ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

KIDNEY WEEK EDITION

KidneyNews

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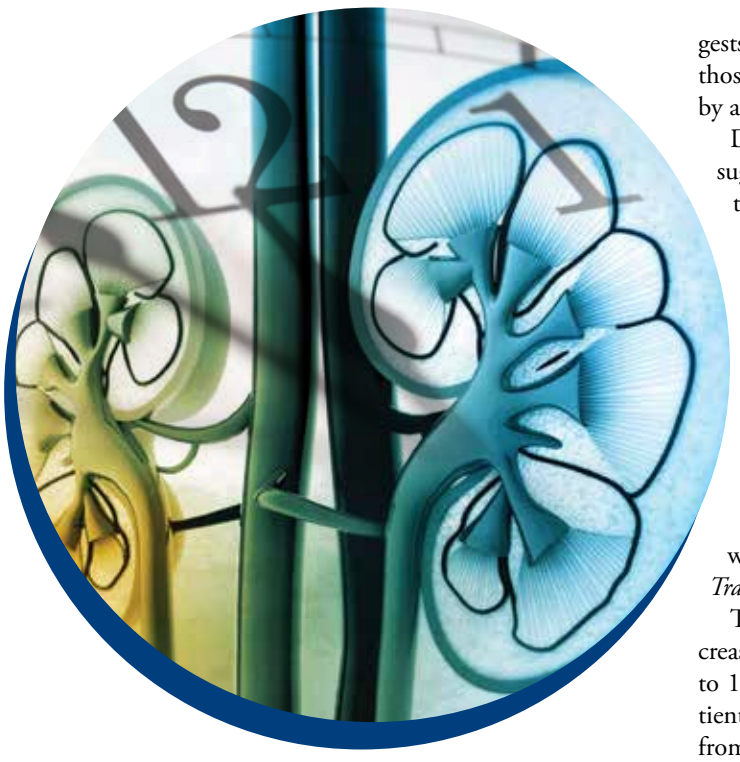
New Kidney Allocation System May Shorten Wait for Deceased-Donor Kidneys

But Data from First Nine Months Show Mixed Results



At the end of 2014, a new deceased donor kidney allocation system (KAS) was introduced, with the goal of improving organ equity and graft-recipient longevity matching. A series of simulations suggests that the KAS is expected to meet at least some of those goals—while cutting the average waiting list time by about six months.

Data from the first months of the "post-KAS" era suggest improved access to deceased donor kidney transplantation (DDKT) for racial/ethnic minorities, younger patients, and highly sensitized patients. But the evidence also raises concerns about delayed graft function, potentially leading to poorer long-term outcomes.

Bekir Tanriover, MD, MPH, of the University of Texas Southwestern Medical Center, Dallas, and colleagues, performed a series of simulations to evaluate the new KAS by using the Kidney-Pancreas Simulated Allocation Model—the same software used by the Organ Procurement and Transplant Network to evaluate policy change. The study appeared in *Transplantation Proceedings*.

The results suggested that the KAS might lead to decreased waiting times for DDKT: from a median of 2.3 to 1.8 years. The estimates also indicated that more patients may undergo transplantation within the first year: from 20.7 to 31.3%.

The simulations also suggested an increased number of transplantations in patients with more than 5 years on dialysis, longevity matching, blood group B, and highly sensitized patients with a calculated panel reactive antibody (CPRA) of 98% or greater. The chances of transplantation would increase for African American and Hispanic patients. Other groups would see a decrease, including patients older than 65, those with less than 3 years on dialysis, and those with diabetes.

"We projected that estimated median waiting time among transplant recipients might be decreased six months (22%) under KAS," Dr. Tanriover and coauthors conclude. These changes may reflect a "bolus effect" related to points awarded for previous dialysis time and priority points based on CPRA. Because the new allocation system is not expected to increase the number of available organs, the decrease in waiting time may diminish over time.

"Mixed record" in first months of post-KAS era

How are those projections playing out in the real world? In a study published in the *Journal of the American Society of Nephrology*, Dorry L. Segev, MD, of Johns Hopkins University analyzed DDKT allocations during the first 9 months after the KAS was introduced—from December 2014 through August 2015.

The proportion of regional imports increased from 8.8 to 12.5% from the pre-KAS to post-KAS era, while national imports increased from 12.7 to 19.1%. Consistent with the simulation finding of increased longevity matching, the percentage of recipients more than 30 years older than their donors decreased from 19.4 to 15.0%. Highly sensitized patients were also more

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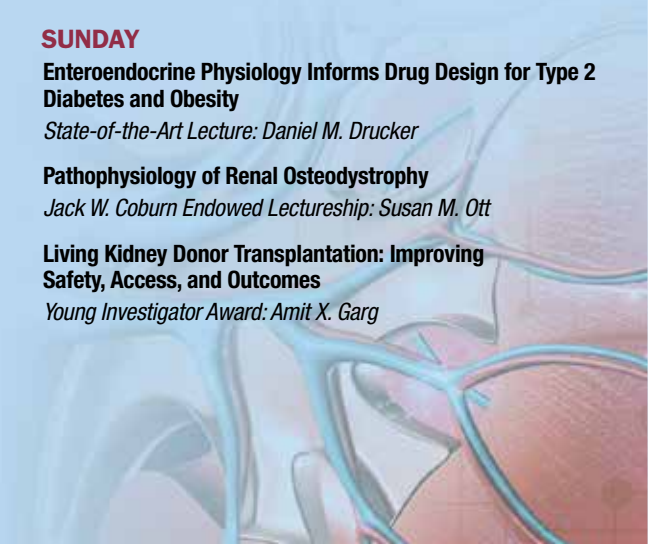

BRIEF SUMMARY
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FULL PRESCRIBING INFORMATION

RAYALDEE® (calcifediol) extended-release capsules, for oral use

Rayaldee®
calcifediol ER capsules
30 mcg

INDICATIONS AND USAGE:

RAYALDEE® is a vitamin D_3 analog indicated for the treatment of secondary hyperparathyroidism in adult patients with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. RAYALDEE is not indicated for the treatment of secondary hyperparathyroidism in patients with stage 5 chronic kidney disease or in patients with end-stage renal disease on dialysis.

CONTRAINDICATIONS:

None

WARNINGS AND PRECAUTIONS

Hypercalcemia may occur during RAYALDEE treatment. Acute hypercalcemia may increase the risk of cardiac arrhythmias and seizures and may potentiate the effect of digitalis on the heart. Chronic hypercalcemia can lead to generalized vascular calcification and other soft-tissue calcification. Severe hypercalcemia may require emergency attention.

Hypercalcemia may be exacerbated by concomitant administration of high doses of calcium containing preparations, thiazide diuretics, or other vitamin D compounds. In addition, high intake of calcium and phosphate concomitantly with vitamin D compounds may lead to hypercalciuria and hyperphosphatemia. In these circumstances, frequent serum calcium monitoring and RAYALDEE dose adjustments may be required. Patients with a history of hypercalcemia prior to initiating therapy with RAYALDEE should be monitored more frequently for possible hypercalcemia during therapy.

Patients should be informed about the symptoms of elevated serum calcium, which include feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, and weight loss. Hypercalcemia of any cause, including RAYALDEE, increases the risk of digitalis toxicity. In patients using RAYALDEE concomitantly with digitalis compounds, monitor both serum calcium and patients for signs and symptoms of digitalis toxicity and increase the frequency of monitoring when initiating or adjusting the dose of RAYALDEE.

Adynamic bone disease with subsequent increased risk of fractures may develop if intact PTH levels are suppressed by RAYALDEE to abnormally low levels. Monitor intact PTH levels and adjust RAYALDEE dose, if needed.

DOSAGE AND ADMINISTRATION

Important Dosage and Administration Information

- Ensure serum calcium is below 9.8 mg/dL before initiating treatment.
- Instruct patients to swallow RAYALDEE capsules whole.
- Instruct patients to skip a missed dose and to resume taking the medicine at the next regularly scheduled time. Do not administer an extra dose.

Starting Dose and Dose Titration

- The initial dose of RAYALDEE is 30 mcg administered orally once daily at bedtime.
- The maintenance dose of RAYALDEE should target serum total 25-hydroxyvitamin D levels between 30 and 100 ng/mL, intact parathyroid hormone (PTH) levels within the desired therapeutic range, serum calcium (corrected for low albumin) within the normal range and serum phosphorus below 5.5 mg/dL.
- Monitor serum calcium, serum phosphorus, serum total 25-hydroxyvitamin D and intact PTH levels at a minimum of 3 months after initiation of therapy or dose adjustment, and subsequently at least every 6 to 12 months.
- Increase the dose to 60 mcg orally once daily at bedtime after approximately 3 months, if intact PTH remains above the desired therapeutic range. Prior to raising the dose, ensure serum calcium is below 9.8 mg/dL, serum phosphorus is below 5.5 mg/dL and serum total 25-hydroxyvitamin D is below 100 ng/mL.
- Suspend dosing if intact PTH is persistently and abnormally low to reduce the risk of adynamic bone disease [see Warnings and Precautions], if serum calcium is consistently above the normal range to reduce the risk of hypercalcemia [see Warnings and Precautions], or if serum total 25-hydroxyvitamin D is consistently above 100 ng/mL. Restart at a reduced dose after these laboratory values have normalized.

USE IN SPECIFIC POPULATIONS

Teratogenic Effects - Pregnancy Category C: Calcifediol has been shown to be teratogenic in rabbits when given in doses of 8 to 16 times the human dose of 60 mcg/day, based on body surface area. There are no adequate and well-controlled studies in pregnant women. RAYALDEE should be used during pregnancy only if the potential benefit justifies potential risk to the fetus.

When calcifediol was given orally to bred rabbits on the 6th through the 18th day of gestation, gross visceral and skeletal examination of pups indicated that the compound was teratogenic at doses of 25 and 50 mcg/kg/day. A dose of 5 mcg/kg/day was not teratogenic. In a similar study in rats, calcifediol was not teratogenic at doses up to and including 60 mcg/kg/day.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No neoplastic changes attributable to calcifediol were observed at subcutaneous doses of 3, 10 and 33 mcg/kg/day in a 26-week rasH2 transgenic mouse study. In vitro or in vivo mutagenicity studies have not been performed with RAYALDEE. No genotoxic or mutagenic effects have been reported with calcifediol. Calcifediol has not been shown to have significant effects on fertility in rats.

Labor and Delivery: The effect of this drug on the mother and fetus during labor and delivery is not known.

Nursing Mothers: Limited available evidence indicates that calcifediol is poorly excreted in human milk. Caution should be exercised when RAYALDEE is administered to a nursing woman.

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

Geriatric Use: Of the total number of subjects in phase 3 placebo-controlled clinical studies of RAYALDEE, 63% were ≥65 years of age and 22% were ≥75 years of age. No overall differences in the safety or efficacy of RAYALDEE were observed between subjects older than 65 years and younger subjects.

Renal Impairment

No difference in efficacy was observed between patients with stage 3 chronic kidney disease or those with stage 4 disease in subgroup analysis. Safety outcomes were similar in these subgroups. The safety and efficacy of RAYALDEE in the treatment of secondary hyperparathyroidism in patients with stage 2 or stage 5 chronic kidney disease and patients with end-stage renal disease on dialysis have not been established [see Indications and Usage].

Overdosage

Excessive administration of RAYALDEE can cause hypercalciuria, hypercalcemia, hyperphosphatemia, or oversuppression of intact PTH. Common symptoms of vitamin D overdosage may include constipation, decreased appetite, dehydration, fatigue, irritability, muscle weakness, or vomiting.

Treatment of acute accidental overdosage with RAYALDEE should consist of general supportive measures. If the overdosage is discovered within a short time, induce emesis or perform gastric lavage to prevent further absorption. Obtain serial serum and urine calcium measurements, and assess any electrocardiographic abnormalities due to hypercalcemia. Discontinue supplemental calcium. Treat with standard medical care if persistent and markedly elevated serum calcium levels occur.

Calcifediol is not significantly removed by dialysis.

ADVERSE REACTIONS

The data in Table 1 are derived from two pivotal studies described below. These data reflect exposure of 285 subjects to RAYALDEE 30 or 60 mcg daily for up to 6 months (mean 24 weeks, range 1 to 31 weeks). The mean age of the study population was 66 years old (range 25-85 years). Half of the subjects were male, 65% were White, and 32% were African-American or Black. At baseline, subjects had secondary hyperparathyroidism, stage 3 (52%) or 4 (48%) chronic kidney disease without macroalbuminuria and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. The most common causes of chronic kidney disease were diabetes and hypertension and the mean estimated GFR at baseline was 31 mL/min/1.73 m^2. At baseline, mean plasma intact PTH was 148 pg/mL, mean serum calcium was 9.2 mg/dL, mean serum phosphorus was 3.7 mg/dL and mean serum 25-hydroxyvitamin D was 20 ng/mL.

Table 1 shows common adverse reactions associated with the use of RAYALDEE in the pooled placebo-controlled trials. These adverse reactions were not present at baseline, occurred more commonly on RAYALDEE than on placebo, and occurred in at least 1.4% of patients treated with RAYALDEE.

Table 1. Common Adverse Reactions in Placebo-controlled Trials Reported in ≥1.4% of RAYALDEE-Treated Subjects

Adverse Reaction	Placebo N=144	RAYALDEE N=285
	%	%
Anemia	3.5	4.9
Nasopharyngitis	2.8	4.9
Blood creatinine increased	1.4	4.9
Dyspnea	2.8	4.2
Cough	2.1	3.5
Cardiac failure congestive	0.7	3.5
Constipation	2.8	3.2
Bronchitis	0.7	2.8
Hyperkalemia	0.7	2.5
Osteoarthritis	0.7	2.1
Hyperuricemia	0.7	1.8
Contusion	0.0	1.8
Pneumonia	0.7	1.4
Chronic obstructive pulmonary disease	0.0	1.4

Increase in Serum Calcium: Patients randomized to RAYALDEE experienced a greater mean (SE) increase in serum calcium (P<0.001) than patients randomized to placebo [i.e., 0.2 (0.02) mg/dL on RAYALDEE versus 0.1 (0.03) mg/dL on placebo from baseline to trial end]. Six subjects (2%) in the RAYALDEE treatment group and no subjects (0%) in the placebo group required dose reductions for protocol-defined hypercalcemia (two consecutive serum calcium values greater than 10.3 mg/dL). A total of 4.2% of RAYALDEE treated subjects and 2.1% of placebo treated subjects experienced at least 1 elevation in serum calcium above the upper limit of normal (10.5 mg/dL).

Increase in Serum Phosphorus: Patients randomized to RAYALDEE experienced a greater mean (SE) increase in serum phosphorus than patients randomized to placebo [i.e., 0.2 (0.03) mg/dL on RAYALDEE versus 0.1 (0.04) mg/dL on placebo from baseline to trial end]. One subject (0.4%) in the RAYALDEE treatment group met protocol-defined hyperphosphatemia (two consecutive serum phosphorus values >5.5 mg/dL deemed to be study drug related) compared to no subjects in the placebo group. A total of 45% of RAYALDEE treated subjects and 44% of placebo treated subjects experienced at least one elevation in serum phosphorus above the upper limit of normal (4.5 mg/dL).

To report SUSPECTED ADVERSE REACTIONS, contact OPKO Pharmaceuticals, LLC at 1-844-729-2539 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

CYP3A Inhibitors

Cytochrome P450 inhibitors, such as ketoconazole, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole, may inhibit enzymes involved in vitamin D metabolism (CYP24A1 and CYP27B1), and may alter serum levels of calcifediol. Dose adjustment of RAYALDEE may be required, and serum 25-hydroxyvitamin D, intact PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor.

Thiazides

Thiazides are known to induce hypercalcemia by reducing excretion of calcium in the urine.

Concomitant administration of thiazides with RAYALDEE may cause hypercalcemia. Patients may require more frequent serum calcium monitoring in this setting.

Cholestyramine

Cholestyramine has been reported to reduce intestinal absorption of fat-soluble vitamins and may impair the absorption of calcifediol, the active ingredient in RAYALDEE. Dose adjustment of RAYALDEE may be required, and serum total 25-hydroxyvitamin D, intact PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with cholestyramine.

Other Agents

Phenobarbital or other anticonvulsants or other compounds that stimulate microsomal hydroxylation reduce the half-life of calcifediol, the active ingredient in RAYALDEE. Dose adjustment of RAYALDEE may be required, and serum total 25-hydroxyvitamin D, intact PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with phenobarbital or other anticonvulsants.

HOW SUPPLIED

RAYALDEE is supplied as 30 mcg calcifediol in blue, oval extended-release capsules, imprinted O:

Bottles of 30 [NDC 70301-1001-1]

Bottles of 60 [NDC 70301-1001-2]

STORAGE AND HANDLING

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

Patent: http://www.opko.com/products/patents/

Rev. 06/2016

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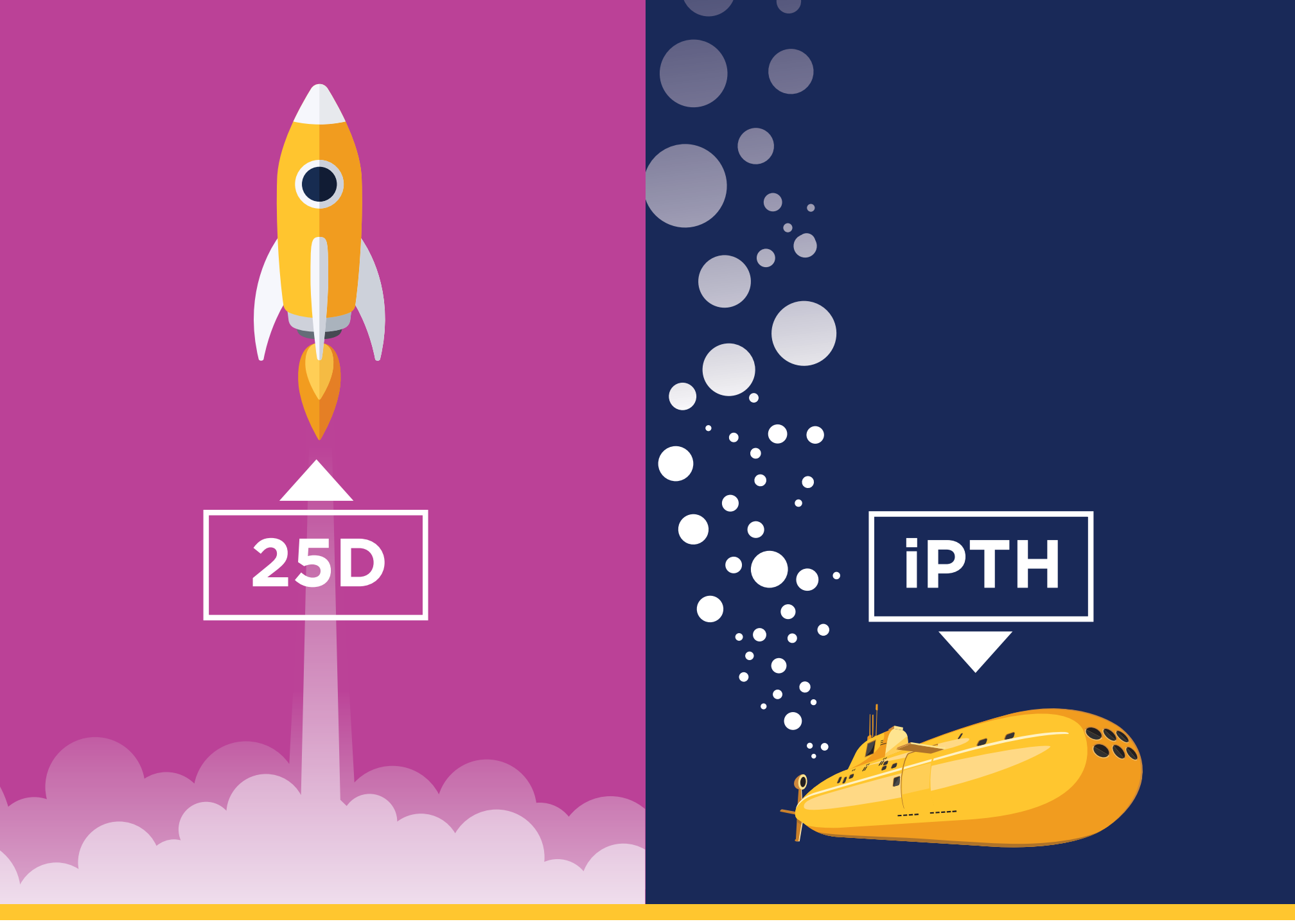

This is what SHPT control should look like

Rayaldee® is the first and only extended-release prohormone of the active form of vitamin D_3 that raises 25-hydroxyvitamin D and lowers iPTH levels.

