award for Contributions in Education

Mark L. Zeidel

Mark L. Zeidel, MD, FASN, will receive the Robert G. Narins Award for his many contributions to medical education.

Dr. Zeidel is the Herrman L. Blumgart Professor of Medicine at Harvard Medical School and chair of the department of medicine at Beth Israel Deaconess Medical Center (BIDMC) in Boston. He is known as a productive and highly original scientist, an innovative educator, and a leader in improving the quality of healthcare. He has made many seminal observations in the field of nephrology: defining the role of atrial peptides in renal salt excretion, characterizing the biophysical function of water channels and barrier membranes, and advancing urothelial cell biology.

His innovations in teaching physiology include an animated textbook; novel, nationally known courses at the Mount Desert Island Biology Laboratories; and an upcoming series of review articles in his field's major clinical journal. He has pioneered the provision of reliable, cost-effective care, both at the University of Pittsburgh and BIDMC. His leadership led to BIDMC's achievement of outstanding clinical outcomes, which have been recognized by the American Hospital Association, Society for Critical Care Medicine, and US Department of Health and Human Services. He also pushed the BIDMC medicine department to develop an innovative curriculum in quality improvement for its residents and fellows.

Dr. Zeidel has served on many regional and national committees and in leadership roles in national organizations. In these positions, he has helped define how residency education can be funded in academic medical centers, how mentorship can be improved for future clinical investigators, and how departments of medicine can lead in improving the quality of care.

Dr. Zeidel received his medical degree from Columbia University College of Physicians and Surgeons. He served as an intern and resident in medicine at Brigham and Women's Hospital in Boston, followed by a renal fellowship at the same institution. He came to BIDMC in July 2005 from the University of Pittsburgh School of Medicine. His tenure at the University of Pittsburgh spanned 12 years, first serving as chief of the renal and electrolyte division, and then as the Jack D. Myers Professor and chair of the department of medicine. As chair of that department, he implemented a new curriculum to enhance the teaching of residents and fellows.

Robert G. Narins

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

Plenary Session

John P. Peters Award to Honor Roger C. Wiggins

Roger C. Wiggins

ASN will recognize the wide-ranging contributions of Roger C. Wiggins, MB, BChir, with the presentation of the John P. Peters Award.

The John P. Peters Award is given for outstanding contributions to improving the lives of patients and to furthering the understanding of the kidney in health and disease. Dr. Wiggins is emeritus professor in the department of internal medicine at the University of Michigan in Ann Arbor, where he served as director of the nephrology training program for 10 years, division chief for 15 years, and director of the George M. O'Brien Kidney Center for 23 years.

His research, which the National Institutes of Health has funded since 1982, has focused on podocyte biology and defining the role of podocyte depletion in glomerulosclerosis and loss of kidney function. These studies started with the identification, cloning, and sequencing of novel markers for podocytes. They moved on to developing transgenic animal model systems to discover, define, and validate the mechanisms and consequences of podocyte depletion. Dr. Wiggins is currently focused on translating discoveries made from model systems to glomerular diseases in man with the goal of providing the practicing clinician with the insights and tools needed to prevent progression.

Dr. Wiggins is a fellow of the Royal College of Physicians and the American Association of Physicians. He has received several awards from the University of Michigan, including teacher of the year from the residents in internal medicine, an award for distinguished research by young faculty members, and a lifetime achievement award. He has given numerous invited lectures, including the Donald Seldin lecture for the American Heart Association. He has served as a study section member for the National Institutes of Health and the American Heart Association, and as an associate editor of the *Journal of the American Society of Nephrology*.

Dr. Wiggins was raised on a farm in Rhodesia (now Zimbabwe). He attended Cambridge University in the U.K. as an undergraduate. He received his medical training at the Middlesex Hospital in London, with postgraduate training in London Hospitals and the Royal Postgraduate Medical School at Hammersmith Hospital. He then spent five years in the department of immunopathology at Scripps Clinic in La Jolla, Calif., for fellowship training and as junior faculty. He was recruited to the University of Michigan in 1981.

ASN to Bestow Belding Scribner Award on Glenn M. Chertow

Glenn M. Chertow

The Belding H. Scribner Award will be tendered to Glenn M. Chertow, MD, MPH, for his career-long contributions to the practice of nephrology.

Dr. Chertow is the Norman S. Coplon Satellite Healthcare Professor of Medicine and chief of the division of nephrology at Stanford University School of Medicine.

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

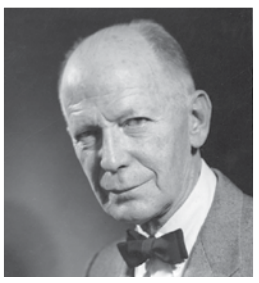
In addition to an active clinical practice, administrative responsibilities, teaching, and mentoring, he has developed and maintained a robust clinical research program. He has served in leadership roles for many clinical trials sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases; National Heart, Lung, and Blood Institute; and industry.

He has served in an advisory capacity to the Medicare Payment Advisory Commission and the National Quality Forum on issues related to end stage renal disease and on National Institutes of Health study sections. He has served ASN in many roles, including on the public policy board and as associate editor of *Journal of the American Society of Nephrology*. He is co-editor of *Brenner and Rector's The Kidney*.

Dr. Chertow has been elected to the American Society for Clinical Investigation and American Academy of Pediatrics. He was honored by the American Kidney Fund with the National Torchbearer Award and the Nephrologist of the Year Award.

Dr. Chertow completed his undergraduate education at the University of Pennsylvania and his medical education at Harvard. He completed his residency in internal medicine and fellowship in nephrology at Brigham and Women's Hospital in Boston before joining the Harvard faculty, where he remained until 1998. He then joined the faculty at the University of California, San Francisco, where he served as director of clinical services in the division of nephrology. He was promoted through the academic ranks to full professor in the departments of medicine and epidemiology and biostatistics. He joined the Stanford faculty in 2007.

John P. Peters



John P. Peters, MD, was one of the fathers of nephrology and former chief of the Metabolic Division in the Department of Medicine at Yale University. He transformed clinical chemistry from a discipline of qualitative impressions to one in which precise quantitative measurements of body fluids comprise a vital part of the patient examination and provide great explanatory value.

He advanced the view that disease is a quantitative abnormality of normal physiological processes and that, by understanding disease, one could gain a deeper understanding of normal physiology. His enduring scientific contributions paralleled his fervent mission to ensure that the physician be an advocate for the patient.

Belding H. Scribner

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

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

2015 Corporate Supporters

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

The ASN Corporate Support Program recognizes supporters year round for their generous contributions to the Society. Through this program, supporters help ASN lead the fight against kidney disease. ASN gratefully acknowledges the following companies for their contributions in 2015.

Diamond Level

AMGEN

FRESENIUS MEDICAL CARE
RENAL THERAPIES GROUP

Hospira

Mallinckrodt Pharmaceuticals

relypsa

Platinum Level

KERYX BIOPHARMACEUTICALS, INC

OPKO Renal

SANOFI RENAL

Gold Level

Alexion Pharmaceuticals, Inc.
AstraZeneca
Genentech, A Member of the Roche Group
Merck
ZS Pharma

Silver Level

Baxter Healthcare Corporation
Raptor Pharmaceuticals

Bronze Level

Akebia Therapeutics, Inc.
Rockwell Medical Inc.
Shire

as of September 10, 2015

Plenary Session

State-of-the-Art Lecture

Biological Engineer to Describe Effort to Develop "Organs on Chips"

Donald E. Ingber

A founder of the emerging field of biologically inspired engineering will deliver a state-of-the-art lecture about "Human Organs on Chips," on Sunday, Nov. 8.

Donald E. Ingber, MD, PhD, is the founding director of the Wyss Institute for Biologically Inspired Engineering at Harvard University, the Judah Folkman Professor of Vascular Biology at Harvard Medical School and Boston Children's Hospital, and professor of bioengineering at the Harvard School of Engineering and Applied Sciences.

At the Wyss Institute, Dr. Ingber oversees a multifaceted effort to identify the mechanisms that organisms use to self-assemble from molecules and cells and to apply these design principles to develop advanced materials and devices for healthcare. He also leads the biomimetic microsystems platform in which microfabrication techniques from the computer industry are used to build functional circuits with living cells as components.

His most recent innovation is a technology for building tiny, complex, three-dimensional models of living human organs, or "organs on chips," that mimic complicated human functions as a way to replace traditional animal-based methods for testing drugs and establishing human disease models. Each organ-on-chip is the size of a memory stick and contains human cells and mimics the blood vessels and tissues of living organs. The chip is a clear flexible polymer that contains hollow microfluidic channels lined by living human cells. Because the microdevices are translucent, they provide a window into the inner workings of human organs. The Wyss Institute team seeks to build 10 different human organs-on-chips and link them together on an automated instrument to mimic whole-body physiology.

The goal is to replace the cell cultures in Petri dishes and animal models used to understand how a human body may react to a drug, toxin, or disease with an instrument that will control fluid flow and cell viability while permitting real-time observation of the cultured tissues and analysis of complex biochemical functions. It could be used, for example, to rapidly assess responses to new drug candidates with information on their safety and efficacy.

In addition to this work, Dr. Ingber has made major contributions to mechanobiology, tissue engineering, tumor angiogenesis, systems biology, nanobiotechnology, and translational medicine. He has authored more than 400 publications and holds 100 patents.

He has received numerous honors including the Holst Medal from the royal Netherlands Academy of Arts and Science, Pritzker Award from the Biomedical Engineering Society, Rous-Whipple Award from the American Society for Investigative Pathology, Lifetime Achievement Award from the Society of In Vitro Biology, Department of Defense Breast Cancer Innovator Award, and Graeme Clark Oration Award.

He received his BA, MA, MPhil, MD, and PhD from Yale University.

Brenner Lectureship to Cover Novel Diabetes Therapy

Jeff M. Sands

A well-known Emory University researcher will present the Barry M. Brenner, MD, Endowed Lectureship on "Novel Therapy for Diabetes Insipidus" on Sunday, Nov. 8.

Jeff M. Sands, MD, is the Juha P. Kokko Professor of Medicine and Physiology and director of the renal division at Emory University School of Medicine. He served as executive vice chair of medicine at Emory from 2009 to 2015 and as associate dean for clinical and translational research from 2006 to 2010.

Dr. Sands' research is directed at understanding the physiology of urea transport proteins, the renal inner medulla, and the urine-concentrating mechanism. His current research projects focus on defining the molecular physiology of urea transporters because urea transport is a key component in the urine-concentrating mechanism. These studies use rat and mouse models of abnormal concentrating and diluting ability, including genetically engineered mice.