Indication and Limitations of Use

Rayaldee®, (calcifediol) extended-release 30 mcg capsules, is indicated for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. Rayaldee is not indicated in patients with stage 5 chronic kidney disease or end-stage renal disease on dialysis.

Important Safety Information

• Hypercalcemia: Excessive administration of vitamin D compounds, including Rayaldee, can cause hypercalcemia and hypercalciuria. Severe hypercalcemia due to substantial overdosage of vitamin D and its metabolites may require emergency attention. Patients should be informed about the symptoms of elevated calcium. • Digitalis toxicity: Potentiated by hypercalcemia of any cause. Monitor serum calcium and signs and symptoms of digitalis toxicity more frequently when initiating or adjusting the dose of Rayaldee. • Adynamic Bone Disease: Monitor for abnormally low levels of intact PTH levels when using Rayaldee, and adjust dose if needed. • The most common adverse reactions (≥3% and more frequent than placebo) were anemia, nasopharyngitis, increased blood creatinine, dyspnea, cough, congestive heart failure and constipation. • Care should be taken while dosing Rayaldee with cytochrome P450 inhibitors, thiazides, cholestyramine or drugs stimulating microsomal hydroxylation due to the potential for drug interactions.
• Serum calcium should be below 9.8 mg/dL before initiating treatment.
• Monitor serum calcium, phosphorus, 25-hydroxyvitamin D and intact parathyroid hormone (iPTH) 3 months after starting therapy or changing dose.

Please see Brief Summary of Prescribing Information on adjacent page, and Full Prescribing Information at RAYALDEE.com.

Rayaldee®
calcifediol ER capsules
30 mcg

www.rayaldee.com

OP-US-0078-092016v.1

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

ASN 50 years

Kidney News

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ASN President's Column

By Raymond C. Harris, MD, FASN

Raymond C. Harris, MD, FASN

Physicians, scientists, and other health professionals are problem solvers. This reality is especially true in nephrology, in which complex diseases and co-existing conditions are often challenging and sometimes daunting. However, this very complexity provides so many of us lifelong career interest and opportunities, and profound satisfaction when we can provide and improve care for our patients with kidney diseases.

As ASN marks its 50th year, it is worth looking back at the landscape for kidney patients and professionals in 1966. Although we nephrologists sometimes bemoan the lack of innovation in our field, the advances made in our field in the past 50 years are astonishing. No doubt most of these changes seemed to have come slowly, but taking a snapshot of 1966 really highlights the curiosity, achievements, and dogged determination emblematic of nephrology professionals.

What did nephrology look like in 1966?

Hospitals that performed transplants managed all aspects of organ procurement themselves; if an organ couldn't be used at that institution, it was discarded.

ASN 50 years

The number of "artificial kidney centers" in the US increased to 43, providing dialysis to approximately 400 patients.

Dialysis care in the United States was rationed because of the scarcity of available machines. The committees charged with deciding who received dialysis considered such diverse criteria as marital status, net worth, educational level, intelligence, and church attendance.

Dialysis carried out at home had been introduced 2 years earlier, in 3 cities: Boston, Seattle, and London.

James E. Cimino, MD, developed a direct artery to vein fistula that permitted a direct flow from an artery to a vein.

The US government noted that most nephrologists had to be trained "out of service."

The National Library of Medicine subject headings for renal topics took up less than one page.

It is a tribute to the commitment and the genius of so many kidney-related investigators that in the past 50 years they were able to provide molecular insight into the transport and cellular functions of all segments of the nephron; unlock the genetic, pathophysiologic, and biochemical underpinnings of a host of kidney diseases; make advances in dialytic therapy; and develop significant improvements in immunosuppression for both kidney transplantation and immunologically mediated diseases of the kidney.

In my next column, I will take a look at the nephrologist of the future. Pondering the amazing trajectory of our field since 1966, I am confident that we can look forward to the kind of new treatments and cures that will continue to improve the lives of our patients and give all of us professional satisfaction.

73%

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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. Rockwell Medical, Inc. Data on File. Independent Market Research Study Conducted in August 2015 with 103 U.S. Based Nephrologists – Based upon efficacy, safety, most appealing aspect, contrast to IV iron and choice between Triferic and IV iron.

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.

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Allocation System

Continued from page 1

likely to receive organs—the percentage with CPRA of 100 increased from 1.0 to 10.3%.

After adjustment for candidate characteristics and wait time, there was no overall change in the DDKT rate under the new system. But some subgroups were more likely to receive a kidney, with incidence rate ratios of 1.19 for black candidates, 1.13 for Hispanic candidates, and 1.47 for those aged 18 to 40 years. In contrast, incidence rate ratios were 0.93 for candidates aged 51 to 60 and 0.90 for those over 70.

The data also suggested an increase in delayed graft function after introduction of the KAS: from 24.8 to 29.9%. This finding was "partly explained" by increases in cold ischemia time: from a median of 15.0 to 16.4 hours. There was also a 10% increase in the odds of organ discard, limited to kidneys with a Kidney Donor Profile Index of 79 or higher.

Dr. Segev and coauthors note that changes in organ allocation policy are an "appropriate tool" to address disparities in access to organ transplantation—but they cannot solve the problem of organ shortages, and "can easily lead to unintended consequences." The authors conclude, "The mixed record of KAS in its first nine months of implementation underscores the need to increase the deceased donor organ pool, as well as to reduce the reliance on DDKT by improving access to and understanding of live donor kidney transplantation."

Too early to call in the jury?

The early increase in organ discard rate is especially disappointing, according to Uday Nori, MD, of The Ohio State University Wexner Medical Center, Columbus—as decreasing organ discards was one objective of the new KAS. "Unfortunately, the actual data showed that the discard rate did not improve, counter to what was expected," he said. (Dr. Nori provided ASN *Kidney News* readers with an update on the revised KAS earlier this year.)

"Studies such as this are important to observe and predict trends, but the results may change depending on the cohort analyzed," he said.

"Whenever new systems are implemented, the early results can be very counter-intuitive. The lack of improvement in the organ discard rate is an example. The software model that was used to run the simulation used an early cohort to draw the conclusions. But many believe that the true impact of the new KAS is likely to be seen at 24 months from the implementation date."

Dr. Nori also raised questions about the results of the simulation study. "I am unable to understand how the waiting time for the deceased donor transplants across all CPRA categories can decrease, while the organ discard rate remains high and the supply of deceased donors remains unchanged. My suggestion is that since this is a simulation model the results are to be taken cautiously. "

"There are many merits to the new KAS—well-intended and most likely to be proven correct with time—and it's too early to call in the jury."

ASN in Review

A Look at ASN's Activities Since Kidney Week 2015

ASN Implements Strategic Plan

ASN established goals for building the nephrology profession over the next 5 years as part of its new strategic plan. The society will assert the value of nephrology to health and science professionals, health care systems, and other stakeholders to ensure high-quality care for patients as well as foster career development for current and future kidney health professionals. ASN will also lead the kidney community by focusing on transformative research, education, communications, policy, and collaboration, and by encouraging kidney health professionals worldwide to contribute to and benefit from ASN's activities.

50 Years of Leading the Fight against Kidney Diseases

ASN celebrates 50 years of advancing kidney care by looking back at what has been accomplished and by looking forward to the amazing advances that lay ahead. Through podcasts, videos, a series of "Distinguished Conversations" with nephrology greats, and a timeline of milestones in the shared history of nephrology and ASN, the society has commemorated its anniversary throughout the year. The culmination of the celebration is a display of the past, present, and future of nephrology and of ASN, located in the exhibit hall at ASN Kidney Week.

White House Organ Summit

ASN participated in a White House Organ Summit in June 2016. Convened to address the shortage of organs available for transplantation, the Summit brought together a wide array of stakeholders committed to improving outcomes for individuals waiting for organ transplants and to encourage support for living organ donors. Leading up to the Summit, ASN engaged in dialogue with the White House regarding new kidney therapeutics and challenges to transplantation.

XPrize

ASN has pledged the first $7 million toward a prize competition in partnership with the XPRIZE Foundation, with the aim of catalyzing innovation that will revolutionize kidney patient care. The competition, announced at the White House Organ Summit, would challenge innovators around the world to develop alternatives to dialysis that restore freedom and quality of life while delivering superior health outcomes for the millions of people around the world suffering from kidney failure.

ASN Online Communities

In March 2016, ASN unveiled to members a new platform for discussion, networking, and collaboration. ASN Online Communities allow members to connect to each other, to the society, and to the broader kidney community in conversations about topics they select. Daily digest emails summarize the latest conversations, and a resource library on the Communities website allows sharing of presentations, documents, and videos. As of October 1, 2016, 738 members from around the world composed a total of 3201 posts across 10 communities. All members are encouraged to join the discussion.

Partnership with US CDC to Transform Dialysis Safety

ASN partnered with the US Centers for Disease Control and Prevention (CDC) in July 2016 to protect dialysis patients from developing infections, the second leading cause of death in this patient population. The 3-year Nephrologists Transforming Dialysis Safety (NTDS) Project will engage the kidney community, health departments, and other stakeholders to implement best practices to safeguard against infection in dialysis patients. Activities will include sessions at ASN Kidney Week, a dedicated issue of the Nephrology Self-Assessment Program (NephSAP), a webinar series on infection prevention, and increased collaboration between nephrologists and healthcare-acquired infection preventionists.

Kidney Health Initiative

The public-private partnership between ASN and the US Food and Drug Administration has steadily increased its membership to nearly 80 organizations. KHI workgroups helped frame the strategic priorities that will stimulate innovation in kidney care and foster solutions to operational, regulatory, and business issues hindering clinical trials in dialysis. The articles "Overcoming Barriers in Kidney Health—Forging a Platform for Innovation" and "Pragmatic Trials in Maintenance Dialysis: Perspectives from the Kidney Health Initiative" were published in *JASN*.

Advocating for Kidney Patients and Professionals

ASN in 2016 gave voice to the kidney community by addressing several critical issues in health care and research, including working to advance legislation to protect living donors; helping physicians navigate the complex new payment system MACRA, which shifts the focus from quantity of care to quality of care; and working with the Centers for Medicare & Medicaid Services to ensure a new law provides appropriate treatment options to acute kidney injury patients who require dialysis. ASN also worked with stakeholders in the research community to secure funding increases for NIDDK and NIH, and urged Congress and Medicare to consider new nephrologist-centered care delivery models encompassing the spectrum of kidney diseases from advanced CKD through ESRD and end-of-life care, emphasizing access to transplant and preemptive transplant care.

Career Development Grants Program Celebrates 20 Years

ASN and the ASN Foundation for Kidney Research celebrate the 20th anniversary of the Career Development Grants Program. Established in 1996, the program funds the most promising research from new investigators, and aims to foster independent research careers. For two decades, this program has served as an investment in the future of nephrology research, with more than $30 million supporting 156 new investigators. Tracking outcomes over time, the ASN Foundation has seen tremendous productivity from grant recipients who succeed in disseminating findings, receiving additional awards, and securing promotions. The Career Development Grants Program develops successful researchers, produces future mentors, identifies tomorrow's leaders, and results in exciting scientific discoveries that will positively affect patient care.

Recertification and Lifelong Learning

Through a member survey, letters to members, *ASN Kidney News* articles, meetings with ABIM leadership, and collaboration with other specialty societies, ASN spearheaded efforts to ensure maintenance of certification remains relevant to nephrology practice and is not redundant with other quality or patient safety efforts. The ASN Recertification Task Force was formed in March 2016 to help identify the ideal pathway to recertification and will present at a Recertification Forum at Kidney Week 2016 on Thursday, November 17.

Growth in Membership

ASN membership increased to more than 16,000 in 2016, an increase of about 3% over the previous year. About 37% of ASN members are from outside the United States.

International Kidney Organizations Collaborate

In a landmark agreement, three leading kidney organizations with worldwide membership signed a Declaration of Collaboration in June 2016. The declaration by ASN, the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA), and the International Society of Nephrology (ISN) recognizes that kidney diseases are a global challenge that respects no boundaries or borders. The organizations committed to using all available synergies to fight kidney diseases and improve the standard of care for kidney patients worldwide.

Kidney News Online

ASN in April 2016 launched a new website, Kidney News Online, www.kidneynews.org, to extend *ASN Kidney News* as a digital platform for daily updates on news, context, and resources for all stakeholders in the kidney community. Kidney News Online offers users the ability to personalize their experience by providing content that matters most to them.

Journals Excel

JASN continues to be a leader among nephrology journals publishing original research, featuring important articles in the science and practice of nephrology, scholarly reviews, and editorials. *CJASN* introduced the Evidence-Based Nephrology Series, notified authors of decisions within 32 days, and published articles within 37 days online and 81 days in print, on average. Rajnish Mehrotra, MD, FASN, will begin his term as the third Editor-in-Chief of *CJASN* on January 1, 2017.

Twitter Chats

ASN and the Nephrology Journal Club (NephJC) teamed up to host increasingly popular monthly #AskASN Twitter chats. Topics ranged from Kidney Health Advocacy Day and the Kidney Health Initiative to a conversation with ASN President Raymond C. Harris, MD, FASN, and another about the society's 50th anniversary. The most popular Twitter Chat looked at how the findings of the SPRINT Trial affect care of those with kidney diseases.

Nephrology Workforce Supply and Demand

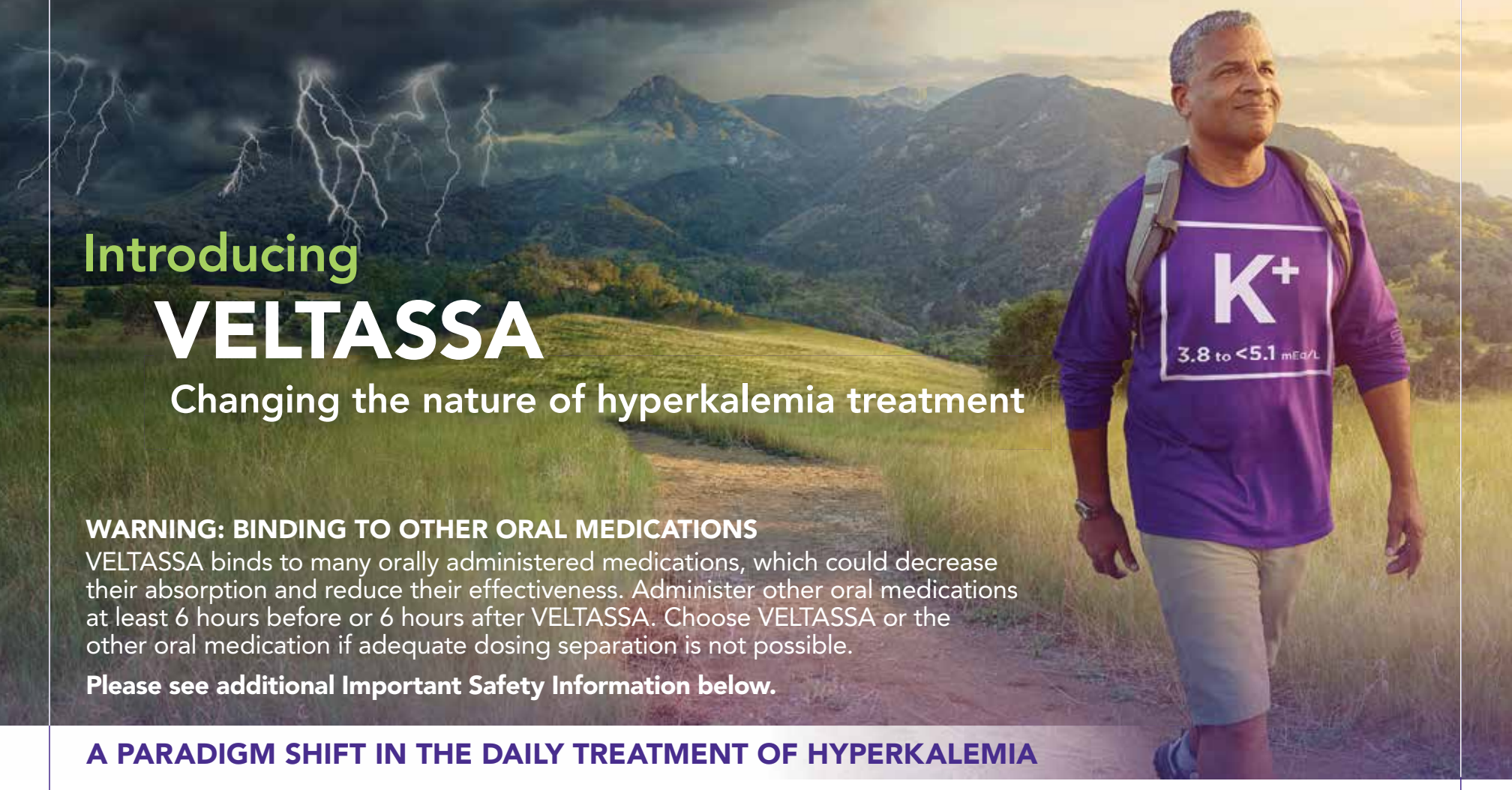
ASN's ongoing workforce research focused on supply across the career spectrum. Employment and job search experiences captured in the Nephrology Fellows Survey provide key market indicators. The 2016 survey of physicians 55 years and older examined how changing practice patterns and retirement plans will influence demand in the short- and midterm. Led by George Washington University, additional research includes potential effects of integrated care delivery models (such as ESRD Seamless Care Organizations or ESCOs) on future nephrologist demand and analysis of Medicare claims data for trends in the diagnosis and treatment of kidney diseases.