Dr. Sands uses a combination of isolated perfused tubule studies to measure urea transport; antibodies to measure changes in the amount, phosphorylation, and localization of the urea transport proteins; Northern analysis and real-time polymerase chain reaction to measure changes in mRNA; and surface biotinylation and confocal microscopy to measure changes in the subcellular localization of urea transporters.

Dr. Sands has served as editor-in-chief of the *American Journal of Physiology—Renal Physiology*, as a councilor of the American Physiological Society, as chair of the 2004 American Society of Nephrology program committee, as chair of the Council on the Kidney of the American Heart Association, as a member of the board of scientific councilors of the National Institute of Diabetes and Digestive and Kidney Diseases, and as a member of the ASN publications and communications committee. He has served on study sections for the National Institutes of Health, American Heart Association, and National Kidney Foundation. He has published 139 original research papers, written 89 invited reviews and book chapters, and co-edited one book.

A graduate of Boston University School of Medicine, Dr. Sands trained in medicine at the University of Chicago and the National Heart, Lung, and Blood Institute, followed by a clinical nephrology fellowship at Emory.

Young Investigator Recognized for CKD Research

Janos Peti-Peterdi

Janos Peti-Peterdi, MD, PhD, will receive the ASN-AHA Young Investigator Award for his groundbreaking research on CKD. He will describe his recent findings in an address: Renal Physiology Is Key to Understand and Augment Nephron Repair.

Dr. Peti-Peterdi is professor in the department of physiology and biophysics and the department of medicine at the University of Southern California (USC).

His laboratory at USC examines kidney and cardiovascular pathophysiology—specifically the mechanisms of the healthy kidney that maintain body fluid volume, electrolyte balance, and blood pressure—and how they are changed in disease.

A main goal is to identify the key molecular players in various renal pathologies as potential therapeutic targets. Dr. Peti-Peterdi's group played an important role in identifying the cellular and molecular processes of a key anatomical site within the kidney—the juxtaglomerular apparatus or JGA—which controls the amount of blood flow and filtration through the kidneys.

Dr. Peti-Peterdi is director of the National Institutes of Health-funded Multi-Photon Microscopy Core at USC for high-resolution intravital (live animal or in vivo) imaging of intact organs in small laboratory animals. During the past decade, the laboratory pioneered several applications of intravital multiphoton microscopy that allow researchers to quantitatively visualize the most basic physiological parameters of kidney and nephron function. The Peti-Peterdi lab is using this imaging technology to examine complex regulatory and disease mechanisms in intact kidney tissue in various animal models.

Over the past five years, he has trained more than 30 investigators from around the world on the use of intravital imaging. Recent studies solved a critical technical barrier, allowing researchers for the first time to quantitatively visualize the function of glomerular cellular and molecular elements in vivo.

The Peti-Peterdi lab recently deployed serial multi-photon microscopy to track the fate and function of individual cells in the same region of the living intact kidney during disease development. This approach has led to significant advances in understanding the highly dynamic kidney tissue and glomerular environment and the mechanisms of glomerular injury and regeneration. The lab is also using renal stem cells to develop a regenerative approach to treat CKD.

Dr. Peti-Peterdi has served on committees for several associations and on the editorial boards of many journals. He is associate editor of the *American Journal of Physiology—Renal Physiology*.

He received his MD and PhD degrees from the Semmelweis University Medical School, Budapest, Hungary. He received his postdoctoral training in renal physiology and nephrology at the University of Alabama at Birmingham.

ASN Foundation for Kidney Research

Time for a Cure

Mission: To prevent and cure kidney diseases through research and innovation

Established in 2012, the ASN Foundation for Kidney Research funds the Ben J. Lipps Research Fellowship Program, the Career Development Grants Program, the William and Sandra Bennett Clinical Scholars Program, and the American Society of Nephrology-Harold Amos Medical Faculty Development Program Award providing over $3,000,000 annually to young investigators, fellows, and nephrology educators.

2015

FOUNDERS CIRCLE MEMBERS

Thanks to the generosity of our Founding Members, the ASN Foundation for Kidney Research has succeeded in raising $20,000,000 in four years to endow the Ben J. Lipps Research Fellowship Program.

Established in 2012, the ASN Foundation has endowed the program to ensure it continues in perpetuity. This is one of many steps the ASN Foundation is taking to guarantee the next generation of nephrology clinicians, researchers, and educators who will fuel innovation and translate findings into improved quality of life for patients.

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

Founding Members

FRESENIUS MEDICAL CARE
$10,000,000

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE
$7,000,000

AMERICANRENAL associates
$1,000,000

AMGEN
$1,000,000

Baxter
$1,000,000

The ASN Foundation for Kidney Research congratulates the talented group of researchers and educators who were awarded grants in 2015.

Ben J. Lipps Research Fellowship Program

Funding ten new research applicants and ten continuing projects annually, the program distributes $50,000 a year per fellow for two years to conduct original, meritorious research.

Ben J. Lipps Research Fellows

Ashima Gulati, MD
Yale University
Identification and Functional Characterization of Novel Genetic Causes of Atypical Hemolytic Uremic Syndrome

Stacy Alana Johnson, MD, PhD*
Duke University
The Role of Branched-chain Amino Acids in Diabetic Nephropathy

Mitchell R. Lunn, MD
University of California, San Francisco
Validation of Patient-Performed Smartphone-Based Albuminuria Quantification

Weizhen Tan, MD*
Boston Children's Hospital
Delineate the Pathogenesis of Nucleoporin Mutations, a Novel Monogenic Cause of FSGS

Abolfazl Zarjou, MD, PhD
University of Alabama at Birmingham
Role of Ferritin as an Inhibitory Mechanism Against Vascular Calcification

Sharon Anderson Research Fellow

Heather M. Perry, PhD*
University of Virginia
Endothelial Sphingosine-1-phosphate Receptor-1 is Necessary for Recovery from Ischemia Reperfusion Injury and Prevents Fibrosis

Dimitrios G. Oreopoulos Research Fellow

Adedotun Adebamiro, MD, PhD
Yale University
Characterization of the Basolateral Oxalate Transport Process that Mediates Active Oxalate Secretion in the Intestine

Donald E. Wesson Research Fellow

Karim Yatim, MD*
University of Pittsburgh
The Sentinel Role of Renal Dendritic Cells in Immune Surveillance

George B. Rathmann Research Fellow

Yu Leng Phua, PhD
University of Pittsburgh
Role of miR-17~92 in Nephron Progenitor Self-renewal and Low Nephron Endowment

ASN Foundation for Kidney Research Fellow

Emilie Cornec-Le Gall, MD*
Mayo Clinic
An In-depth Study of Hypomorphic Alleles of the PKD1 Gene in a Large International Population of ADPKD Patients

---

William and Sandra Bennett Clinical Scholars Program

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

Belinda T. Lee, MD
Tulane University School of Medicine
A Longitudinal Competency-Based Renal Curriculum for Undergraduate Medical Training

---

ASN Foundation for Kidney Research-AAIM Junior Development Grant in Geriatric Nephrology

Supplementing an award from the National Institute on Aging (NIA), this grant supports the development of academic subspecialists interested in careers focused on the geriatric and gerontology aspects of nephrology.

Rasheeda Hall, MD
Duke University
Improving Quality of Life Measurement in Older Dialysis Patients

---

Career Development Grants Program - Funding for New Investigators

Funding up to ten new applicants and ten continuing projects annually, the program invests $100,000 a year per investigator for two years to foster independent research careers and ensure a pipeline of innovative research in the field of nephrology.

Carl W. Gottschalk Research Scholar Grants

Mitsi A. Blount, PhD
Emory University School of Medicine
Compartmentalized Regulation of Urea Permeability in the Inner Medullary Collecting Duct

Paul E. Drawz, MD*
University of Minnesota
Treatment of Masked Hypertension

Nadja Grobe, PhD
Henry M. Jackson Foundation for the Advancement of Military Medicine
Molecular Imaging of the Renin Angiotensin System for the Discovery of Novel Biomarkers in Chronic Kidney Disease

Mark Parker, PhD
University at Buffalo: State University of New York
Cause and Consequence of Acidosis by the Sodium/bicarbonate Cotransporter NBCe1

Nirupama Ramkumar, MD, MPH*
University of Utah
Functional Role of Nephron Prorenin Receptor in Regulation of Blood Pressure, Sodium and Water Homeostasis

M. Sampson, MD
University of Michigan
Genetic Risk in Nephrotic Syndrome from an Integrative Genomics Approach

Jennifer M. Sasser, PhD
University of Mississippi Medical Center
Mechanisms and Mediators of the Preeclamptic Phenotype in the Dahl S Rat

NephCure Kidney International-ASN Foundation for Kidney Research Grant

Evren U. Azeloglu, PhD*
Icahn School of Medicine at Mount Sinai
Mechanosensitive Control of Podocyte Cytoskeleton and Remodeling

Norman Siegel Research Scholar Grant

Karel F. Liem, Jr., MD, PhD
Yale University
Characterization of a Novel Mouse Model of Ciliopathic Cystic Renal Disease

**Kidney Week 2015 oral and/or poster abstract presenter*

ASN Kidney Week 2015

Educational Symposia Schedule

Thursday, November 5 – Saturday, November 7

Manchester Grand Hyatt San Diego

Continuing Education Credit

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

Breakfast or lunch will be served at each session.

Seating is limited and available on a first-come, first-served basis to fully paid Annual Meeting participants.

Doors open 15 minutes prior to each session.

Thursday, November 5 • 12:45 p.m. – 1:45 p.m.

Biosimilars on the Horizon: Biologics and Biosimilars in Anemia Management
*Support for this symposium is provided by an educational grant from **Hospira, a Pfizer Company**.*

Glomerular and Tubular Targetable Pathways: Thinking Out of the Box
*Support for this symposium is provided by an educational grant from **Mallinckrodt Pharmaceuticals**.*

Grading the Evidence for Hepatitis C Therapies: Can We Do Better than a "C"?
*Support for this symposium is provided by an educational grant from **Merck**.*

Iron-Based Phosphate Binders: Pharmacology for Patients with CKD and ESKD
*Support for this symposium is provided by an educational grant from **Keryx Biopharmaceuticals, Inc.***

Management of Secondary Hyperparathyroidism: The Role of Vitamin D
*Support for this symposium is provided by an educational grant from **OPKO Renal**.*

Friday, November 6 • 6:45 a.m. – 7:45 a.m.