Gauging Interest in Nephrology Careers, Training Trends

ASN implemented several initiatives to strengthen the candidate pipeline. A Workforce Committee project analyzes institutions graduating the most physicians choosing nephrology. The Best

Continued on page 10

A daily, **SODIUM-FREE** treatment for hyperkalemia



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Changing the nature of hyperkalemia treatment

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Please see additional Important Safety Information below.

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VELTASSA K+onnect℠

Indication and Limitation of Use

VELTASSA is indicated for the treatment of hyperkalemia.

VELTASSA should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

Important Safety Information

Contraindications: VELTASSA is contraindicated in patients with a history of a hypersensitivity reaction to VELTASSA or any of its components.

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

Hypomagnesemia: VELTASSA binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of patients treated with VELTASSA. Approximately 9% of patients in clinical trials developed hypomagnesemia with a serum magnesium value <1.4 mg/dL. Monitor serum magnesium. Consider magnesium supplementation in patients who develop low serum magnesium levels.

Adverse Reactions: The most common adverse reactions (incidence ≥2%) are constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort and flatulence. Mild to moderate hypersensitivity reactions were reported in 0.3% of patients treated with VELTASSA and included edema of the lips.

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ASN in Review

Continued from page 8

Practices Project identifies approaches to successfully instill interest in the specialty, first in medical schools and then internal medicine residency programs. These methods will be disseminated so they can be modeled at other institutions. The Graduate Medical Education (GME) Database is compiling data on adult and pediatric training programs to provide workforce researchers with accurate, definitive data on the nephrology training landscape to enable better monitoring of the supply of future nephrologists and changes in the number of training positions.

Kidney TREKS

Thirty students trekked to Mount Desert Island Biological Laboratory to participate in a course on renal physiology. The weeklong Kidney TREKS (Tutored Research and Education for Kidney Scholars) course also includes a long-term mentorship program. In 2017, ASN will expand to a second TREKS site at the University of Chicago that will offer a blend of complementary clinical and research opportunities.

Trainee Travel Support

ASN provided more than $250,000 in travel support to 314 students, residents, and fellows to attend ASN Kidney Week 2015. Program highlights included Kidney STARS and the Karen L. Campbell, PhD, Travel Support Program for Fellows. Kidney STARS supported more than 200 students and residents with tailored programming and mentorship guidance throughout the annual meeting. Named for ASN's former Executive Director, the Campbell Fellows Program supported 25 fellows, who also served as mentors for the Kidney STARS program. The Campbell Fellows Program expanded in 2016 to include 70 fellows. Annually, the William E. Mitch, III, MD, FASN, International Scholars Travel Support Program supports five fellows from Central America, South America, and Spanish-speaking countries in North America, as well as three fellows in the US or Canada who are underrepresented minorities.

ASN Kidney Week—New in 2016

Reinventing Nephrology: From Molecule to Man

This year's Kidney Week includes exciting new features and resources.

Early Programs

ASN offers 10 Early Programs on Tuesday, November 15, and/or Wednesday, November 16, preceding the Annual Meeting (November 17–20). New Early Programs are:

- The **Advances in Research Conference—Metabolic Phenotyping: From Mouse to Man** provides a systems approach to better understanding of diabetes and metabolic diseases. An emphasis is placed on the pathogenesis of metabolic diseases, state-of-the-art tools to study metabolism, the impact of diabetes on renal function, and new therapeutic advances in treating metabolic diseases.
- The **Evaluation and Management of Kidney Stones** program reviews the current state of the art with respect to evaluation and management of all forms of stone disease. The role of stone imaging modalities is reviewed, including considerations regarding radiation risk. Finally, the indications, risks, and benefits of various surgical approaches for stone removal are presented.

ASN's 50th Anniversary

Honoring the Past as We Prepare for the Future 50 Years of Leading the Fight ASN marks 50 years of leading the fight against kidney diseases in 2016. Throughout the year, ASN has recognized kidney health advances from the last half century and looks forward to new innovations in kidney care. ASN Kidney Week 2016 is the culmination of the 50th anniversary celebrations. Learn more at www.asn50.org.

"As we commemorate the 50th anniversary of the founding of the American Society of Nephrology, it allows us to reflect on the role that ASN has played in helping to shape our discipline and to look forward to how nephrology will evolve. Since its inception, ASN has played decisive roles in promoting education, research, and advocacy for our patients and our profession, and going forward we will continue to lead the fight to prevent, treat, and cure kidney diseases throughout the world."

— Raymond C. Harris, MD, FASN, ASN President

ASN50 years

Welcome Reception

Thursday, November 17, 6:30 p.m. – 7:30 p.m. To commemorate ASN's 50th anniversary, the society will host a Welcome Reception for all Kidney Week participants in the exhibit hall. This celebratory event will provide participants with an additional unopposed hour to engage with exhibitors and explore the exhibit hall.

In addition to the Welcome Reception, ASN will have booths celebrating the past, present, and future of both ASN and nephrology in the exhibit hall. Take a walk down memory lane in one of these booths celebrating our history and the history of nephrology.

ASN 50 years

ASN honors the eminent nephrologists and scientists who have led the society as ASN President or Secretary-Treasurer during the society's 50 years of leading the fight against kidney diseases.

Former Presidents of ASN

2014–2015	Jonathan Himmelfarb, MD, FASN
2013–2014	Sharon M. Moe, MD, FASN
2012–2013	Bruce A. Molitoris, MD, FASN
2011–2012	Ronald J. Falk, MD, FASN
2010–2011	Joseph V. Bonventre, MD, PhD, FASN
2009–2010	Sharon Anderson, MD, FASN
2008–2009	Thomas M. Coffman, MD, FASN
2007–2008	Peter S. Aronson, MD, FASN
2006–2007	William L. Henrich, MD, FASN
2005–2006	Thomas D. DuBose, Jr., MD, FASN
2004–2005	Tomas Berl, MD, FASN
2003–2004	William E. Mitch, III, MD, FASN
2002–2003	Norman J. Siegel, MD
2001–2002	Roland C. Blantz, MD, FASN
2000–2001	Robert Jay Alpern, MD
1999–2000	Thomas H. Hostetter, MD
1998–1999	William M. Bennett, MD, FASN
1997–1998	Wadi N. Suki, MD
1996–1997	Robert G. Luke, MD
1995–1996	William G. Couser, MD
1994–1995	Ramzi S. Cotran, MD
1993–1994	Thomas E. Andreoli, MD
1992–1993	Alfred F. Michael, MD
1991–1992	Richard L. Tannen, MD
1990–1991	C. Craig Tisher, MD
1989–1990	Michael J. Dunn, MD
1988–1989	Jay H. Stein, MD
1987–1988	Thomas F. Ferris, MD
1986–1987	Barry M. Brenner, MD
1985–1986	Saulo Klahr, MD
1984–1985	Juha P. Kokko, MD, PhD
1983–1984	Richard J. Glassock, MD
1982–1983	Robert W. Schrier, MD
1981–1982	Roscoe R. Robinson, MD
1980–1981	Maurice B. Burg, MD
1979–1980	Robert L. Vernier, MD
1978–1979	Belding H. Scribner, MD
1977–1978	Laurence E. Earley, MD
1976–1977	Floyd C. Rector, Jr., MD
1975–1976	Carl W. Gottschalk, MD
1974–1975	William B. Schwartz, MD
1973–1974	Jack Orloff, MD
1972–1973	Robert H. Heptinstall, MD
1971–1972	Gerhard H. Giebisch, MD
1970–1971	George E. Schreiner, MD, PhD
1969–1970	Louis G. Welt, MD
1968–1969	Robert W. Berliner, MD
1967–1968	Donald W. Seldin, MD
1966–1967	Neal S. Bricker, MD

Former Secretary-Treasurers of ASN

2007–2013	Donald E. Wesson, MD, FASN
2004–2006	Alan M. Krensky, MD
1998–2003	John B. Stokes, III, MD, FASN
1996–1997	Josephine P. Briggs, MD
1993–1995	Diana Marver, MD
1990–1992	James A. Schafer, PhD
1988–1989	Jared J. Grantham, MD
1985–1987	Ruth Bulger, PhD
1982–1984	Saulo Klahr, MD
1979–1981	Robert W. Schrier, MD
1976–1978	Martin Goldberg, MD
1973–1975	Floyd C. Rector, Jr., MD
1970–1972	Jack Orloff, MD
1968–1969	George E. Schreiner, MD, PhD

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INDICATIONS

Injectafer is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, and in adult patients with non-dialysis dependent chronic kidney disease.

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Injectafer is contraindicated in patients with hypersensitivity to Injectafer or any of its inactive components.

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 Injectafer. 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 Injectafer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

In clinical studies, hypertension was reported in 3.8% (67/1775) of subjects. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

In the 24 hours following administration of Injectafer, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer.

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In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a single maximum dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by ≥2% of Injectafer-treated patients were nausea (7.2%); hypertension (3.8%); flushing/hot flush (3.6%); blood phosphorus decrease (2.1%); and dizziness (2.0%).

The following serious adverse reactions have been most commonly reported from the post-marketing spontaneous reports: urticaria, dyspnea, pruritus, tachycardia, erythema, pyrexia, chest discomfort, chills, angioedema, back pain, arthralgia, and syncope.

To report adverse events, please contact American Regent at 1-800-734-9236. You may also contact the FDA at www.fda.gov/medwatch or 1-800-FDA-1088.

Please see Brief Summary on the following page.

For more information, please visit **Injectafer.com**

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Policy Update

Transforming, Ensuring Access to Optimal Kidney Care Top ASN Public Policy Board 2017 Agenda

There is nothing permanent except change. —Heraclitus

Heraclitus could have been speaking about the present-day practice of medicine with his gaze focused on the future—especially in nephrology. American Society of Nephrology (ASN) President Raymond C. Harris, MD, FASN, recently underscored this thought in *ASN Kidney News* when he wrote "how we practice currently will be very different from practice patterns 20, 10, or even 5 years from now."

Currently, ASN's Public Policy Board (PPB), along with other key partners in the kidney care community, are working to channel that change into three separate, yet complementary, paths as it plans for 2017 and beyond.

Innovation

Kidney transplantation is the optimal form of therapy for the nearly half million Americans and millions of people around the world suffering from kidney failure. However, the US kidney transplant waitlist—approximately 100,000 Americans—is growing, and the average wait time for a transplant is 5 years. Most patients on dialysis will die before their name is ever called.

ASN is pledging the first $7 million toward a global prize competition to develop a novel wearable or implantable device that replaces kidney function and improves patient quality of life, in partnership with the XPRIZE Foundation. XPRIZE designs and implements innovative competition models that utilize the unique combination of gamification, crowd-sourcing, incentive prize theory, and exponential technologies to solve the world's grandest challenges.

Furthering the progress of innovation, ASN and the Veterans Administration have announced the Kidney Innovation Initiative, a partnership of ASN and the US Department of Veterans Affairs (VA) that challenges innovators worldwide to compete in developing technology resources that improve quality of life and outcomes for people with kidney diseases and those anticipating a kidney transplant. The first step will be the development of an app for veterans and others with kidney disease to use to monitor their health and help them take control of their disease. More than 1 million veterans suffer from kidney diseases.

ASN and 34 other kidney care community members are advocating for a research budget of $2.165 billion for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for 2017. The group is pushing Congress for an additional $150 million per year over 10 years for NIDDK kidney research above the current funding level. With nearly 7% of Medicare's budget dedicated to the treatment of patients with kidney diseases—even though they are only 1% of the Medicare population—the federal government must increase its funding of kidney research.

Transforming Care

MACRA is just beginning to shape the future of health care delivery. ASN and other organizations strongly urged the Centers for Medicare & Medicaid Services (CMS) to provide flexibility in the first performance period slated to begin January 1, 2017, and CMS has done so. Providing a solid base for the transformation of quality care should not be rushed. Now, physicians in the Merit-Based Incentive Payment System (MIPS) may:

a. Test the quality payment program with some data from January 1, 2017, or after,
b. Participate by submitting data for part of the 2017 calendar year in the three categories of quality, technology use, and practice improvement,
c. Participate for the full calendar year of 2017,
   or
d. Participate in an Advanced Alternative Payment Model in 2017.

With the goal of advancing quality care for patients with advanced chronic kidney disease (CKD), ASN is building support at CMS and the Center for Medicare and Medicaid Innovation (CMMI) for the creation of a care delivery model encompassing the spectrum of advanced CKD for the duration of a patient's life. The model should be in keeping with the development of Alternative Payment Models (APMs) as MACRA is implemented. The model could include both individuals receiving and not receiving kidney replacement therapy and prioritizing transplantation (including preemptive transplantation) or comprehensive conservative care management as appropriate, while aligning incentives to deliver the most high-quality, cost-effective, individualized care for patients with kidney diseases.

Advocating for improvements in the Quality Incentive Program (QIP), the ASN Public Policy Board continues to voice its goal of fewer and more meaningful quality measures that accurately measure high value care for patients with kidney diseases.

Access to Optimal Care

Patients with advanced kidney diseases almost always have multiple serious chronic co-morbidities, including diabetes, hypertension, peripheral vascular disorders, and heart failure. More than 50% of patients with CKD have 5 or more other co-morbid conditions, and CKD is included among 4 of the 5 most costly chronic condition combination triads in the Medicare program (CMS Office of Information Products and Data Analytics, August 2014). Therefore, access to optimal care can take multiple forms when it comes to CKD, end stage renal disease (ESRD), and acute kidney injury (AKI).

Transplantation

Every 14 minutes a patient is added to the 100,000+ person kidney waitlist, and 13 Americans die each day waiting for a kidney transplant. Yet the number of living organ donations has slowed over the past 10 years. The Living Donor Protection Act (LDPA – H.R. 4616/S. 2584) strongly supported by ASN would help address these grim statistics by eliminating obvious and unnecessary barriers to living organ donation. LDPA effectively would:

a. Ensure living organ donors have equal access to life, disability, and long-term care insurance,
b. Allow living organ donors Family and Medical Leave Act "time off" to recover, and
c. Educate Americans about living donation.

ESRD is the only pre-existing condition that explicitly prevents Medicare patients from enrolling in Medicare Advantage (MA) plans, thereby barring them from selecting a plan that best fits their medical and financial needs. To address this concern, ASN is advocating for the Expanding Seniors Receiving Dialysis Choice Act of 2016, the ESRD Choice Act (H.R. 5659). This bill could help end that prohibition and create equitable choice for patients with ESRD.

Following the June 2016 White House Organ Summit, ASN is working with the Administration to continue advocating for policy solutions to the organ donor shortage. Looking forward, ASN is working to identify policy solutions to address barriers in wait-listing, including addressing the many patients who cannot get wait-listed because they do not have secondary insurance.

Home Dialysis and AKI-D

The Government Accountability Office (GAO) has verified that home dialysis utilization is significantly lower than experts and stakeholders believe it could and should be. ASN and other members of the kidney care community have urged CMS to identify and remove some of the disincentives to home dialysis. These efforts include increasing payments for home dialysis training/retraining and adding home dialysis monthly codes to the Medicare telehealth list among other steps.

Further expanding patient-specific access to care is at the heart of advocacy efforts to promote policies that recognize the unique needs and courses of care for patients with dialysis-requiring acute kidney injury (AKI-D), especially as these patients are discharged from the hospital to outpatient ESRD facilities to continue dialysis while awaiting recovery. Patients with AKI-D require a care delivery process that facilitates their rehabilitation and is distinct from care for patients with ESRD. ASN continues to work with CMS to fine tune policies that allow nephrologists and ESRD facilities to individualize AKI-D care and allow Medicare to reimburse those services accordingly.

Food as Medicine: No More Renal "Diet"

By Sharon M. Moe, MD; Deidra C. Crews, MD, ScM; Orlando M. Gutiérrez, MD, MMSc; Pamela Hoyt-Hudson, BSN, RN; Susie Q. Lew, MD; Beth Shanaman, RD; Barry H. Smith, MD; Daniel E. Weiner, MD, MS; and Donald Wesson, MD, on behalf of The Rogosin Institute and Center for Health Action and Policy Roundtable on Nutrition Health in Kidney Disease

Health food stores abound in strip malls. Vitamin shops are a multibillion dollar business. Consumer labeling such as "gluten free," "heart healthy," "organic," "non-GMO" and "contains anti-oxidants" adorn food labels, encouraging purchase. Organic foods and farmers markets have become the newest trend. The overall goal of equating nutrition with health is becoming better recognized, but messaging is filled with contradictions from food marketers, the media, and health care. People generally want to be healthy and recognize that good food may be the way to go, but following a "diet" can have a negative, forced, or even punitive connotation. "Diet" usually implies restricting food, either to lose weight or for medical reasons. Renal patients faced with the conflicting messages of the importance of good food and the mandate to follow the "renal diet" are left feeling unsure which way to turn.

"Many foods that are culturally relevant to me are completely off-limits. Foods that I can have often conflict with my diabetic diet. Almost all foods have some phosphorus. Renal-friendly food labels would make better selections more obvious."

—Angela Davis, dialysis patient, President, 4kidneyssake

In May 2016, The Rogosin Institute and its Center for Health Action and Policy in New York (see end note) convened a Roundtable of patient activists, health care professionals (including physicians, nurses, social workers, and dietitians), health/food policy advocates, scientists, and community organizations to brainstorm about changing the focus in chronic kidney disease (CKD) away from the "renal diet" and toward "nutrition health." The goals of the discussion were identification of the major issues/problems in renal nutrition, generation of pilot projects to improve nutrition health for individuals with kidney disease, and publication of reports on project outcomes. The consensus of the panel was that we need to move away from the negative and punitive connotations of a restrictive renal diet and instead educate patients about the reality that healthy food promotes kidney and overall health. We have to be realistic about what we can expect the patient and their family members to be able to do. We also have to be cognizant of the contextual factors of what they eat. We want to empower our patients to be advocates to take more responsibility for their own nutrition health through education and encouragement.

The renal diet—restricting sodium, potassium, phosphorus, and liquids—is complex and is certainly not easy to follow. While it has a sound basis in what we know about malfunctioning and failed kidney physiology, it contributes no value if patients cannot comply with it. In early CKD, patients are faced with conflicting recommendations about the dietary balance of protein and carbohydrates from their nephrologist and endocrinologist. And, of course, a low-sodium diet is nearly impossible to follow if a patient wants to eat outside the home or consume convenience foods. With progression of kidney disease and the initiation of dialysis, potassium and phosphorus restrictions are added. Adherence to a renal diet requires the patient to read and fully understand food labels; understand that "sodium" means "salt"; know exactly what a portion size in milligrams is; and do arithmetic to determine how much potassium, for example, is in a portion by multiplying portion weight by milligrams. Beyond that, he/she has to be able to look for one or more of the over 300 types of phosphate food additives. Still further, there are carbohydrates and sugar, saturated and unsaturated fats, and cholesterol, among other terms. It is like learning a new language!