Calcium or No Calcium: That Is the Question
*Support for this symposium is provided by an educational grant from **sanofi US**.*

Cystinosis: What the Adult Nephrologist Needs to Know
*Support for this symposium is provided by an educational grant from **Raptor Pharmaceuticals**.*

The Role of Intravenous Iron in Chronic Dialysis
*Support for this symposium is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*

Friday, November 6 • 12:45 p.m. – 1:45 p.m.

At What Cost Should Blood Transfusion Be Avoided in CKD Patients?
*This activity is supported by educational funding provided by **Amgen**.*

Basic Science Symposium: Live Cell-Fluorescent Biosensors
*This symposium is sponsored by the **American Society of Nephrology (ASN)**.*

Maintenance Therapy in ANCA Vasculitis: Give Enough but Not Too Much
*Support for this symposium is provided by an educational grant from **Genentech**.*

Management of Hyperphosphatemia: Binders and Beyond
*Support for this symposium is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*

New Agents in the Management of Hyperkalemia
*Support for this symposium is provided by an educational grant from **ZS Pharma**.*

Saturday, November 7 • 12:45 p.m. – 1:45 p.m.

Anemia, Erythropoiesis, and the Nephrologist
*Support for this symposium is provided by an educational grant from **AstraZeneca and FibroGen**.*

Fluid Management in Hemodialysis: Physiology and Management
*Support for this symposium is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*

Management of Chronic Hyperkalemia
*Support for this symposium is provided by an educational grant from **Relypsa, Inc.***

Secondary Hyperparathyroidism and Hyperphosphatemia in Dialysis Patients
*This activity is supported by educational funding provided by **Amgen.***

Kidney Health Initiative Expands Offerings

The Kidney Health Initiative (KHI) is a public-private partnership founded in September 2012 by the American Society of Nephrology and the U.S. Food and Drug Administration (FDA). Since its inception, KHI has steadily increased its membership to more than 70 member organizations.

KHI advances its mission through a portfolio of innovative, collaborative, and member-driven projects. The collaborative will complete six of its 13 initial projects by the end of 2015:

- Pharmacokinetics in Patients Receiving Continuous Renal Replacement Therapy
- Outcome Measures in Lupus Nephritis
- Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions
- Pragmatic Trials in Dialysis: Challenges and Opportunities
- Regulatory Policies and Positions Affecting Device Approval in the US: Tools to Assess the Process and Foster Device Development for Patients with Kidney Disease
- Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease

Innovation in kidney disease is substantially lagging behind other specialty areas, despite the enormous toll that chronic kidney disease and end stage kidney disease exacts on its patients. No one stakeholder—be it regulatory, payer, industry, patients, or health professionals—has the capability and resources to reverse this approximately 60-year trend. Rather, the diverse membership of KHI, including members from each of the critical stakeholders, is in an excellent position to pose solutions to these critical barriers and serve as a platform for their implementation.

The KHI "Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions" workgroup helps frame the strategic priorities that will stimulate innovation in kidney disease and identifies several transformative initiatives to support. Please look for their publication in the coming months.

KHI hosted a workshop titled "Understanding Patients' Preferences: Stimulating Medical Device Development in Kidney Disease" in August 2015. The workshop was organized by the KHI "Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease" workgroup, and balanced education with small group breakout discussions, allowing patients to share their ideas directly with the FDA, scientists, doctors, nurses, and technicians. The KHI workshop was attended by more than 100 participants including over 50 patients, care partners, and family members.

"KHI's early progress gives kidney patients hope for a better tomorrow and emphasizes that real advances can be made through a collaborative approach that brings together all the stakeholders in the kidney space," observed Prabir Roy-Chaudhury, MD, PhD, FASN, who co-chairs the KHI Board of Directors along with Patrick Archdeacon, MD, a medical officer in the Office of Medical Policy with the Center for Drug Evaluation and Research (CDER) at the FDA.

To advance efforts to improve patient safety and promote the development of therapies for diseases that affect the kidneys, KHI established a Patient and Family Partnership Council (PFPC) in 2015. PFPC has worked closely with the KHI Board of Directors, interacting, advising, and making recommendations on KHI member proposals, projects, and efforts so that patient involvement is meaningful and effective.

The KHI membership thanks the KHI Board of Directors for their leadership and service. In particular, the membership recognizes four leaders who are stepping off the KHI Board of Directors at the end of 2015:

- Nancy M. Gallagher, RN, CNN
- Kristine Kuus, PhD
- Sam M. Pederson

KHI would also like to recognize the new members of the KHI Board of Directors who will begin serving in 2016:

- Paul T. Conway
- Wendy St. Peter, PharmD
- Roberta L. Wager, MSN, RN
- Alexander S. Yevzlin, MD

To obtain additional information or to discuss KHI, the initiative's projects, or the KHI PFPC, please contact the KHI staff at KHI@asn-online.org.

Findings

Directed Kidney Donors Would Consider Kidney Paired Donation

More than 90 percent of directed living kidney donors and recipients would be willing to participate in kidney paired donation (KPD) programs, reports a survey study in *Transplantation*.

The researchers surveyed 222 directed living kidney donors and their recipients treated at one Canadian center between 2001 and 2009. Respondents were asked whether they would have been willing to participate in KPD programs if that opportunity had been available at the time of their donation. The impact of various types of incentives, monetary and otherwise, was assessed as well.