New FDA food labels coming out over the next few years may offer some help. These labels will have more appropriate portion sizes and potassium quantification. But phosphorus additives remain in very small font and are not quantified. Patients will still have to do multiple calculations of portion size times milligrams (http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM501646.pdf).

Dietary commercial weight-loss programs have demonstrated through years of experience that a diet's ease of use and lack of overly restrictive provisions are the keys to success. Empowering patients to learn how to make reasonable choices—through reading food labels, employing easy-to-use apps, and participating in support groups and chat rooms—has been critical to the success of programs. Some go so far as to prepare properly nutritious food for participants. But for the renal diet, we give patients lists, ask them to read labels, and focus on what not to eat.

Compounding the problem is the fact that physicians and caregivers often provide piecemeal information when patients are seen: "avoid salt" if the intradialytic weight gain is high; "avoid fruits and vegetables" if the potassium is high; "no dairy or cola" if the phosphorus is high. We physicians often focus on what not to eat and not enough on what to eat. Valuable office visit time is spent discussing diets, with limited time to fully understand the realities of what patients are eating. This leaves the patient confused, and sometimes with conflicting information as physicians usually do not have the time to help guide patients through the complexities of the renal diet.

Dieticians are trained to look at the overall diet and help patients individualize meal plans. Yet this important role of the dietician is undervalued in the dialysis industry, with a patient-to-dietitian ratio that does not always facilitate the education time needed for the patient to understand the complexities and dynamics of the renal diet goals. Further, Medicare mandates do not take into account the stages of change to ensure successes when patients are ready to improve their diet. Unfortunately, many patients with CKD stage 1–5 do not have access to a dietitian to provide education on healthy food choices to slow the progression of renal disease, and thereby delay the time to initiation of dialysis or prepare a patient for nutritional stability before transplant.

Given the complexities of the renal diet and a goal of improving nutrition health for patients with kidney disease, some have asked whether digital technology can help address the dietary problems faced by patients. In fact, over the past 5 years, apps designed to help patients with CKD navigate the complexities of the renal diet have appeared. But the current level of technology may be beyond the financial, educational, or generational norms for the preponderance of people with CKD or currently on dialysis.

On another front, new research demonstrates that fruits and vegetables help improve some metabolic complications of CKD and supports the notion that they may be as beneficial as pills of sodium bicarbonate in the prevention of the progression of kidney disease. This research supports the concept of good nutrition as positive medicine for renal patients and suggests that nephrologists should put more emphasis on nutrition as therapy. Still other research has demonstrated that not all forms of phosphate are equally absorbed so that naturally occurring phosphate in foods (legumes, nuts) can be eaten, while artificial phosphate additives in many foods contribute to high phosphorus levels. In other words, these studies indicate that patients should eat fresh foods, including fruits and vegetables, as opposed to processed foods.

Despite the progress, many obstacles remain. Health literacy levels remain low among many of our patients. Generalized recommendations for diet don't make cultural sense to many patients, or point to ingredients that are not available to them. Still more patients on dialysis may live in "food deserts" where they simply do not have access to fresh produce or affordable foods. Knowledge of how to cook basic meals has been in decline. Further, patients on dialysis may miss meals owing to their hectic and long dialysis schedules and can feel so poorly after dialysis that the fast food "drive-thru" is more appealing than preparing a meal from scratch. Transportation issues may make shopping difficult and/or leave no time to eat or prepare a meal. Clearly broad-based, multisector efforts are needed to ameliorate the social, cultural, and medical challenges faced by patients with kidney disease.

The consensus at the summit sponsored by The Rogosin Institute was that we need to make the radical change from a focus on the renal diet to a focus on **Good Food First**, and the recognition that food is as critical as medications in the management of patients with CKD. In order to achieve this change, there must be an emphasis on the **A, B, C, D's** of kidney nutrition health:

A. Access to affordable, fresh foods

B. Back to basics

C. Cooking: You can do it!

D. Deliver information a patient can understand

In short, we need to make good food (and nutrition) *cool, fun, funky, and fresh*.

Putting nutrition in its proper place as a positive therapeutic tool in kidney diseases and making good nutrition attractive to the people we serve will require a multi-pronged approach. Many ideas were exchanged at The Rogosin Roundtable. Five overall goals were agreed upon:

- **Make nutrition health a priority by eliminating the negative connotations of the renal diet and by empowering people to make healthier food choices.** This will require a broad-based, but targeted, outreach campaign through various media, including social media outlets, to change the focus in nutrition education curricula for kidney health providers and patients.
- **Explore, and perhaps endorse, the best of technology-based tools for nutrition management,** ascertaining their relevance to the different subgroups of patients we serve and maintaining a high level of scrutiny for cultural meaning and appropriateness.
- **Increase access to fresh foods by activating and working with community leaders to bring fresh food to patients.** For example, programs exist in many communities to bring unused but still healthy foods from restaurants to those in need. Why not bring food to the dialysis unit, where most patients are on fixed incomes? Many produce distributors or farmers would gladly donate surplus produce rather than discard it in the trash. Promoting farmers' markets in communities has the potential to be yet another important effort in this regard.
- **Educate and encourage patients and their families to cook healthy, kidney-friendly, meals and to enjoy it while they are doing it.** Among the possibilities are cooking demonstrations at dialysis units, development of patient-friendly, culturally relevant cookbooks, and provision of sample ingredients that a patient can purchase to prepare his/her own meal.
- **Promote policy changes at the national and state levels** that promote better dietician-to-patient ratios (in CKD stages 1–5 as well as ESKD), improve reimbursement for SNAP benefits for kidney patients, insurance coverage for food post-hospitalization, and provide for mandatory phosphate quantitation on food labels. The latter is a prerequisite for a fully functional nutrition app to empower patients.

The road to optimal kidney nutrition health may ultimately be long and winding, but we need to begin to make the needed changes now for the sake of the well-being of our patients with both CKD and ESKD. It is time to put Good Food First with the A, B, C, D's of kidney nutritional health.

End note

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, Weill Cornell Medical College, and is a member of New York-Presbyterian Healthcare System, Kidney Care Partners, and the Kidney Care Council. Rogosin provides patient-centered care for individuals with chronic diseases, including kidney disease, diabetes, hypertension, cholesterol or triglyceride disorders, and cancer. Having worked over the past 25 years with health promotion and basic health care in 30 countries around the world, The Institute is uniquely equipped to advance programs that prevent disease and to promote good health in underserved communities.

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Kidney Care and Depression

A Patient's Perspective on the Challenges of Chronic Kidney Disease

By James "Mike" Guffey

I am not sure there is a good way to start dialysis, but I am certain that crashing into it is not the way to go.

These impressions had nothing to do with the quality of care I received but reveal how overwhelming and impersonal the experience was, especially considering I was not functioning at top level when the situation began.

In one morning, I went from being on vacation away from home, thinking I had the flu while recovering from bronchitis and altitude sickness, to being admitted to the intensive care unit (ICU) with kidney failure.

How long have you had kidney issues? Is there a history of kidney disease in your family? How long have you been diabetic? Is there a history of diabetes in your family? Are your blood platelets usually this low? Is your BP always this high? How long have you had this edema in your legs? Have you been diagnosed with hepatitis? Do we need to test your blood for HIV?

These and many more questions like them greeted me in rapid fire in the emergency room. I barely got the chance to answer one before the next one came, with no chance to really process what was being asked. It was like being on the receiving end of a firehose as the team attempted to cover my entire medical history as quickly as possible. After all of the questions had been answered and I was admitted to the ICU, the situation did not greatly improve. The questions were replaced with an overflow of information.

What you have is officially called ESRD. Don't worry, that is just a classification used for insurance and treatment purposes. It might be acute and go away over time, or it might be chronic. We are going to take you to surgery in a few minutes to get you a catheter in your chest so you can start dialysis as soon as possible. We will also be putting you on a renal diet.

End stage does not sound good. That sounds terminal. Catheter? Dialysis? Can we slow this down so I can understand what you are talking about? It is my life and my body, and I am feeling totally overwhelmed and don't know how I will explain the situation to my family and close friends.

That afternoon, I was whisked away for catheter surgery and back to the ICU for an initial dialysis treatment. The next morning, I was having what seemed a great breakfast with bananas and strawberries. Then, the dialysis technician walked in, saw what I was eating, and took it away! The hospital had me on the heart-friendly diet and not the renal diet, and I had no clue what the difference was. I felt bad about eating the wrong thing, but I didn't know what the right thing was. This drove home the idea that a lot was changing, and I had a lot to learn to succeed in my new circumstances.

There were lots of things to learn quickly, and there were initially no documents I could read on my own time, nowhere I could go to look for answers to my own questions. Slowly, I got some of the answers from visitors (the dialysis technician, the nephrologist, the dietician), and materials started to trickle in. Over the next few days, I began to feel a little more comfortable with the hospital treatment.

Then, the next stage of feeling overwhelmed set in. There was a lot I needed to figure out before I was released. How soon could I go home? How would I be able to bathe myself every day without getting the catheter site wet? Where would I dialyze when I got home? Would I be cleared to work? (And if cleared, would I be able to work?) These were all major questions without immediate answers, and all needed to be resolved quickly. It was hard not to again feel powerless, overwhelmed, and depressed.

Thankfully, over time, the answers did come, including good information about websites I could visit to get my questions answered plus many that I did not know I had. I also was fortunate to have a good support team who helped me negotiate my way back home and back to work.

It is important to realize that there are two very different life changes that come with crashing into dialysis. The first is physical: adjusting to the requirements and potential limitations of life on dialysis—the fluid restrictions, the renal diet, the treatments, and their effect on your body. The second is psychological: finding ways to avoid allowing all of the physical changes to overwhelm you and drag you into depression. Although it is natural to feel overwhelmed when experiencing a major life change, such as ESRD, it is important to find ways to cope and not to fall into anxiety and/or depression. It is important to remember that, although there are parts of your lifestyle that are beyond your control, you can control how you respond and not let the situation control you.

James "Mike" Guffey is a board member and patient advocate of Dialysis Patient Citizens.

Screening for and Treating Depression in Patients with Chronic Kidney Disease

By Nicole C. Allen and Philip R. Muskin

Approximately one in five women and one in 10 men will suffer from depression over the course of their lives (1). Chronic illness generally confers an even greater risk for depression. Patients with chronic kidney disease (CKD) and in particular, those who are on hemodialysis (HD) are at a relatively high risk for depression. It is difficult to determine the exact rate of major depressive disorder (MDD) in patients with CKD because the somatic symptoms of depression are similar to the symptoms of uremia (e.g., decreases in appetite, energy, sexual interest, and sleep). Aches and pains are common in patients with CKD, patients on HD, and patients with MDD.

Depression is thought to be the most common psychiatric abnormality in HD patients, with the prevalence likely between 5% and 10% (2). Depression in patients on HD can stem from the variety of losses that these patients suffer, including loss of kidney function, employment, physical strength, and social function (3). Patients on HD with MDD are twice as likely to die or require hospitalization within a year as those without depression (4). The suicide rate in ESRD patients is also higher than that of the general population (5). Recently, the Centers for Medicare & Medicaid Services added a new requirement in its Quality Incentive Program to screen and follow up as indicated for depression in all patients 12 years of age and older with CKD on HD. The Centers for Medicare & Medicaid Services Quality Incentive Program does not require use of a specific screening tool, and it does not define which member of the care team must do the screening. Identifying and appropriately treating MDD can have an extraordinary effect on quality of life for patients with CKD.

Generally, it makes sense to screen for depression anyone who looks unhappy, bearing in mind that not everyone who looks unhappy has a psychiatric disorder. It is important to differentiate between MDD and an appropriate sad reaction to a difficult life situation, because the therapeutic approach will be different. Patients who have just received a difficult diagnosis or who have had a recent health crisis may be quite upset; however, this reaction often does not progress to MDD (i.e., a psychiatric disorder). People who are ill but not depressed will retain interest in things that have historically brought them joy. For example, a devoted Yankees fan who is chronically ill but not depressed may be sad, because he cannot stay awake to watch a game on television; however, he will still be interested in the score. When that same patient seems completely uninterested in baseball season for days at a time, depression may be the culprit.

Any health care provider can do a basic screening for depression. To start, ask the patient how things are going and how he has been sleeping. Any patient who has had difficulty falling or staying asleep in the absence of difficulty breathing, frequent nighttime urination, pain, etc., should then be asked if he is feeling sad or blue and if he has lost interest or pleasure in things he usually finds fun. These two questions, each rated on a scale of zero to three over the last 2 weeks with zero being never and three being nearly every day, constitute the Patient Health Questionnaire-2 (PHQ-2). The PHQ-2 is a very brief, basic version of the more comprehensive PHY-9, a nine-question screening tool commonly used to quickly assess for symptoms of depression (Figure 1). The PHQ-9 is available in many languages. A patient who scores three or more on the PHQ-2 should be asked to fill out a PHQ-9. The PHQ-2 has 97% sensitivity and 67% specificity in adults, whereas the PHQ-9 has 61% sensitivity and 94% specificity in adults (6). Almost 90%

of patients who score 10 or higher on the PHQ-9 have MDD; generally, scores of 5, 10, 15, and 20 correspond to mild, moderate, moderately severe, and severe depression, respectively (7).

The most concerning outcome of MDD is suicide. Some people worry that assessing for suicide can give a patient the idea to kill himself. This fear is unfounded; there is no evidence that screening for suicide leads to an increased risk of suicide. Another concern that can lead health care providers to avoid screening for depression is the fear that asking the patient about sadness will lead to an emotional crisis (opening Pandora's box), which the provider will be obligated to manage. This fear is not accurate; sometimes probing an emotional subject can lead to an expression of feelings by the patient, but this outcome, although potentially intimidating to the provider, is optimal in that it can lead to the patient getting necessary treatment for depression.

Treating major depressive disorder

In general, the two strategies for treating MDD are psychotherapy and medication. Choosing a treatment strategy depends on a variety of factors, including the severity of the illness, the patient's preference, treatment availability, and the patient's ability to engage in certain forms of psychotherapy. For patients with very mild depression or who are reacting to a recent health crisis, having a space to talk about their experience with a compassionate listener is most helpful; medication alone is typically not effective in symptom reduction for these patients (8). For patients with mild to moderate depression, psychotherapy alone or in combination with medication can be useful. There are multiple types of psychotherapy that can be helpful for patients with CKD and MDD; for example, cognitive behavioral therapy can help patients address overvalued fears and misconceptions about themselves and their illness while providing patients with coping mechanisms to use in times of stress. Coping mechanisms such as deep breathing can also be taught alone. The advantages of psychotherapy are that there are no medical downsides and that the techniques learned can be remembered and used at later times (9). The disadvantages of psychotherapy are that it requires a skilled psychotherapist, a minimum level of patient engagement (including cognitive capacity and motivation), and regular, relatively frequent sessions.

Antidepressant medication should, with minimal exception, be prescribed to patients with severe depression and may be helpful either alone or in combination with psychotherapy in patients with mild to moderate depression. Psychotherapy alone is not useful in patients with severe depression. Medications that are metabolized by the kidneys, such as paroxetine and venlafaxine, should be avoided in patients with CKD. Citalopram and sertraline can be considered first-line medications, and duloxetine can be considered for patients with coexisting neuropathic pain. Dosages of most antidepressants should be initially reduced given that the kidney generally excretes the liver metabolites of antidepressants (10). It is important to remember that antidepressant medication can take 6 to 8 weeks to be maximally effective and that many patients will require doses higher than the starting dose to get better. When patients do not respond to therapeutic doses of antidepressants, are suicidal, or have a history of episodes of mania or hypomania (bipolar disorder), consider consulting with a psychiatrist in managing the care of the patient.

Screening for MDD is a simple process that can be accomplished by any health care provider. Although discussing emotions in the setting of a difficult medical diagnosis can be intimidating, treatment for MDD is effective, and the positive effect on patient outcomes can be tremendous.

Figure 1. Patient Health Questionnaire for Depression

Patient Name: _____ **Date:** _____

	Not at all	Several days	More than half the days	Nearly every day
1. Over the *last 2 weeks*, how often have you been bothered by any of the following problems?				
a. Little interest or pleasure in doing things	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless	☐	☐	☐	☐
c. Trouble falling/staying asleep, sleeping too much	☐	☐	☐	☐
d. Feeling tired or having little energy	☐	☐	☐	☐
e. Poor appetite or overeating	☐	☐	☐	☐
f. Feeling bad about yourself or that you are a failure or have let yourself or your family down	☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television.	☐	☐	☐	☐
h. Moving or speaking so slowly that other people could have noticed. Or the opposite; being so fidgety or restless that you have been moving around a lot more than usual.	☐	☐	☐	☐
i. Thoughts that you would be better off dead or of hurting yourself in some way.	☐	☐	☐	☐
2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
	☐	☐	☐	☐

PHQ-9* Questionnaire for Depression Scoring and Interpretation Guide

For physician use only

Scoring:
Count the number (#) of boxes checked in a column. Multiply that number by the value indicated below, then add the subtotal to produce a total score. The possible range is 0-27. Use the table below to interpret the PHQ-9 score.

Not at all (#)_____ x 0 =_____
Several days (#)_____ x 1 =_____
More than half the days (#)_____ x 2 =_____
Nearly every day (#) _____ x 3 = _____

Total score: _____

Interpreting PHQ-9 Scores		Score	Actions Based on PH9 Score
		Score	**Action**
Minimal depression	0-4	< 4	The score suggests the patient may not need depression treatment
Mild depression	5-9		
Moderate depression	10-14	> 5 - 14	Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment
Moderately severe depression	15-19		
Severe depression	20-27		
		> 15	Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment.

* PHQ-9 is described in more detail at the McArthur Institute on Depression & Primary Care website www.depression-primarycare.org/clinicians/toolkits/materials/forms/phq9/

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Screening for and Treating Depression

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Assessment and Treatment of Depression in Patients Undergoing Maintenance Dialysis

By Rajnish Mehrotra, MD

Patients who need dialysis for the treatment of ESRD have a high burden of disease because they have numerous coexisting illnesses (such as diabetes and congestive heart failure), high health care utilization with frequent hospitalizations and high rates of readmission, and a very high daily pill burden. The dialysis regimen adds further to this burden, because patients have to make significant changes in their day-to-day lives, including in their diets, to accommodate the treatment schedules and minimize risks to their health. Patients have further challenges in coping with the numerous demands imposed by a diagnosis of ESRD if they also suffer from depression. The ability to cope may be even more decreased with the added stress of a transition in care.

Unfortunately, comorbid depression is very common: a large number of studies from around the world using a variety of assessments seem to suggest that anywhere from one-quarter to one-third of all patients needing dialysis support have significant depressive symptoms (1). A greater severity of depressive symptoms is associated with higher risks for hospitalization and death (2). There is a significant body of evidence that a large part of the health risk associated with depression in dialysis patients arises from their inability to adhere to the prescribed dialysis regimen, diet, and/or medications (3). This observation raises hope that, if patients with depression can be identified early and offered adequate treatment, their depressive symptoms will improve and they will better adhere with their treatment, resulting in better health outcomes.