Eighty-six donors responded to the survey: a rate of 42 percent. Of the responding donors, 93 percent said they would have been willing to participate in a KPD program. Most donors said they would be more willing if offered reimbursement for lost wages and travel. However, cash payments—up to $50,000—had little effect. Donors were also more willing to participate if there was some advantage to the recipient, such as a younger donor or a better HLA match. Willingness decreased with delays longer than 3 months or need for the donor to travel.

The researchers also approached 38 recipients during routine follow-up visits, all of whom participated. Ninety-two percent said they would have been willing to participate in a KPD program.

Kidney paired donation programs are an emerging approach to increase living donor transplantation among patients who have a willing but incompatible donor. If compatible living donors and recipients were to participate, the number of KPD transplants could be doubled.

A large majority of both directed donors and recipients would be willing to participate in KPD programs, the survey suggests. Participation might be increased by reimbursement for costs and increasing the efficiency of KPD, although not by cash incentives. The researchers note, "The finding that compatible donors and their recipients may be more willing to participate in KPD in exchange for a better kidney highlights the need for education and transparency in order to ensure compatible donors and recipients are adequately informed before engaging in KPD" [Hendren E, et al. Willingness of directed living donors and their recipients to participate in kidney paired donation programs. *Transplantation* 2015; 99:1894–1899].

Donor Hypothermia Reduces Delayed Graft Function

In deceased organ donors, inducing a period of mild hypothermia reduces the rate of delayed kidney function after transplantation, concludes a trial in the *New England Journal of Medicine*.

After declaration of death according to neurologic criteria, deceased organ donors in two donation service areas were assigned to hypothermia, 34° to 35° C; or normothermia, 36.5° to 37.5° C. The temperature protocols began as soon as donation was authorized and continued until the patient left the intensive care unit for organ recovery. The main outcome of interest was the rate of delayed graft function, defined as need for dialysis in the first week after kidney transplant.

The study was terminated early when interim analysis showed the "overwhelming efficacy" of hypothermia. At that time, 370 deceased donors had been enrolled and 572 patients had received a kidney transplant.

Delayed graft function occurred in 28 percent of patients receiving kidneys from donors assigned to hypothermia versus 39 percent for recipients of kidneys from the normothermia group. On multivariable analysis, the odds ratio for delayed graft function with organs from the normothermia group was 0.62. The benefit of hypothermia was greater in renal grafts from expanded-criteria donors and other high-risk subgroups.

Delayed graft function occurs in up to half of recipients of kidneys from deceased donors. This trial found that inducing mild therapeutic hypothermia in the donor after declaration of death reduces the risk of delayed function after kidney transplantation. The improvement in clinical outcomes may be most pronounced in recipients of kidneys from the highest-risk donors [Niemann CU, et al. Therapeutic hypothermia in deceased organ donors and kidney-graft function. *N Engl J Med* 2015; 373:405–414].

Continued on page 42

KIDNEYWEEK 2015

Career Fair

November 5–7, 2015
9:30 am – 2:30 pm
San Diego Convention Center
San Diego, CA

Connect with top employers looking to hire you!

Attend the American Society of Nephrology (ASN) Kidney Week Career Fair at this year's Annual Meeting to connect with top employers looking to hire ASN members! If you are unable to attend, simply upload your CV/resume on tthe ASN website and allow Career Fair employers to get in touch with you directly.

Stop by the Career Fair located in the Main Exhibit Hall.

visit http://careers.asn-online.org

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

VA Funds New Kidney Studies that Will Use Million Veteran Program Data

The Department of Veterans Affairs (VA) has funded four grants that will serve as pioneers in using data from the VA's Million Veteran Program (MVP), a major step in the VA's effort to advance precision medicine. The four funded grants will answer key questions about heart disease, kidney disease, and substance use.

The MVP has enrolled more than 400,000 veterans so far and has become the largest US database linking genetic, clinical, lifestyle, and military exposure information. The VA's electronic medical records, which contain longitudinal clinical information, laboratory data, and pharmacy files, will help make this initiative invaluable for carefully delineating phenotypes and medication exposure.

The MVP, which will include understudied African American and Hispanic veteran populations, ties into the broader national Precision Medicine Initiative announced by President Obama earlier this year.

For the MVP pioneer grants, consortia of VA researchers and collaborators from major academic centers will explore specific questions related to chronic illnesses commonly seen among veterans. They will help to establish new methods for securely linking MVP data with other sources of health information, including non-VA sources such as the Centers for Medicare & Medicaid Services (CMS).

Adriana Hung, MD, a dual-appointed VA and Vanderbilt University Medical Center (VUMC) investigator with a background in pharmacoepidemiology and genetics, will be principal investigator for one of the grants to study kidney disease. Dr. Hung has a longstanding interest in metabolic complications of kidney disease and has assembled a diverse group of investigators to study the genetic factors that may influence renal outcomes in high-risk populations. The grant includes three areas of study:

- pharmacogenomics of diabetic management
- genetic risk factors for hypertension and associated kidney disease
- pharmacogenomics of immunosuppressive drugs used in kidney transplantation

Dr. Hung will lead the arm examining how patients with diabetes mellitus respond differently to the drug metformin, the standard first-line treatment for diabetes, based on their genetic profile.

The second area of study will look at the genetics of hypertension, a major risk factor for kidney disease. Key contributors to this arm are Csaba Kovesdy, a nephrologist and epidemiologist at the Memphis, TN, VA and the University of Tennessee Memphis School of Medicine, and Todd Edwards, MD, a genetic epidemiologist at Vanderbilt University, Nashville, TN. Dr. Edwards is principal investigator for a consortium meta-analysis of blood pressure in an African American ancestry cohort (COGENT).

The third arm will study the pharmacogenomics and short- and long-term metabolic complications of tacrolimus in patients who have received a kidney transplant. Kelly Birdwell, MD, a transplant nephrologist and pharmagenomics expert in Nashville, TN, will be a key contributor to this portion of the award.

Finally, Christianne Roumie, MD, an expert in pharmacoepidemiology; Jeffrey Smith, MD, an expert in medical genetics; and Michael Matheny, MD, MPH, an expert in bioinformatics, all from the VA Tennessee Valley Healthcare System and VUMC, will also participate in the project. The goal of this team of investigators is to aid in the MVP's overarching goal of creating highly accurate phenotypic data that can be used for future investigations to advance precision medicine, in this case for the care of patients at risk for or with chronic kidney disease.

Findings

Continued from page 39

Cognitive Impairment in Stage 5 CKD Is "Partly Reversible"

Patients with stage 5 chronic kidney disease (CKD) show significant improvement in several aspects of cognitive function after a single dialysis session, reports a study in *Nephrology Dialysis Transplantation*.

The researchers administered a battery of neuropsychologic assessments to 28 patients with stage 5 CKD in medically stable condition. The patients' mean age was 55 years, and their mean time on dialysis was 46 months. The cognitive tests were performed twice within 24 hours: 1 hour before and 19 hours after the end of dialysis. To control for learning effects, one group was assessed after a first dialysis session and again before a second session. A group of age-matched individuals with normal kidney function was assessed as well.

The CKD patients scored significantly lower on tests of alertness, attention, working memory, logical and visual memory, word fluency, and executive function. Short-term memory, selective attention, and problem-solving and planning were similar for CKD patients versus control individuals.

Repeated testing after dialysis showed significant improvement in several cognitive measures, including logical and visual memory, memory quotient, psychomotor speed, executive function, and concentration. Other areas showed no difference from before to after dialysis; performance remained below the level shown by non-CKD control individuals.

Patients with stage 5 CKD have well-recognized impairment in cognitive function. There is ongoing debate as to whether some part of this impairment is reversible, particularly in response to hemodialysis.

The new study shows improvements in memory, executive function, and psychomotor ability from before to after a single dialysis session in maintenance hemodialysis patients. The results suggest a "reversible component" of decreased cognitive function in stage 5 CKD. "Treatment of cognitive deficits should start early in the beginning of a kidney disease to ensure the best psychological and nephrological care geared to specific patient needs," the researchers conclude [Schneider SM, et al. Effect of a single dialysis session on cognitive function in CKD5D patients: a prospective clinical study. *Nephrol Dial Transplant* 2015; 30:1551–1559].

Index to Advertisers

Better Outcomes with HHD versus Peritoneal Transplant Trends for Black and White Patients: Deceased and Living

The rates of deceased-donor kidney transplants for black patients have risen in recent years, but racial differences in living-donor transplants persist, according to a research letter in *JAMA Internal Medicine*.

Using data from the United Network for Organ Sharing, the researchers analyzed trends in kidney transplantation for all recipients and for those with deceased and living donors. The analysis focused on patterns of racial disparity, using the race-stratified incidence of ESRD as the denominator, rather than patients on the transplant waiting list.

From 1998 to 2011, kidney transplantation was performed in 13.5 percent of patients with ESRD in the United States. Of these recipients, 37.1 percent had a living donor. In black patients, the incidence of kidney transplantation increased by 2.8 percent per year. By 2010, there was no difference in the incidence of kidney transplantation for black versus white patients.

For white patients, transplantation from deceased donors declined, whereas living-donor transplants remained stable. In contrast, for black patients, transplants from deceased donors rose by 3.49 percent per year, whereas living-donor transplants were unchanged. Throughout the period studied, 15.5 percent of live kidney donations were from black donors.

Deceased donor transplants for black patients with ESRD have increased since the late 1990s. The authors ascribe this finding to changes in organ allocation eliminating priority points for HLA-B matching.

However, black patients continue to have lower rates of living kidney donors. The authors discuss the implications for efforts to increase rates of living-donor kidney transplantation [Sood A, et al. Rates of kidney transplantation from living and deceased donors for blacks and whites in the United States, 1998 to 2011. *JAMA Intern Med* 2015 Aug 31. DOI:10.1001/jamainternmed.2015.4530].

Higher Mortality and Admissions after Long Interdialytic Gap

In patients receiving hemodialysis three times weekly, the 2-day gap between dialysis sessions is consistently associated with increased mortality and hospitalization rates, according to a study from the United Kingdom in *Kidney International*.

The study used data on 5864 patients from the UK Renal Registry from 2002 through 2006, linked to data on hospitalizations and deaths. The associations of these outcomes with the long (2-day) interdialytic gap were assessed, including the effects of different thrice-weekly schedules.

Hospitalization rates were higher after the 2-day gap: 2.4 per year, compared with 1.4 for the rest of the week. This difference was significant whether the thrice-weekly dialysis schedule began on Monday or Tuesday. The greatest increase was seen for admissions for fluid overload, or conditions associated with a high risk of fluid overload.