Unfortunately, few studies have examined whether treatment methods recommended for patients without kidney disease are effective for patients with kidney failure who need dialysis, and none have tested whether such treatment reduces the need for hospitalization or risk for death. Despite this lack of evidence, the Centers for Medicare & Medicaid Services has instituted financial incentives to dialysis facilities linked to screening all Medicare beneficiaries undergoing dialysis for the presence of depression and instituting a plan of care. So what do we know about this issue to allow us to implement this policy imperative in a manner that is safe and effective?

There are many ways to screen for the presence of depression, but it is important to keep some caveats in mind. First, survey instruments like Patient Health Questionnaire (PHQ)-2, PHQ-9, or others, are only meant for screening and identifying patients who need further evaluation and should not be used to make a diagnosis of depression (4). Although a formal diagnosis of depression should only be made using a structured clinical interview, treatment decisions in some patients may be appropriate even without such additional assessment. Second, we must also recognize that many of the symptoms experienced by patients with depression are the same symptoms caused by kidney failure (e.g., fatigue, loss of appetite, and difficulty sleeping). At least 20% of patients who screen positive for depression on survey instruments do not have the disease, and treatment, particularly with antidepressant medications, would be inappropriate (4). For many of the survey instruments, the cutoff score for the diagnosis of depression in patients treated with dialysis is higher than that for patients without kidney disease. Even when the patient's score is above this higher cutoff score, some patients' symptoms result from their kidney failure and other coexisting illnesses, not from depression.

Even though there is limited evidence to date for health benefits from treatment of depression, lack of evidence is not the same as lack of benefit, and treatment should be offered to selected patients. Even today, a diagnosis of depression has stigma attached with it, and many patients are unwilling to accept the label and/or treatment even when offered. Hence, tremendous clinical skill is needed to communicate the results of diagnosis and options for treatment.

Treating depression

There are two major ways to treat depression in patients without kidney disease—cognitive behavioral therapy (a special form of psychotherapy) or antidepressant medications. Two clinical trials have shown that cognitive behavioral therapy is effective for improving depressive symptoms in patients who need dialysis, regardless of whether delivered one on one or in a group setting (5,6). There is virtually no high-quality data to determine if antidepressant drugs are effective in improving depressive symptoms in dialysis patients. However, there is one small study that has compared cognitive behavioral therapy with antidepressant drug therapy for patients with ESRD and found them to be equally effective (7).

To better inform clinical practice, the ASCEND Study is a multicenter, randomized, controlled clinical trial supported by the Patient Centered Outcomes Research Institute that is presently underway in three cities in the country (Albuquerque, NM; Dallas, TX; and Seattle, WA) (8). Patients are screened for the presence of depressive symptoms using the Beck Depression Inventory II. If the diagnosis is formally confirmed, the patients are offered to be randomized to cognitive behavioral therapy while undergoing dialysis or antidepressant drug therapy each for a period of 12 weeks (8). The results of the study are likely to be available in early 2018 and, it is hoped, will provide better guidance to clinicians.

In summary, even though depression is common among patients undergoing dialysis, little is known regarding how to best treat such patients. The public policy is premature for the level of guidance that we have from research studies. Treatment decisions must be made using our best clinical judgment until better evidence becomes available.

Rajnish Mehrotra, MD, is affiliated with the Kidney Research Institute and Harborview Medical Center, Division of Nephrology, University of Washington, Seattle.

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Don't Stress About Conceptualizing Depressive Symptoms: Just Address Them

By Daniel Cukor, PhD, and Steven Weisbord, MD

Major depression is a complicating comorbid diagnosis in a variety of chronic medical conditions, but may be a particular diagnostic and treatment challenge to the patient with end stage renal disease (ESRD). New Medicare guidelines mandate that dialysis providers must screen for depression, and soon they will be required to document a treatment plan. This new requirement is forcing kidney care providers to seriously consider the best approaches to accurately diagnose and treat patients on dialysis once they have been identified as having depression. There are a variety of diagnostic tools used to screen for depression, each with their own psychometric properties. Some of these instruments are designed to cast a wide net, with few missed diagnoses but tolerant of more false positives. Others are designed to be more discriminating, allowing for fewer false positives; however, these frequently have a higher test burden.

Beyond measurement issues, there is also the issue of the interpretation of the particular sympom as etiologically related to depression (Table 1). For example, if a patient exhibited recent weight gain, which is quite common in patients on chronic dialysis, how would the clinician definitively determine if this is indicative of the increased appetite and lethargy often seen in clinical depression, or associated with edema or a consequence of diet or fluid non-compliance? One way of conceptualizing this challenge is through the context of "lumping versus splitting." "Lumping" involves looking for underlying commonalities across diagnostic entities, seeking to describe the difficulties in the most parsimonious way. "Splitting" seeks to identify each diagnostic category that each symptom could be applied to. As an example, in a patient in the midst of a depressive episode who demonstrates an inability to remain asleep, insomnia could be conceptualized to be attributable to depression or could be viewed as an independent sleep disorder.

The most recent version of the Diagnostic and Statistical Manual for Mental Disorders (DSM 5) has undergone a conceptual shift away from "comorbid" or "secondary" specifiers, commonly used in the DSM IV, and toward the diagnosis of the additional disorder independent of the presence or absence of other psychiatric or medical conditions. The rationale for this approach is the improved detection and management of the individual, without regard to overlapping co-morbidities, as this will ultimately lead to a faster and more substantive improvement in the patient's quality of life. In essence, the new DSM advocates for "etiological blindess," with the clinician not charged with making the determination as to which complex is the primary driving force for this symptom, rather for the clinician to note the symptom in as many domains as relevant.

Table 1. Overlap of depression symptoms

Uremic symptoms	DSM 5 symptoms of major depression	Other possible diagnosic categories
	Depressed mood	
	Anhedonia	
Anorexia/edema	Weight change	Non-adherence
Neuropathy/arthropathy	Insomnia/hypersomnia	Insomnia, sleep apnea, restless leg
Encephalopathy	Psychomotor agitation/retardation	Anxiety
Anemia/volume overload/ congestive heart failure	Fatigue	Exhaustion/frailty
	Worthlessness/guilt	
Encephalopathy	Diminished ability to think	Cognitive impairment
	Thoughts of death	

In our example, the clinician does not have to make a discretionary judgment as to whether the weight gain is due to depression or dietary non-compliance, but rather should include the weight gain as being possibly related to both. A further advantage of this approach is that it does not mandate a dualistic approach, as the weight gain may indeed be due to both depression and non-compliance. Similarly, patients may receive superior care if the symptoms shared between depression and sleep disorders, pain disorders, sexual dysfunction, and anxiety disorders are recorded as being part of each diagnostic entitity, because the symptom can simultaneously be both a sign of depression and an indication of another problem.

We believe ultimately that this "splitting" approach will lead to more targeted interventions and that once the patients' interest in treatment is verified, their distress can be adressesed more directly. Although it is possible that the successful treatment of depression could eventually impact the patient's insomnia, targeting the insomnia specifically from the outset may allow for a quicker resolution of that particular symptom and may have other positive consequences on the treatment of depression. As the new Medicare screening requirements are being implemented, we have heard many clinicians question their meaningfulness. However, we believe that increased identification of depression and engagement with patients about their symptoms and interest in treatment will lead to improved management and enhanced quality of life, even if the true etiology of the symptom remains unclear.

Suggested Reading

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Daniel Cukor, PhD, is affiliated with the Department of Psychiatry and Behavioral Science at SUNY Downstate Medical Center in Brooklyn, NY. Steven D. Weisbord MD, FASN, is affiliated with the University of Pittsburgh Medical Center in Pittsburgh, PA.

Kidney Care and Depression

Dialysis and People: The Value of Compassion and Empathy

By Herbert Pardes

Having recently experienced an excellent meeting on mental health, chronic kidney disease (CKD), and ESRD, I wanted to offer some thoughts about the extraordinary role that psychology and people play in the course of this illness and its treatment. I commend the Rogosin Institute for convening a marvelous group of leaders from various parts of the country to deliberate on these issues.

What does one learn from such a roundtable? First and foremost, that kidney disease has a potential for dramatically disturbing a person's sense of well-being. Many people with serious kidney disease are not aware that they have it. It comes as a shock. It is important to realize that the individual with CKD has substantial challenges to handle. It is not easy to travel. It is more formidable to take on a full day's work. Fear, unfortunately, arises from all kinds of unnerving developments in the course of CKD.

CKD can affect people of all ages. The psychological effects most frequently seen are depression, anxiety, and even post-traumatic stress disorder. Although florid psychosis is rare, depression is estimated as present in some 37% of dialysis patients. The greater the depression, the higher the risk for a downward course.

In the psychology of individuals, it is not uncommon for a patient to feel that their illness represents punishment for something. It is important to make clear that this illness has nothing to do with guilt and that there are medical, biological, and psychological phenomena that cause CKD and its problems.

Another problem is financial support. Although Medicare provides payment for most patients with ESRD, practical help and advice from knowledgeable social workers or others who understand health care finance are important in reducing the stress.

There is an interactive effect in that the better the patient's attitude toward the illness, the better their course. Inducing people to take charge as opposed to feeling overwhelmed or devastated is critical. Finding ways to have the patients contribute is important. A person who feels consequential and that their life has value feels much better.

A good barometer for whether an individual will be able to effectively deal with kidney disease is how well he or she was able to cope previously. When people have successfully managed challenges before, there is a greater likelihood that they will be able to manage the life changes required by CKD.

Family support is critical. Family can be very helpful in not discouraging patients from work. Patients with CKD can travel, work, and have prospects of a lengthy life. There are CKD patients who have lived more than 40 years after diagnosis. That said, patients and their families need both physical and psychological space. Some patients manifest great anger, and it takes the care team as well as the family to be able to help patients deal with that anger. Occasionally, a caring spouse can become a needy spouse, requiring more team support to get through that crisis. Attention must be given to the care partners as well as the entire family. There must be relief for them and understanding of how valuable they are. Group therapy can be very helpful.

So, how can we do this better? How can we bring as many caring people as possible into the situation to maximize the general welfare of the individual with CKD? Efforts should focus on strengthening quality of life by expanding the individual's interests and the opportunity for enjoyment and good social contact. We are clearly asking patients to do a lot, including taking on a tough diet, taking multiple medications, and altering their daily lives. We must treat all of our patients as human beings with all of the feelings, worries, good times, and bad times that all of us experience and do everything that we can to enhance their overall feeling of wellness, involvement, and importance. It is well suggested that the patient should feel that the various professional and nonprofessional caretakers are partners. We are in this together and will strive for the best possible life, much happiness, and positive experiences and developments in the setting of these very demanding challenges.

Herbert Pardes, MD, is Executive Vice Chairman of the Board of Trustees, New York-Presbyterian Hospital.

Depression and Kidney Disease?

By Charlie Thomas

What do you mean my kidneys are failing?" "What is dialysis?" "Am I going to die?" "This can't be happening to me." "What about my family?" "I am afraid . . . ." The diagnosis of kidney disease is a life-changing event for individuals and their families. Their entire world has just changed. They have lost their safe and secure view of their own sense of good health and well-being. Their sense of the future is not as certain. They are in crisis and grief. Crisis can be viewed as a critical event that requires people to develop new ways and acquire new skills to cope and manage a new normal. This new normal for a chronic kidney disease (CKD) patient requires many changes, including implementing a kidney-friendly diet and reorganizing time and plans to accommodate scheduled dialysis treatments.

The National Kidney Foundation (NKF) reports that 20% to 40% of people with kidney failure have depression, which may be related to a feeling of grief arising from a sense of loss (1). Kubler-Ross (2) described stages of grief and loss as denial, anger, bargaining, depression, and acceptance in her work *On Death and Dying*. For many individuals, these feelings do not fall into rigidly defined stages but are more like a "spiral of emotions," which increases and decreases depending on other factors, such as physical distress, social support, role conflict, loss of employment and income, and increased financial costs.

How can the kidney health care team help? The NKF's *Living Well with Kidney Failure* series notes how important it is for patients to be taught how to manage this new normal physically, mentally, and emotionally (1). This includes keeping track of laboratory results and working closely with their care team to set reachable goals. Critical steps in self-care management include taking medications as prescribed and managing any side effects. Many patients will need to make dietary changes to limit sodium, potassium, phosphorus, and fluid intake. Regular physical activity will help give energy and reduce stress. Managing stress helps patients improve both physical and emotional health. Remaining connected to family and friends and continuing to be involved with enjoyable activities are important. Individuals with kidney disease should be supported to seek mental health services when needed.

Family members and caregivers are often the silent heroes for individuals with kidney disease. It is not uncommon for other family members to take over important roles that the person with CKD can no longer perform. The roles assumed may include responsibility for employment and income issues, transportation, household tasks and activities, and caring for children or dependent adults. Life partners may also be depressed by the changes that kidney disease brings to their intimacy. All of these changes often create conflict and stress. Family caregivers may be reluctant to disclose how stressed they are feeling to avoid placing an additional burden on the patient. The caregiver may even feel guilty or that they do not have a right to care for themselves and their own issues. Caregivers are at risk for depression and "burn out" if they neglect their own physical, mental, and social needs.

How can the CKD care teams help with the needs of the patient and caregivers? What are the "best practices" for incorporating these topics into patient and family education? First, early diagnosis and referral for CKD education can help many individuals prepare for the eventual transition to life with dialysis. Second, some people are diagnosed late in the course of the disease and face dialysis with very little time to prepare. These individuals must learn to adapt quickly. Third, patients and families must continue to cope with the evolving and changing demands of CKD and its treatment (dialysis or transplant) for the rest of their lives. This includes learning new skills to manage as one's physical condition changes and learning to cope with the ever-present emotional "ups and downs."

The dialysis center is often viewed as the "second" home for the dialysis patient, with other patients and treatment staff seen as family. A meaningful and open relationship between patients and the CKD care team is important for successful self-management. Successful self-management can help patients cope with the physical and emotional aspects of dialysis and mitigate depression. The care team has an important role in educating and helping patients learn to cope. The book F*acilitating Treatment Adherence: A Practitioner's Guidebook* suggests several steps to help patients and families cope (3):

- Clearly introduce oneself and one's role with CKD patients, explaining how you can help.
- Explore patient's worries, goals, and expectations; empathize.
- Answer all patient questions.
- Avoid medical jargon; avoid being too technical.
- Discuss treatment pros, cons, and tradeoffs.
- Ask for the patient's suggestions and preferences and negotiate any disagreements.

Self-management is an important strategy to help CKD patients deal with the stress of treatment, including depression. Open and supportive communication and education between the individual with CKD and the care team are critical.

Charlie Thomas is a social worker with Banner-University Medical Center Phoenix, Transplant and Advanced Liver Disease, in Phoenix, AZ.

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Using Creative Arts Therapy for Healing

By Sharon Itkoff

Creative arts therapy is a form of psychotherapy that draws on the creative process along with traditional talk therapy to facilitate personal growth, insight, and resilience. Because chronic illnesses, such as ESRD and chronic kidney disease, can have psychosocial and spiritual effects on one's mind, body, and relationships, art therapy as a treatment modality can be used to supplement traditional medical approaches to help one seek balance, wholeness, and self-actualization instead of just focusing on the cure. When one's energy is shifted from finding a cure to improving his or her quality of life in the here and now, the locus of control moves from external to internal, which is healing in and of itself. Art making in a therapeutic context can also provide a less threatening way to access feelings that may otherwise be too overwhelming. Moreover, creating "art for art's sake" is an exercise of self-care that can cultivate self-compassion and aid in healing.

Stress is a contributing factor to developing ESRD, and symptoms often include feeling generally ill and fatigued, drowsy, confused, and having difficulty concentrating. The organizing, containing, and stress-reducing effects of art making can alleviate free-floating anxiety and build self-esteem through helping one to develop a sense of mastery over the successful completion of an art project that is within one's control. Feelings of self-worth are also cultivated through engaging in the challenge of learning a new skill and thereby, taking healthy creative risks. Feelings of hopelessness and depression are combated through opportunities to show utility and continuity by creating an art object that withstands time as a sort of tangible personal legacy (1).

Art making provides a healthy distraction that can aid in pain management as well, because research has shown that spiritual or emotional suffering can lower one's physical pain threshold (2). Becoming absorbed in a creative project can also shift attention away from negative thought loops and improve frustration tolerance in working on a task step by step over time. Moreover, art therapy can allow patients to "re-author the dominant narrative of their ailment and provide a way to explore 'posttraumatic growth'" and the creation of a post-illness identity (3).

In an art therapy group or private session, the relational component of having another person witness a creative process can reduce the isolation that often occurs when one defends against the depression or anger toward the physical health condition or illness. From a humanistic perspective, a new social identity as artist can be fostered as opposed to just patient. The therapeutic alliance that develops between an art therapist and patient can enhance a sense of relatedness and connection and help one feel seen, validated, and understood, because the creative process is witnessed through a compassionate lens; moreover, in viewing patient artwork, family, friends, and caregivers are also invited into the patient's creative process and can view them more multidimensionally than simply ill (2).

In sum, living with chronic illness and experiencing associated depressive symptoms can wear on one's mind, body, and personal coping tools. Art therapy is an effective treatment modality for helping one to reconnect with his or her life energy and innate creativity and thereby, facilitate transformative healing from the inside out.

Sharon Itkoff is a licensed creative arts therapist in New York, NY.