There was a similar increase in mortality after the 2-day gap: 20.5 versus 16.7 per 100 patient-years, rate ratio 1.22. This mainly reflected an increase in out-of-hospital deaths: rate ratio 1.59, compared with 1.06 for in-hospital deaths. The increase in mortality associated with the long interdialytic gap was limited to white patients.

These data from the UK are consistent with previous studies reporting increased mortality and hospitalization after the 2-day interdialytic gap. The increase in admission may be associated with an increase in fluid overload; the increase in out-of-hospital mortality may reflect an increased incidence of sudden death. The authors discuss the implications for measures to minimize interdialytic intervals or limit fluid overload [Fotheringham J, et al. The mortality and hospitalization rates associated with the long interdialytic gap in thrice-weekly hemodialysis patients. *Kidney Int* 2015; 88:569–575].

Classified Ads

Kidney News
Classified Advertising Information

Classified space is for advertising positions available, open faculty positions, course announcements, seminars, meetings and educational courses.

Display Advertising Rates

Ad Size	1x	3x
Full Page	**$2,525**	**$2,345**
1/2 Page	$1,665	$1,485
1/3 Page	**$1,435**	**$1,375**
1/4 Page	$1,205	$1,090
1/6 Page	**$1,035**	**$1,025**

Line Advertising Rates

Please contact for rate information

Closing Date & Cancellations:

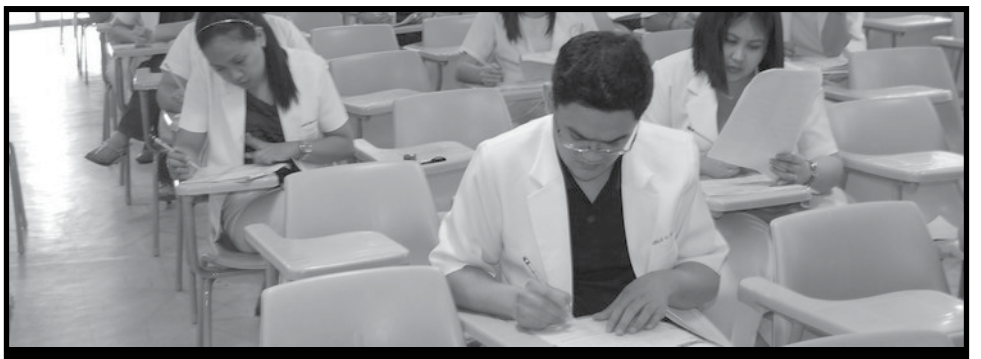
Copy must be received four weeks in advance of the month in which the ad is to appear. Cancellation requests must be made in written form by fax, e-mail or postal mail and will be honored for the earliest applicable issue.

All Ads Must be Prepaid

Contact:
Rhonda Truitt
rhonda.truitt@wt-group.com
P: 443-512-8899 x. 106 F: 443-512-8909

Work in beautiful Colorado Springs

Pikes Peak Nephrology Associates (PPNA), a long-standing and successful Colorado Springs medical practice, is actively recruiting a physician to join its team to assist with growing patient demand. The ideal candidate will have the training and experience to successfully assume responsibility for a full patient workload, to include a busy clinic schedule and rounding in a number of dialysis centers. We are unable to provide sponsorships for J-1 candidates. We offer a competitive compensation package, and excellent benefits. Colorado Springs has exceptional schools, many cultural amenities, is a short drive to the state's premier ski towns, and enjoys 300-plus days of sunshine per year. For more information and consideration please submit a cover letter and your C.V. to: Phil Mella, Practice Administrator, Phil.Mella@pikespeaknephrology.com.



Nephrology Board Review Question Bank

Face the boards with confidence

RENAL PREP

Maximize your readiness for ABIM Nephrology board examination @ 54 cents/day

This nephrology question bank is on a software platform, the first of its kind for nephrologists like never before. This is designed for fellows and practicing nephrologists preparing for ABIM nephrology certification and recertification exams. These challenging questions are evidence-based and written by board-certified nephrologists. About 400+ high yield questions patterned on ABIM guidelines. Questions match the style and difficulty level seen on ABIM board exams. Review in practice mode or test mode. Comprehensive coverage of - CKD/ESRD, FLUID/ELECTROLYTES, ACID-BASE, ARF, GN, TRANSPLANT, HTN. Create your own practice exam sets. Receive feedback on your weak areas.

Review in the comfort of your home at your own pace than time away from family and practice. This Q bank will give you the confidence to succeed in the ABIM nephrology board exam.

Review the demo questions at www.renalprep.com

Avail the introductory price
ONLY 99.99$ FOR 400+ QUESTION BANK @ WWW.RENALPREP.COM

Education | Renal Prep© 2015
*We are not affiliated with ABIM, ASN, FSMB

If you're looking for a trusted laboratory partner, don't just take our word for it.

The proof is in the numbers.

Just look at the numbers and you'll discover why more dialysis providers rely on Spectra than any other lab. When you partner with Spectra, you get more than just timely, reliable test results. Unlike other labs, we provide on-site training by certified renal professionals and an extensive courier network. We also have bicoastal operations with dedicated start-up, IT and customer support teams who are ready to address your needs.

Experience the difference. Email us today at **spectra.laboratories@fmc-na.com** to learn more.

spectra® laboratories

bicoastal operations in:
Milpitas, CA • Rockleigh, NJ

www.spectra-labs.com