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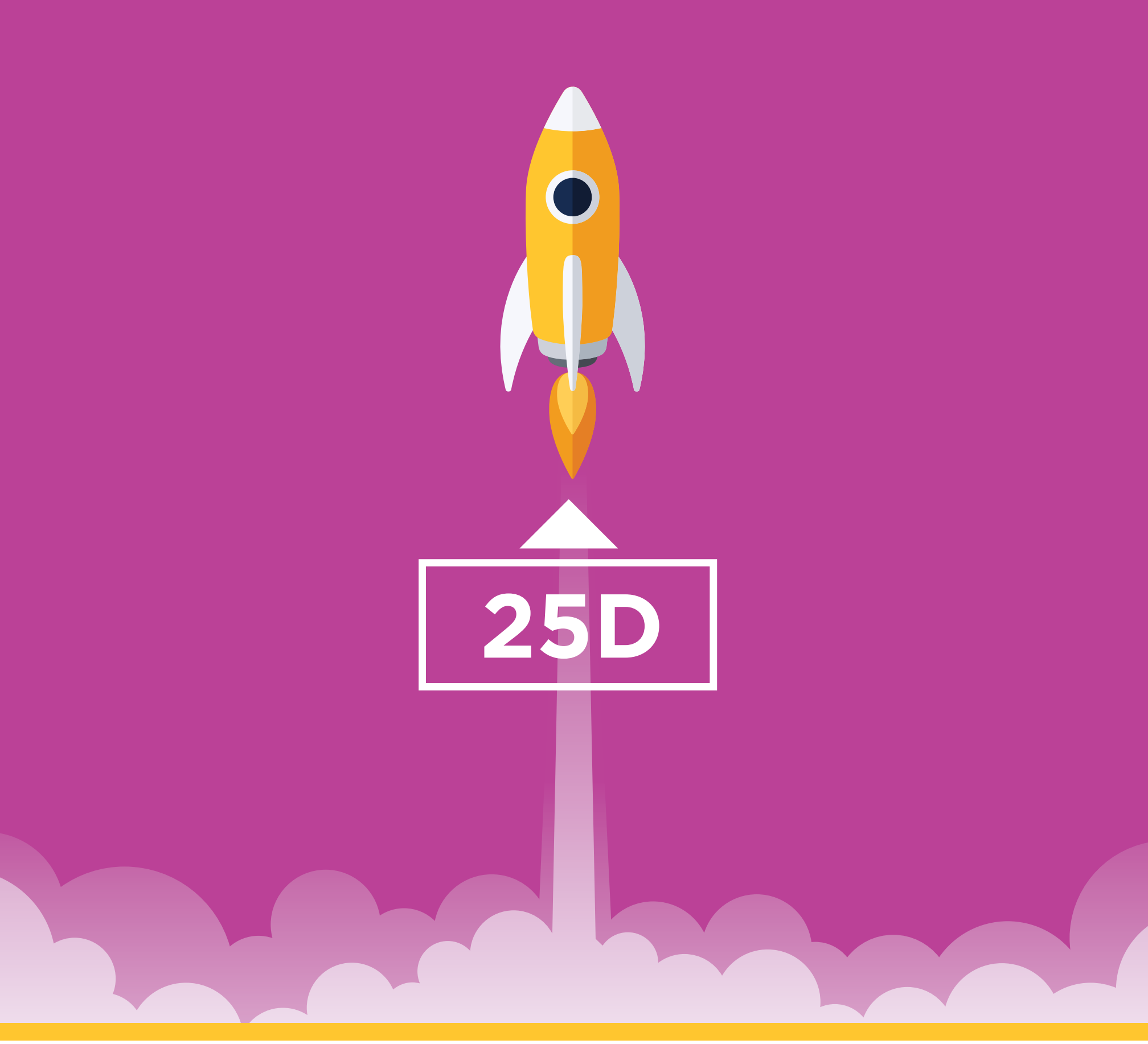

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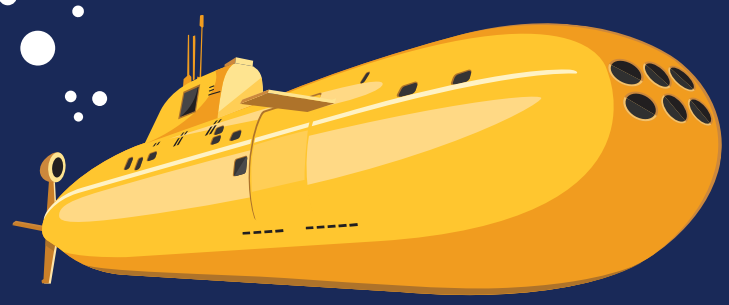

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Findings

Diabetes Becomes Top Cause of Chronic Kidney Disease in China

Diabetes has overtaken glomerulonephritis as the most common cause of chronic kidney disease (CKD) in China, according to a research letter in *The New England Journal of Medicine*.

Using Chinese national hospital and population databases, the researchers analyzed trends in CKD from 2010 through 2015. Based on medical history and laboratory data, cases of CKD were classified as related to diabetes or glomerulonephritis.

In 2010, the percentage of hospitalized patients with diabetes-related CKD was 0.82% and 1.01% with CKD related to glomerulnephritis. The percentage with diabetes-related CKD became larger starting in 2011, with a widening gap in subsequent years. By 2015, the figures were 1.10% for diabetes-related CKD versus 0.75% for glomerulonephritis-related CKD.

In a nationally representative population sample of about 47,000 participants in 2009–10, the percentage with diabetes-related CKD was 1.23% while 0.91% had glomerulonephritis-related CKD. Diabetes-related CKD was more prevalent in both urban and rural areas, although the difference was smaller for rural residents.

In developing countries, glomerulonephritis has been the predominant cause of end stage renal disease. In China, the prevalence of diabetes has increased in recent decades.

The new findings show that diabetes is now the predominant cause of CKD in China, in hospitalized patients as well as in the general population. Based on a 21.3% rate of CKD among diabetics, the researchers estimate there are 24.3 million patients with diabetes-related CKD in China [Zhang L, et al. Trends in chronic kidney disease in China. *N Engl J Med* 2016; 375:905–906].

Delayed Treatment Linked to Renal Scarring in Children with UTIs

For children with febrile urinary tract infections (UTIs), the risk of new renal scarring increases with each hour of delay to antimicrobial treatment, suggests a study in *JAMA Pediatrics*.

The retrospective analysis included data on 482 children from two previous longitudinal studies. Both studies included 2- to 72-month-old children (median age 11 months) with their first or second UTI. Ninety percent of children were girls and 78% had vesicoureteral reflux. Duration of fever before the start of antimicrobial therapy was analyzed for association with new renal scarring, based on the finding of photopenia plus contour change on a dimercaptosuccinic acid renal scan at two-year follow-up.

New renal scarring occurred in 7.2% of children. Delays to antimicrobial therapy were associated with renal scarring. Median duration of fever before the start of antimicrobial treatment was 72 hours in children with renal scarring versus 48 hours in those without scarring.

The association remained significant after adjustment for age, race/ethnicity, bacterial cause, and previous or interim UTIs. For each hour's delay to antimicrobial therapy, there was a 0.8% increase in the odds of new renal scarring. Number of segments with renal scarring was independently associated with height of fever and interim UTIs, but not with delay to treatment.

Delays to antibiotic treatment have been suggested to increase the risk and extent of renal scarring in children with febrile UTIs. The new results indicate that delaying treatment for 48 hours or longer increased the odds of new renal scarring by nearly 50%. The investigators conclude, "[C]linicians should not delay testing in febrile children who could potentially have a UTI" [Shaikh N, et al. Early antibiotic treatment for pediatric febrile urinary tract infection and renal scarring. *JAMA Pediatr* 2016; 170:848–854].

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Plenary Session

State-of-the-Art Lecture

Genetics of Obesity to be Subject of State-of-the-Art Lecture

Stephen O'Rahilly, MD

Stephen O'Rahilly, MD, will speak on "The Causes and Consequences of Obesity: Lessons from Genetics" in a state-of-the-art lecture on Thursday, Nov. 17.

Dr. O'Rahilly is professor of clinical biochemistry and medicine and head of the department of clinical biochemistry at the University of Cambridge and honorary consultant physician at Addenbrooke's Hospital in Cambridge, UK. He is active in clinical practice and in teaching medical students.

In his research, he has sought to better understand the molecular mechanisms leading to diabetes, obesity, and related metabolic and endocrine disorders. Dr. O'Rahilly led the establishment of the Wellcome Trust-MRC Institute of Metabolic Science, which he co-directs along with directing the institute's metabolic diseases unit. He is scientific director of the National Institute for Health Research's Cambridge Biomedical Research Centre.

Dr. O'Rahilly is currently president of the Society for Endocrinology. He served as chair of the UK Medical Research Society and as a member of the biological awards committee of the Royal Society.

He was the founding editor of *Cell Metabolism, Disease Models & Mechanisms*, and *EMBO Molecular Medicine*, where he still serves on the editorial board. He currently serves on the editorial board of *Reviews in Endocrine & Metabolic Disorders* and has been on the boards of the *Quarterly Journal of Medicine, Diabetic Medicine*, and *PLOS Biology*.

Dr. O'Rahilly has won many national and international awards, including the Heinrich Wieland Prize, the Inbev Baillet Latour Prize, the Zülch Prize, and the first European Association for the Study of Diabetes/Novo Nordisk Foundation Diabetes Prize for Excellence. He was elected to the Royal Society in 2003 and as a foreign associate of the US National Academy of Sciences in 2011. He is an honorary member of the German Society for Internal Medicine. He was appointed a Knight Bachelor in 2013.

He received his medical degree from the National University of Ireland and undertook postgraduate training in London, Oxford, and Boston before setting up his laboratory in Cambridge in 1991.

Blagg Lectureship to Cover Patients' Hospital Transition Process

David O. Meltzer, MD, PhD

David O. Meltzer, MD, PhD, will discuss "Optimizing Transitions for Our Patients in and out of the Hospital: Justifying Theory and Practice" in the Christopher R. Blagg, MD, Lectureship in Renal Disease and Public Policy on Thursday, Nov. 17.

Dr. Meltzer is chief of the section of hospital medicine, director of the Center for Health and the Social Sciences, director of the UChicago Urban Health Lab, and chair of the Committee on Clinical and Translational Science at the University of Chicago. He is also the Fannie L. Pritzker Professor in the department of medicine, the Harris School of Public Policy Studies, and the department of economics.

Dr. Meltzer's research explores problems in health economics and public policy with a focus on the theoretical foundations of medical cost-effectiveness analysis and the cost and quality of hospital care. He has performed randomized trials on the use of hospitalists to specialize in inpatient care. He is currently leading a Center for Medicare and Medicaid Innovation challenge award to study the effects of improved continuity in the doctor-patient relationship between the inpatient and outpatient setting, focusing on the costs and outcomes of care for frequently hospitalized Medicare patients.

He helped lead the formation of the Chicago Learning Effectiveness Advancement Research Network (Chicago LEARN), which helped pioneer collaboration of Chicago-area academic medical centers in hospital-based comparative effectiveness research. He was also a leader of the Chicago Area Patient Centered Outcomes Research Network (CAPriCORN), which was funded by the Patient-Centered Outcomes Research Institute (PCORI).

Dr. Meltzer is a research associate of the National Bureau of Economic Research, an elected member of the American Society for Clinical Investigation, and past president of the Society for Medical Decision Making. He has served on several Institute of Medicine panels, including one examining US organ allocation policy.

He also has served on the Advisory Committee on Healthy People 2020 of the US Department of Health and Human Services, on the PCORI methodology committee, as a council member of the National Institute for General Medical Studies, and as a health economics adviser for the Congressional Budget Office. Dr. Meltzer has received many awards, including the Eugene Garfield Award from Research America, the Eisenberg Excellence in Mentoring Award from the Agency for Healthcare Research and Quality, and the Learning Healthcare System Award from the Association of American Medical Colleges. He is a member of the National Academy of Medicine.

Dr. Meltzer received both his MD and his PhD in economics from the University of Chicago and completed his residency in internal medicine at Brigham and Women's Hospital in Boston.

Genetics of Renal Diseases to Be Outlined in Winn Lecture

Cheryl Ann Winkler, PhD

A pioneer in investigations to reveal the host's genetic architecture related to infectious diseases and associated co-morbidities will speak on "GWAS in Nephrology." Cheryl Ann Winkler, PhD, will deliver the Michelle P. Winn, MD, Endowed Lectureship on Thursday, Nov. 17.

Dr. Winkler is a senior investigator in the basic research laboratory and head of the molecular genetic epidemiology section at the National Cancer Institute. She led the genetics team that used admixture mapping to identify the region of chromosome 22 harboring *MYH9* and *APOL1*, two genes associated with kidney diseases. That research identified *MYH9* as a major susceptibility gene for common etiologies of chronic and end stage renal disease and *APOL1*'s role in the greatly increased susceptibility of African Americans to HIV-associated nephropathy and focal segmental glomerulosclerosis (FSGS).

APOL1 variants are predictors of chronic kidney disease and markers for progression, but they also protect against the tropical disease trypanosomiasis, commonly known as sleeping sickness. Her team is now identifying the spectrum of phenotypes associated with *APOL1* risk alleles in American and African cohorts and investigating the pathophysiological mechanism leading to glomerular injury. They are studying the influence of *APOL1* risk variants on living kidney donors and on kidney graft survival in African Americans. A goal of this research is to develop biomarkers for diagnostics and prognostics and to identify drug targets to treat kidney diseases.

Her team is also participating in the Family Investigation of Nephropathy and Diabetes (FIND) consortium, with the goal of discovering genetic risk factors for diabetic nephropathy and end stage renal disease.

Dr. Winkler is author or co-author of more than 160 publications. She is also a senior principal scientist with Leidos Biomedical Research at the Frederick National Laboratory for Cancer Research as well as an honorary professor in the school of clinical medicine at the University of KwaZulu-Natal in South Africa.

Dr. Winkler received a master's degree in genetics and a PhD in immunogenetics from the University of Maryland, College Park. She completed her dissertation research and a postdoctoral fellowship at the laboratory of genomic diversity at the National Cancer Institute.

Biomarkers of Diabetic Kidney Disease to Be Subject of Schrier Lectureship

Robert G. Nelson, MD, PhD

A researcher with decades of experience will deliver the Robert W. Schrier, MD, Endowed Lectureship, entitled "Biomarkers of Structural Pathology in Diabetic Kidney Disease and Renal Function Decline," on Friday, Nov. 18.

Robert G. Nelson, MD, PhD, is a senior investigator with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). He has conducted studies of type 2 diabetes and its complications in the Pima Indians for the past 30 years. His research focuses primarily on the kidney complications of type 2 diabetes, and his areas of special interest include the natural history, genetic and environmental determinants, pathophysiology, and treatment of diabetic nephropathy. His most recent work focuses on studies of glomerular structure, gene expression in kidney tissue, and biomarkers of diabetic nephropathy.

He has worked with National Kidney Foundation committees on practice guidelines for diabetes and chronic kidney disease (CKD); proteinuria and other markers of CKD; and evaluation, classification, and stratification of CKD. He serves on an expert group on diabetes complications for the World Health Organization's global burden of disease study. He has served on the executive committee of the European Diabetic Nephropathy Working Group and on the scientific sessions planning committee of the American Diabetes Association. He is currently a member of the World Congress of Nephrology's scientific program committee.

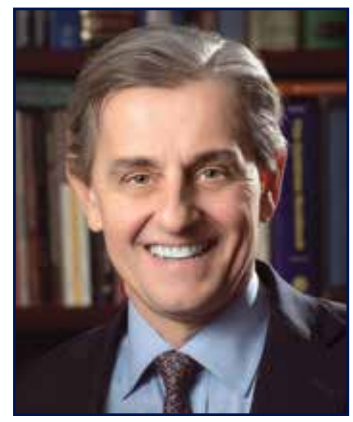
Dr. Nelson has been on the editorial board of the *American Journal of Kidney Diseases* and is currently on the boards of *Primary Care Diabetes* and *Nephrology News & Issues*. His research and other activities have resulted in almost 300 publications.

He has received many awards, including the Ruth Osterby Award from the European Diabetic Nephropathy Study Group, several plain language awards for educational videos from the National Institutes of Health, and the L.S. Goerke Memorial Award from the UCLA School of Public Health.

Dr. Nelson received his medical degree from Loma Linda University, an MPH from Harvard University, and a PhD in epidemiology from the University of California, Los Angeles.

State-of-the-Art Lecture

Lecturer Will Discuss Replacing Drugs with Electronic Devices



Kevin J. Tracey, MD

Reflex Circuits in Immunity: Bioelectronic Medicine" is the title of a state-of-the-art lecture on Friday, Nov. 18.

Kevin J. Tracey, MD, is president and CEO of the Feinstein Institute for Medical Research, professor of neurosurgery and molecular medicine at Hofstra Northwell School of Medicine, and executive vice president for research at Northwell Health in Manhasset, NY.

The main focus of Dr. Tracey's laboratory is the molecular basis of inflammation and the mechanism by which neurons control the immune system. His laboratory discovered the molecular mechanism for the neural control of inflammation, now termed the inflammatory reflex. This discovery led to the development of devices that use electrons delivered to neurons as a replacement for anti-inflammatory drugs—a new approach called bioelectronic medicine.

His lab participated in the first successful clinical trial demonstrating that vagus nerve stimulation can be effective in methotrexate-resistant rheumatoid arthritis patients.

An inventor with more than 60 US patents, Dr. Tracey is also cofounder of the Global Sepsis Alliance, a nonprofit organization supporting the efforts of 1 million caregivers in more than 70 countries to understand and combat sepsis. He is the author of *Fatal Sequence* and more than 320 scientific papers.

He has been inducted into the American Society of Clinical Investigation, the American Association of Physicians, and the Long Island Technology Hall of Fame, and is a fellow in the American Association for the Advancement of Science. His honors include an honorary degree from the Karolinska Institute, Stockholm, Sweden, and lectureships from Harvard, Yale, Rockefeller University, the National Institutes of Health, among others.

Dr. Tracey received his MD from Boston University. He trained in neurosurgery at the New York Hospital/Cornell University Medical Center, and was a guest investigator at the Rockefeller University. Since 1992, he has directed the Laboratory of Biomedical Science in Manhasset, where he was appointed president of the Feinstein Institute in 2005.

Fibrotic Changes Could Be Key to Progression from Injury to Chronic Disease

Benjamin D. Humphreys, MD, PhD

The leader of a laboratory focused on kidney injury will speak on "Fibrotic Changes Mediating AKI to CKD Transition."

Benjamin D. Humphreys, MD, PhD, FASN, will deliver the Barry M. Brenner, MD, Endowed Lectureship on Friday, Nov. 18.

Dr. Humphreys is the Chromalloy Associate Professor of Medicine and chief of the division of nephrology at Washington University School of Medicine in St. Louis. He leads a division of 33 faculty members with $5.5 million in yearly research grants.

His National Institutes of Health-funded laboratory focuses on adult kidney injury (AKI) and repair. The laboratory has special expertise in genetic mouse models of kidney diseases and stem cell biology, employing these approaches to identify new treatments for patients suffering from acute and chronic kidney diseases. To validate its discoveries in mice, the laboratory generated a substantial human kidney biobank. The researchers' current efforts focus on defining transcriptional profiles in individual kidney cell types from human kidney biopsies.

Prior to joining Washington University in 2015, Dr. Humphreys was director of the Harvard Stem Cell Institute Kidney Program and associate professor of medicine at Harvard Medical School and Brigham and Women's Hospital in Boston. The Harvard Stem Cell Institute uses mouse genetics, genomic techniques, and traditional molecular and biochemical approaches to study and model human kidney diseases in two main areas: 1) In AKI, where research into signaling pathways that enable kidney repair identified novel pathways regulating epithelial proliferation and re-differentiation after injury. 2) In chronic kidney disease, where the researchers identified the cells responsible for kidney fibrosis and designed new approaches to limiting the damage these cells do to kidney tissue.

Dr. Humphreys has authored over 100 publications and many book chapters. He holds five patents.

He is a member of the American Society of Clinical Investigation and an established investigator with the American Heart Association. He received the National Kidney Foundation Young Investigator Award and the American Society of Nephrology Gottschalk Research Scholar Award.

Dr. Humphreys earned his medical and doctoral degrees from Case Western Reserve University. He completed a residency in internal medicine at Massachusetts General Hospital and a fellowship in nephrology at Brigham and Women's Hospital.

Plenary Session

State-of-the-Art Lecture

Drosophila Researcher to Describe Lessons for Nephropathy

Ross L. Cagan, PhD

A pioneer in the field will deliver a state-of-the-art lecture on "A Fly Model of Diabetic Nephropathy" on Saturday, Nov. 19.

Ross L. Cagan, PhD, is a professor in the department of developmental and regenerative biology as well as senior associate dean of the graduate school of biological sciences at the Icahn School of Medicine at Mount Sinai in New York City. He is also director of the Center for Personalized Cancer Therapeutics and co-founder of the biotechnology company Medros.

Dr. Cagan is an expert in using the fruit fly *Drosophila* to explore cell–cell signaling and epithelial patterning with a particular interest in translational science. He has pioneered the use of *Drosophila* to develop complex models of diabetes and of breast, lung, colorectal, and thyroid cancers. Taking advantage of a century of powerful genetic tools, his laboratory has developed complex, multigenic models of specific aspects of human disease to pursue polypharmacological as well as personalized approaches to treatment. His laboratory's emphasis has been on in situ exploration of cellular phenomena using approaches that include live visualization, cell ablation, computational modeling, and high-throughput drug screening.

In addition to studying the mechanisms that direct diabetes and cancer, including diabetic nephropathy and diabetic cardiomyopathy, he has developed a novel robotics-based approach for screening whole animals for therapeutic drugs. He is conducting a clinical trial in which robotics-based screening of personalized fly avatars is used to develop tailored therapeutics for colorectal and thyroid cancer. His work helped lead to Food and Drug Administration approval of the first chemotherapy for medullary thyroid carcinoma.

Dr. Cagan is editor-in-chief of the journal *Disease Models and Mechanisms* and is on the editorial board of *Breast Cancer: Targets and Therapy*.

He received his doctoral degree in developmental neurobiology from Princeton University. After a postdoctoral fellowship at UCLA, he achieved the rank of professor at Washington University School of Medicine before joining the Icahn School of Medicine in 2007.

ASN Kidney Week 2016

Educational Symposia Schedule

Thursday, November 17 – Saturday, November 19
McCormick Place and Hyatt Regency

Continuing Education (CE) Credit

This activity is eligible for CE credit.
Visit *www.asn-online.org/KidneyWeek* for more information.

Lunch will be served at each symposium. Seating is limited and available on a first-come, first-served basis to fully paid Annual Meeting participants.

Doors open 15 minutes prior to each session.

Thursday, November 17 — 12:45 p.m. – 1:45 p.m.	Location
A Balanced Approach to Phosphorus Balance *Support for this symposium is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*	**Hyatt Regency** **Regency Ballroom**
CKD-MBD Guideline Update: A Critical Appraisal of Recent Studies *Support for this symposium is provided by an educational grant from **Sanofi US**.*	**McCormick Place** **W196**
Diagnosis and Management of Tubular Disorders in Children *Support for this symposium is provided by an educational grant from **Raptor Pharmaceuticals**.*	**McCormick Place** **S401**
Hepatitis C Virus Infection and Patients with Kidney Disease *Support for this symposium is provided by an educational grant from **Merck**.*	**McCormick Place** **S100B-C**
Prevention and Treatment of Chronic Hyperkalemia *Support for this symposium is provided by an educational grant from **Relypsa, Inc**.*	**McCormick Place** **S100A**

Friday, November 18 — 12:45 p.m. – 1:45 p.m.	Location
Approach to the Management of Acute and Chronic Hyperkalemia in the Complicated Patient *Support for this symposium is provided by an educational grant from **ZS Pharma**.*	**McCormick Place** **S401**
Basic Science Symposium–New Approaches for High Resolution Imaging: From Proteins to Cells to Tissue *This symposium is sponsored by the **American Society of Nephrology (ASN)**.*	**Hyatt Regency** **Prairie Room**
Emerging Trends in the Management and Role of Vitamin D Insufficiency *Support for this symposium is provided by an educational grant from **OPKO Renal**.*	**McCormick Place** **W196**
Expanding the Therapeutic Armamentarium for Treatment of Anemia of Kidney Disease *Support for this symposium is provided by an educational grant from **AstraZeneca and FibroGen**.*	**McCormick Place** **S100A**
Fluid Management in Hemodialysis: Determining the Goal and Reaching It *Support for this symposium is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*	**McCormick Place** **S100B-C**
KDIGO Guidelines in CKD-Mineral and Bone Disorder: Time for Reassessment? *This activity is supported by educational funding provided by **Amgen**.*	**Hyatt Regency** **Regency Ballroom**

Saturday, November 19 — 12:45 p.m. – 1:45 p.m.	Location
Hypoxia-Inducible Factors: The Future of Anemia Management in CKD? *Support for this symposium is provided by an educational grant from **Akebia Therapeutics**.*	**McCormick Place** **S100A**
Iron and Anemia in Chronic Kidney Disease: Oral Iron Intake Revisited *Support for this symposium is provided by an educational grant from **Keryx Biopharmaceuticals, Inc**.*	**McCormick Place** **W196**
Urgent-Start Peritoneal Dialysis: Has It Come of Age? *Support for this symposium is provided by an educational grant from **Fresenius Medical Care Renal Therapies Group**.*	**McCormick Place** **S100B-C**

Plenary Session

State-of-the-Art Lecture

Diabetes Drug Designer to Speak on the Development Process

Daniel M. Drucker, MD

An endocrinologist whose research has led to new treatments for diabetes will share insights from this work in a state-of-the-art lecture on Sunday, Nov. 20, entitled "Enteroendocrine Physiology Informs Drug Design for Type 2 Diabetes and Obesity."

Daniel M. Drucker, MD, is a senior scientist at the Lunenfeld-Tanenbaum Research Institute at Mt. Sinai Hospital and a professor of medicine at the University of Toronto.

A pioneer in diabetes treatment, Dr. Drucker's work has provided important insights leading to the development of new drugs for the treatment of type 2 diabetes. His lab carried out the basic science supporting the development of two new classes of therapies for type 2 diabetes and a new therapy for patients with short bowel syndrome requiring parenteral nutrition. His research also shows tremendous promise for the treatment of obesity.

"My laboratory studies the molecular biology, physiology, and mechanism(s) of action of peptide hormones, and their G-protein-coupled receptors. We are particularly interested in the translational relevance of these peptidergic networks for the treatment of human metabolic disorders, and the emphasis in our laboratory is on translational science with therapeutic potential," Dr. Drucker says. The lab's focus is the family of hormones produced in the pancreas, gastrointestinal tract, and brain that control blood glucose and insulin secretion as well as regulate appetite, nutrient absorption, and the conversion of those nutrients to energy.

His team's contributions to this field are reflected by several hundred publications, more than 40,000 citations of those publications, and 33 US patents covering various therapeutic aspects of peptide hormone action. Dr. Drucker's lab is internationally known not only for its research, but also for pursuing the clinical relevance of scientific breakthroughs.

Dr. Drucker has served on the editorial boards of the *American Journal of Physiology-Endocrinology* and *Metabolism* and *Endocrine Reviews*. He is currently on the boards of *Nature Reviews Endocrinology, Gastroenterology*, and *Diabetes*, and is associate editor of *Endocrinology*.

He has received an array of international awards, including the Clinical Investigator Award from the Endocrine Society, the Oon International Award for Preventive Medicine from the Cambridge University School of Medicine in the UK, the Banting Medal for Scientific Achievement from the American Diabetes Association, the Manpei Suzuki International Prize for Diabetes Research from the Manpei Suzuki Foundation in Japan, and the Canadian Diabetes Association Outstanding Young Scientist Award.

Dr. Drucker trained in internal medicine and endocrinology at the Johns Hopkins Hospital in Baltimore and Toronto General Hospital. He completed a research fellowship in molecular endocrinology at Massachusetts General Hospital. He established his own laboratory research program in 1987 in Toronto.

Young Investigator Honored for Living Donor Work

Amit X. Garg, MD, PhD

The ASN-AHA Young Investigator Award and Address will focus on kidney transplants on Sunday, Nov. 20. Amit X. Garg, MD, PhD, will speak on "Living Kidney Donor Transplantation: Improving Safety, Access, and Outcomes."

Dr. Garg is a professor of medicine, epidemiology, and biostatistics at Western University in London, Ontario; site director of the Institute for Clinical Evaluative Sciences (ICES) Western Facility; and provincial leader of the ICES kidney, dialysis, and transplantation program. He practices general nephrology and is director of living kidney donation at the London Health Sciences Centre.

Dr. Garg is active in clinical, health services, and population-health kidney research, with more than 370 peer-reviewed publications. Some examples of the impact of his research include the introduction of new information for living kidney donor candidates as part of the informed consent process; an improved understanding of the long-term outcomes of *E. coli* O157:H7 poisoning that has been cited in litigation to compensate victims of food or water mishandling; and findings about unsafe drug prescribing causing acute kidney injury that led to label changes by the US Food and Drug Administration.

Dr. Garg currently serves as president of the Canadian Society of Nephrology, which he previously served as secretary-treasurer. He recently co-chaired the international Kidney Disease: Improving Global Outcomes clinical practice guidelines in living kidney donation committee. He serves on the living kidney donor advisory committee of Canadian Blood Services. He is also the medical lead for the Ontario Renal Network, working for greater access to kidney transplantation.

He serves on the editorial boards of the *American Journal of Kidney Diseases* and the *Journal of the American Society of Nephrology*.

He has received a National Kidney Foundation international distinguished medal for his research contributions to renal medicine, a premier of Ontario research excellence award, and a trainee research award from the Canadian Society of Nephrology.

Dr. Garg received his MD from the University of Toronto, completed an internal medicine residency at McMaster University, completed a nephrology fellowship at Western University, and received a PhD in health research methodology from McMaster University.

Researcher to Explore Kidney Diseases' Effects on Bone

Susan M. Ott, MD

Susan M. Ott, MD, will describe the "Pathophysiology of Renal Osteodystrophy" in the Jack W. Coburn, MD, Endowed Lectureship on Sunday, Nov. 20. Dr. Ott is professor of medicine at the University of Washington. She performed her first research with Dr. Donald Sherrard and Dr. Jack Coburn, investigating the effect of aluminum on renal osteodystrophy. Other studies have involved bone density measurements, bone histomorphometry, medical treatments for osteoporosis, effects of reproduction on the skeleton, and long-term effects of bisphosphonates.

Dr. Ott served on data safety and monitoring committees for the National Institutes of Health's clinical nutrition and bone trials. She also participated on the KDIGO (Kidney Disease: Improving Global Outcomes) international committee that developed a clinical guideline for treatment of the mineral and bone disorder aspects of chronic kidney disease.

She was on the editorial boards of the *Journal of Bone and Mineral Research* and the *Journal of Clinical Endocrinology and Metabolism*. She served on the council of the American Society of Bone and Mineral Research. Among her honors, she received a clinical investigator award from the National Institutes of Health and a young investigator award from the International Symposium on Osteoporosis.

Dr. Ott attended medical school at the University of Washington and residency training at the University of California at Davis. She returned to the University of Washington for a fellowship during the last year that Dr. Belding Scribner was chairman of nephrology.

ASN 50 years

As part of ASN's 50th anniversary, the society recognizes all the individuals who have received awards to honor their work in leading the fight against kidney diseases.

Robert G. Narins Award

The Robert G. Narins Award honors individuals who have made substantial and meritorious contributions in education and teaching. This award is named for Robert G. Narins, who is also the first recipient of the award.

Dr. Narins' contributions to education and teaching started in 1967 when he was appointed to the faculty of the University of Pennsylvania. At Penn, and on the faculties of UCLA, Harvard, Temple, and Henry Ford Hospital, he taught and mentored many residents and fellows. For eight years he chaired the ABIM's Nephrology Board and also worked on the ACP's Annual Program Committee. His contributions to education in the fields of fluid-electrolyte and acid-base physiology are prodigious and well-recognized.

Dr. Narins was also involved in the creation and planning of many ASN educational programs during Renal Week and throughout the year, including: Board Review Course and Update, one- and two-day programs at Renal Week, Renal WeekEnds, and NephSAP. He also was instrumental in the decision to develop the *Clinical Journal of the American Society of Nephrology (CJASN)*, the establishment of the Fellow of the American Society of Nephrology (FASN) program, and negotiated the successful partnership agreements with HDCN and UpToDate. Dr. Narins has been at the forefront of collaborative efforts with the American College of Physicians to increase the exposure of nephrologists to relevant updates in Internal Medicine and internists to chronic kidney disease. Collaborative educational programs with societies in Europe and Asia have helped to spread education and teaching in nephrology on a global scale.

Award Winners

- 2015 Mark L. Zeidel, MD, FASN
- 2014 Stuart L. Linas, MD, FASN
- 2013 Mark E. Rosenberg, MD, FASN
- 2012 Donald E. Kohan, MD, PhD, FASN
- 2011 Agnes B. Fogo, MD
- 2010 Barry M. Brenner, MD
- 2009 Burton D. Rose, MD
- 2008 Mitchell L. Halperin, MD
- 2007 Richard J. Glassock, MD
- 2006 Robert G. Narins, MD, FASN

John P. Peters Award

The John P. Peters Award recognizes individuals who have made substantial research contributions to the discipline of nephrology and have sustained achievements in one or more domains of academic medicine including clinical care, education, and leadership. Established in 1983, this annual award is named for one of the fathers of the discipline of nephrology.

Dr. Peters spent his entire faculty career at Yale University where he was chief of the Metabolic Division in the Department of Medicine from 1922 to 1955. Building on the principles of his mentor, Donald Van Slyke, Dr. Peters transformed clinical chemistry from a discipline of qualitative impressions to one of precise quantitative measurements. These advances changed the nature of measurements of body fluids into a vital part of the patient examination, capable of great explanatory power. He advanced the view that disease was a quantitative abnormality of normal physiological processes; and that by understanding disease, one could gain deeper understanding of normal processes.

His enduring scientific contributions paralleled his intense commitment to the care of the sick and a fervent mission to ensure that the physician was an advocate for the patient. These many qualities stand as a lofty monument to the art and science of nephrology.

Award Winners

- 2015 Roger C. Wiggins, MB, BChir
- 2014 Josephine P. Briggs, MD
- 2013 David J. Salant, MBChB, MD
- 2012 Thomas D. DuBose, Jr., MD, FASN
- 2011 Jared J. Grantham, MD
- 2010 Roland C. Blantz, MD, FASN
- 2009 William E. Mitch, III, MD, FASN
- 2008 Robert Jay Alpern, MD
- 2007 Giuseppe Remuzzi, MD
- 2006 Gerhard H. Giebisch, MD
- 2005 Eric G. Neilson, MD, FASN
- 2004 Charles B. Carpenter, MD
- 2003 Eberhard Ritz, MD
- 2002 Alfred F. Michael, MD
- 2001 C. Craig Tisher, MD
- 2000 Barry M. Brenner, MD
- 1999 Ramzi S. Cotran, MD
- 1998 Saulo Klahr, MD
- 1997 Robert W. Schrier, MD
- 1996 Robert L. Vernier, MD
- 1996 Clark D. West, MD
- 1995 Charles R. Kleeman, MD
- 1994 Willem J. Kolff, MD
- 1993 Robert H. Heptinstall, MD
- 1993 Priscilla Kincaid-Smith
- 1992 Arnold S. Relman, MD
- 1992 William B. Schwartz, MD
- 1991 Neal S. Bricker, MD
- 1991 Roscoe R. Robinson, MD
- 1990 John H. Laragh, MD
- 1990 Louis Tobian, MD
- 1989 George E. Schreiner, MD, PhD
- 1988 Henry J. M. Barnett, MD
- 1988 Renee Habib, MD
- 1987 Jacob Churg, MD
- 1987 Conrad L. Pirani, MD
- 1986 Belding H. Scribner, MD
- 1985 Franklin H. Epstein, MD
- 1984 Jean Hamburger, MD
- 1984 John P. Merrill, MD
- 1983 Donald W. Seldin, MD

Continued on page 30

ASN 50 years

Belding H. Scribner Award

The Belding H. Scribner Award is presented annually to one or more individuals who have made outstanding contributions that have a direct impact on the care of patients with renal disorders or have substantially changed the clinical practice of nephrology. Established in 1995, this award honors the physician who developed the arteriovenous shunt that first made long-term hemodialysis for chronic renal failure possible.

Dr. Scribner spent his entire faculty career at the University of Washington in Seattle where he was Head of the Division of Nephrology in the Department of Medicine from 1958 to 1982. He and his co-workers made numerous contributions to the care of 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 contributions had an enormous effect in transforming nephrology into a major subspecialty of internal medicine.

Dr. Scribner and colleagues also played a major role in persuading Congress to fund the Medicare ESRD Program. His scientific contributions, his training of physicians interested in dialysis, his persistence in overcoming difficulties, his attention to ethical concerns, and his absolute commitment to the care of patients played major roles in the development of end stage renal disease care as it is today. These numerous accomplishments stand as an outstanding example of a dedicated physician who made major contributions to the care of patients with kidney disease.

Award Winners

- 2015 Glenn Matthew Chertow, MD, MPH, FASN
- 2014 Allan J. Collins, MD
- 2013 Andrew S. Levey, MD
- 2012 Nathan W. Levin, MD
- 2011 Neil R. Powe, MD, FASN
- 2010 Hans-Henrik Parving, MD
- 2009 James E. Cimino, MD
- 2008 Marshall D. Lindheimer, MD
- 2007 Edmund J. Lewis, MD
- 2006 Joel D. Kopple, MD, FASN
- 2005 William M. Bennett, MD, FASN
- 2004 Philip J. Held, PhD
- 2004 Friedrich K. Port, MD
- 2004 Robert A. Wolfe, PhD
- 2003 Jack W. Coburn, MD
- 2003 Jacob Lemann, Jr., MD
- 2002 R. Curtis Morris, Jr., MD
- 2002 Anthony Sebastian, MD
- 2001 Allen C. Alfrey, MD
- 2000 Fredric L. Coe, MD, FASN
- 2000 Charles Pak, MD
- 1999 Eduardo Slatopolsky, MD
- 1998 Dimitrios G. Oreopoulos, MD, PhD
- 1997 Karl D. Nolph, MD
- 1996 Frank A. Gotch, MD
- 1995 Jack Moncrief, MD
- 1995 Robert P. Popovich, PhD

Homer W. Smith Award

The Homer W. Smith Award is presented annually to an individual who has made outstanding contributions which fundamentally affect the science of nephrology, broadly defined, but not limited to, the pathobiology, cellular and molecular mechanisms and genetic influences on the functions and diseases of the kidney. Established in 1964, this award recognizes one of the major intellectual forces in renal physiology.

Dr. Smith spent the majority of his professional career at New York University, moving there in 1928 following a three-year tenure as Chairman of Physiology at the University of Virginia. As director of the Physiology Laboratories at NYU he developed and refined his concepts of glomerular filtration and tubular absorption and secretion of solutes. The clarity of his 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 into the field, not only to NYU, but also to the Mount Desert Island Biological Laboratory where he spent many summers studying renal physiology in fish.

His use of comparative approaches to explain normal human physiology stands as a model for students of biology and scientists attempting to unravel the mysteries of normal and disordered renal function. This award is in recognition of those who follow in his footsteps and contribute to our understanding of how the kidney functions normally and in disease states.

Award Winners

- 2015 Dontscho Kerjaschki, MD
- 2014 Friedhelm Hildebrandt, MD
- 2013 Stefan Somlo, MD
- 2012 Ernest M. Wright, PhD
- 2011 Anita Aperia, MD, PhD
- 2010 Wilhelm Kriz, MD
- 2009 René J. Bindels, PhD
- 2008 Peter C. Harris, PhD
- 2007 Qais Al-Awqati, MBChB
- 2006 Terry B. Strom, MD
- 2005 Walter F. Boron, MD, PhD
- 2004 Thomas J. Jentsch, MD, PhD
- 2003 Billy G. Hudson, PhD
- 2002 Jurgen B. Schnermann, MD
- 2001 Mark A. Knepper, MD, PhD
- 2000 Karl Tryggvason, MD, PhD
- 1999 Peter C. Agre, MD
- 1998 Richard P. Lifton, MD, PhD
- 1997 Steven C. Hebert, MD
- 1996 Bernard C. Rossier, MD
- 1995 Thomas E. Andreoli, MD
- 1994 Peter S. Aronson, MD, FASN
- 1993 James A. Schafer, PhD
- 1992 Jared J. Grantham, MD
- 1991 Heini Murer, PhD
- 1990 Klaus W. Thurau, MD
- 1989 Rolf Kinne, MD
- 1988 Marilyn G. Farquhar, PhD
- 1987 Joseph S. Handler, MD
- 1986 Emile L. Boulpaep, MD
- 1985 Philip R. Steinmetz, MD
- 1984 Barry M. Brenner, MD
- 1983 Eberhard Fromter, MD, PhD
- 1982 Floyd C. Rector, Jr., MD
- 1981 Alexander Leaf, MD
- 1980 Isidore S. Edelman, MD
- 1979 Francois Morel, MD
- 1978 Erich E. Windhager, MD
- 1977 Maurice B. Burg, MD
- 1976 Frank J. Dixon, MD
- 1975 Karl J. Ullrich, MD
- 1973 Jack Orloff, MD
- 1972 Hugh E. de Wardener, MD
- 1971 Gerhard H. Giebisch, MD
- 1970 Carl W. Gottschalk, MD
- 1969 James A. Shannon, MD, PhD
- 1968 Jean R. Oliver, MD
- 1967 Heinrich Wirz, MD
- 1966 Hans H. Ussing, PhD
- 1965 Robert W. Berliner, MD
- 1964 Robert F. Pitts, MD, PhD

ASN 50 years

Young Investigator Award

The Young Investigator Award is presented annually to an individual with an outstanding record of achievement and creativity in basic or patient-oriented research related to the functions and diseases of the kidney. This award is co-sponsored by the American Society of Nephrology and the Council on the Kidney of the American Heart Association and is limited to individuals who are age 45 or younger on December 31 of the year during which the award is presented.

The award consists of a certificate of recognition, an unrestricted grant of $5,000 to the laboratory of the awardee, and paid travel expenses to the meeting. The Young Investigator Award recipient also gives a presentation during the plenary session at the annual meeting.

Award Winners

- 2016 Amit X. Garg, MD, PhD
- 2015 Janos Peti-Peterdi, MD, PhD
- 2014 Myles S. Wolf, MD
- 2013 Jeremy Stuart Duffield, MBChB, MD, PhD
- 2012 Tobias B. Huber, MD
- 2011 Katalin Susztak, MD, PhD
- 2010 Nicholas Katsanis, PhD
- 2009 Matthias Kretzler, MD
- 2008 S. Ananth Karumanchi, MD
- 2007 Michelle P. Winn, MD
- 2006 Thomas Benzing, MD, FASN
- 2005 Raghu Kalluri, MD, PhD
- 2004 Jeffrey H. Miner, PhD, FASN
- 2003 Peter Mundel, MD
- 2002 Fadi G. Lakkis, MD
- 2001 Fiona E. Karet, MD, PhD
- 2000 Jing Zhou, MD, PhD, FASN
- 1999 Sanjay K. Nigam, MD
- 1998 Michael J. Caplan, MD, PhD
- 1997 Benjamin L. Margolis, MD
- 1996 Laurence A. Turka, MD
- 1995 Robert A. Star, MD
- 1994 Richard J. Johnson, MD
- 1993 Alan S. Verkman, MD, PhD
- 1992 Stephen L. Gluck, MD
- 1991 Stephen T. Reeders, MD
- 1990 Alan M. Krensky, MD
- 1989 Rajiv Kumar, MBBS, FASN
- 1988 Martin G. Cogan, MD
- 1987 Eric G. Neilson, MD, FASN
- 1986 Walter F. Boron, MD, PhD
- 1985 Peter S. Aronson, MD, FASN

President's Medal

ASN awards the ASN President's Medal to individuals who have helped advance ASN's mission to "lead the fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients."

The medal also recognizes individuals who have made contributions, broadly defined, to the kidney community, and who are unlikely to be eligible for ASN's other five awards. As a result, patients, members of Congress, and other advocates have received the ASN President's Medal in the past.

In considering candidates for the president's medal, ASN considers the society's strategic goal of "increasing diversity—including age and experience, ethnicity, and gender—at all levels of the society."

Award Winners

- 2015 George Lopez
- 2014 Representative Tom Marino
- 2014 Representative Jim McDermott
- 2013 Lori Hartwell
- 2012 Dolph Chianchiano
- 2007 Karen L. Campbell, PhD

Securing the Future

ASN Foundation for Kidney Research
Time for a Cure

THE CAMPAIGN FOR THE ASN FOUNDATION FOR KIDNEY RESEARCH

Today, ASN and the ASN Foundation for Kidney Research are leading the fight against kidney diseases by serving as the top advocates for—and major private funders of—nephrology research. Nephrology is primed for innovation, and current medical advancements make scientific breakthroughs more likely than ever. However, the pace of discovery and innovation in nephrology does not match the impact of kidney diseases on mortality and morbidity.

Together, ASN and the ASN Foundation for Kidney Research are making significant commitments to increase funding for fellows and early career investigators, improve diversity, and enhance mentorship. Success will be possible only if the kidney community comes together to prioritize funding for nephrology research. To this end, the ASN Foundation for Kidney Research is excited to launch the ***Securing the Future Campaign***.

THE CHALLENGE

- Lack of funding for kidney research compared to other diseases.
- Limited public awareness regarding the prevalence of kidney diseases.
- Lag of innovation in kidney care.
- Poor diversity in the nephrology workforce, especially when compared to the patient population.
- Small number of funded investigators when compared to the number of people suffering from kidney diseases.

The kidney community understands the importance of innovation and research in finding effective therapies and treatments. At no other time has the opportunity and promise been so great.

THE SOLUTION
Commitment to Research

ASN Foundation for Kidney Research

- Ben J. Lipps Research Fellowship Program - endowed in 2015 ☑
- William and Sandra Bennett Clinical Scholars Program
- ASN-Harold Amos Medical Faculty Development Program
- **Career Development Grants Program**
  - The program funds clinical, translational, and basic research.
  - Grants support candidates who show the most promise in producing innovative research to advance nephrology.
  - Tracking outcomes over time, the ASN Foundation has seen tremendous productivity from grant recipients.
  - Endowing the program will ensure this much needed research funding is available in perpetuity.
  - A fundraising effort is underway to endow annual grants by 2018.

Funding → **Next generation of nephrology clinicians, researchers, and educators** → **Innovation** → **Improved quality of life for patients**

Career Development Grants: Recipient Productivity (1996–2014)

133 Researchers	Published 1,606 Manuscripts	Received 123 Additional Awards*	35% Promoted in Academic Rank

The program develops successful researchers, produces future mentors, identifies tomorrow's leaders, and results in exciting scientific discoveries that will positively impact patient care.

*67 established investigator awards (R awards, VA merit); 22 career development awards (K-awards, VA awards); 34 foundation awards. Data as of 2014.

Since 1996, ASN and the ASN Foundation for Kidney Research have awarded $40,000,000 to support research, with over $30,000,000 dedicated to Career Development Grants.

Already, the ASN leadership has personally pledged more than $1,000,000 to the campaign.

MAKE AN IMPACT

The continued success of the Career Development Grants Program calls for increased engagement from the kidney community. The impact of this effort is far-reaching.

- **For patients** – the ASN Foundation's commitment to discovery means a chance for a greater quality of life and increased hope of ultimately curing kidney diseases.
- **For clinicians** – these grants fuel the innovation and pave the way for the new therapies and updated treatments that will improve the lives of their patients and change the way they practice nephrology.
- **For academia** – this funding makes it possible for early-career investigators to pursue and transition to independent research careers that will help them identify trends and areas of discovery.
- **For industry** – research funding will attract the best and brightest to consider the many challenges in renal research that will serve as the impetus for collaboration or additional studies to ensure better treatments and therapies for those with kidney diseases.

ASN and the ASN Foundation for Kidney Research are strengthening the kidney community's commitment to ensuring future funding for nephrology research.
To succeed, we need your help.

The time for change is now.
The time to secure our future is now. **Please join us.**

Visit www.asn-online.org/donate for more information and to see an updated list of donors.

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

A Special Thank You

to the following ASN Members
for their generous gifts and pledges to the
Securing the Future Campaign*

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AMGEN

Thank you to the *Securing the Future Campaign* Committee for leading this important effort.

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**donor list as of 9/26/16*

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 more than $3,000,000 annually to young investigators, fellows, and nephrology educators.

Founders Circle Members

Thanks to the generosity of our Founding Members, the ASN Foundation for Kidney Research endowed the Ben J. Lipps Research Fellowship Program in 2015, ensuring 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 to the Ben J. Lipps Research Fellowship Program:

Ben J. Lipps Research Fellowship Program Donors

FRESENIUS MEDICAL CARE

$10,000,000

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

$6,500,000

AMERICANRENAL® associates

$1,000,000

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$1,000,000

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$1,000,000

PKD FOUNDATION
Polycystic Kidney Disease

$500,000

The ASN Foundation for Kidney Research congratulates the talented group of researchers and educators who were awarded grants in 2016.

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

Pui Cheung, MD*
Massachusetts General Hospital
Inhibition of EGFR Signaling as a Novel Therapy for Nephrogenic Diabetes Insipidus

Evelyne Huynh Cong, PhD
Boston Children's Hospital
WT1 Regulation of the HIPPO Signaling in Podocyte Diseases

Adele Mitrotti, MD
Columbia University
Genetics of Human Focal Segmental Glomerulosclerosis

Harini Sarathy, MD
University of California, San Francisco
Feasibility and Reliability of Non-Invasive Central Pressure Measurement in Elderly Persons with Hypertension and Chronic Kidney Disease: A Pilot Study

Monica Sircar, MD
Massachusetts General Hospital
Development of a Novel Biomarker for Diabetic Nephropathy

ASN FOUNDATION FOR KIDNEY RESEARCH FELLOW

Ashish Solanki, PhD
Medical University of South Carolina
A Novel Mutation in CLCN5 Associated with FSGS

SHARON ANDERSON RESEARCH FELLOW

Gaia Muallem, MD*
University of Pennsylvania
A Role for IL-27 in Limiting Immune Pathology After Crescentic Glomerulonephritis

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The Role of Endothelin in Sickle Nephropathy

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Hila Milo Rasouly, PhD
Columbia University
Genetic Basis of Congenital Kidney Malformations

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.

Joshua King, MD
University of Virginia
An Interactive Curriculum for Nephrology Fellows in Clinical Pharmacology and Toxicology

Career Development Grants Program - Funding for New Investigators

Funding up to nine new applicants and nine 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

Jennifer Charlton, MD*
University of Virginia
Detecting Renal Pathology in Mouse Model of Prematurity Using MRI-based Biomarkers

Benjamin Freedman, PhD
University of Washington
Modeling Human Kidney Disease with Pluripotent Stem Cells

Sarah Huen, MD, PhD
Yale University School of Medicine
The Role of Kidney FGF21 in Surviving Sepsis

Kenneth Kwon, PhD*
Medical University of South Carolina
Exosome Biogenesis in Renal Tubule Growth and Acute Kidney Injury

Joshua Stern, MD
Albert Einstein College of Medicine
Evidence for a Distinct Gut Microbiome in Kidney Stone Patients

Crystal West, PhD
Georgetown University
Proteinase-activated Receptor 2 (PAR2) in the Altered Renal Electrolyte Handling of Pregnancy

JOHN MERRILL GRANT IN TRANSPLANTATION

Sanjeev Kumar, MD, PhD
Cedars Sinai Medical Center
Role of Sox9 in the Repair of Acutely Injured Mammalian Kidney

NEPHCURE KIDNEY INTERNATIONAL-ASN FOUNDATION FOR KIDNEY RESEARCH GRANT

Astrid Weins, MD, PhD
Brigham and Women's Hospital
Regulation of DNA Damage Repair in Podocytes

NORMAN SIEGEL RESEARCH SCHOLAR GRANT

Suttira Intapad, PhD
University of Mississippi Medical Center
Role of Sphingosin-1-phosphate on Kidney Function and Blood Pressure of Intrauterine Growth Restricted Mice

American Society of Nephrology-Harold Amos Medical Faculty Development Program

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

Gentzon Hall, MD, PhD*
Duke University
Novel Gene Discovery in African Americans with Hereditary Focal Segmental Glomerulosclerosis

**Kidney Week 2016 oral and/or poster abstract presenter*

ASN Scientific Exposition

Thursday, November 17 – Saturday, November 19

Exhibits and Posters
West Building, Level 3
Hall F1/F2
9:30 a.m. – 2:30 p.m.

Highlights Include:

- Over 160 Exhibiting Companies
- ASN: Past, Present and Future Booths
- ASN Services
  - General Information, Foundation, KHI, Membership Services, NTDS Project, Publications, and Web Services
- Career Fair
- Complimentary Refreshment Breaks
- Cyber Center
- Exhibitor Spotlights
- "Locate Me Kiosks" – Posters/Exhibitors
- Poster Sessions
- Welcome Reception
- Wi-Fi

Exhibitor Spotlight Schedule

Thursday, November 17 - Saturday, November 19
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.

Welcome Reception

Thursday, November 17, 6:30 p.m. – 7:30 p.m.
To commemorate ASN's 50th anniversary, the society will host an all participants Welcome Reception in the exhibit hall the evening of Thursday, November 17. Please join us in celebrating this milestone event.

Supported by
relypsa

Thursday, November 17

10:00 a.m. – 11:00 a.m. Theater 1
Converting from Epoetin Alfa to Aranesp® (darbepoetin alfa): Highlighting Key Considerations in the Conversion of Patients with CKD on Dialysis
Presented by AMGEN

11:00 a.m. – 12:00 p.m. Theater 2
Triferic: The Newest Anemia Therapy Maintains Hemoglobin and Overcomes High Ferritin and Functional Iron Deficiency (FID)
Presented by ROCKWELL MEDICAL

12:00 p.m. – 1:00 p.m. Theater 1
Combating Iron Deficiency Anemia in the NDD-CKD Patient: Emerging Trends in Treatment Options
Presented by AMERICAN REGENT

1:00 p.m. – 2:00 p.m. Theater 2
Advances in Understanding Focal Segmental Glomerulosclerosis (FSGS)
Presented by Mallinckrodt Pharmaceuticals

Friday, November 18

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)
Presented by AMGEN

11:00 a.m. – 12:00 p.m. Theater 2
Velphoro: A Potent, Non-Calcium, Iron-Based Phosphate Binder with a Low Pill Burden
Presented by FRESENIUS MEDICAL CARE RENAL THERAPIES GROUP

12:00 p.m. – 1:00 p.m. Theater 1
Dietary and Pharmacologic Management of Electrolyte Disorders in Chronic Kidney Disease
Presented by relypsa

1:00 p.m. – 2:00 p.m. Theater 2
Understanding and Treating Chronic Hepatitis C Infection in Patients with Chronic Kidney Disease
Presented by MERCK

Saturday, November 19

10:00 a.m. – 11:00 a.m. Theater 1
Rituxan® (rituximab) for the Treatment of Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) with Updated Data for GPA/MPA
Presented by Genentech, A Member of the Roche Group

11:00 a.m. – 12:00 p.m. Theater 2
Medical Mystery: 22 Year Old Male with Unexplained Proteinuria
Presented by SANOFI GENZYME

12:00 p.m. – 1:00 p.m. Theater 1
Advancing ESRD Therapy Through HDx (Expanded Hemodialysis)
Presented by Baxter

1:00 p.m. – 2:00 p.m. Theater 2
Evaluation of Patients with Thrombotic Microangiopathy: A Case-Based Discussion on Identifying Patients with Atypical Hemolytic Uremic Syndrome
Presented by ALEXION

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relypsa **Booth 1015**

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OPKO Renal **Booth 515**

Study: More Liberal Use of Renal Replacement Therapy in US Compared with Other Developed Nations

In most developed countries, receipt of renal replacement therapy (RRT) is highly age-dependent and is the exception rather than the rule, but a new study indicates that most US patients with advanced chronic kidney disease (CKD)—even the oldest patients with the highest burden of comorbidity—have likely already received or are preparing to receive RRT. The study, which assessed a national cohort of patients within the Department of Veterans Affairs (VA), is published in the *Clinical Journal of the American Society of Nephrology*.

The US Medicare Program spends more than $30 billion annually to provide maintenance dialysis and kidney transplantation to more than 400,000 Americans with advanced chronic kidney disease, and the annual incidence of such RRT in the US is severalfold higher than in many European nations. Investigators have wondered whether this higher incidence reflects a greater burden of kidney disease or differences in treatment practices.

To look into the issue, Susan Wong, MD, of the University of Washington and her colleagues conducted a retrospective study that included 28,568 patients with very advanced CKD who were receiving care within the VA between 2000 and 2009. Using a combination of linked administrative data from the VA, Medicare, and the United States Renal Data System, the researchers identified patients who received RRT through October 1, 2010. For a 25% sample of the remaining patients, the researchers performed an in-depth review of VA-wide electronic medical records to understand the clinical course and treatment status of patients' CKD.

Administrative data revealed that 67.1% of cohort members received RRT. Based on the results of chart review, the team estimates that an additional 7.5% of cohort members had in fact received at least one dialysis treatment not captured in administrative data, 10.9% were discussing and/or preparing for dialysis but had not yet started dialysis at the end of follow-up, and a decision had been made not to pursue dialysis in 14.5% of patients.

The results indicate that at most recent follow-up, the overwhelming majority (85.5%) of patients had either received, or were preparing to receive, RRT. Even among those aged ≥85 years with the highest burden of comorbidity, most received or were preparing to receive RRT at the last follow-up point; 41.1% of these patients were actually treated with RRT.

"Our findings signal more liberal use of dialysis in our study cohort as compared with other developed countries, with differences being especially striking for older age groups," said Dr. Wong. In Canada, investigators estimated that 51.4% of patients with kidney failure, and only 6.8% of those ≥85 years, are treated with RRT. In New Zealand and Australia, an estimated 51.2% of patients, and <5.0% of elderly patients, are treated with RRT.

"Life expectancy after initiation of maintenance dialysis in very old patients is severely limited, and older patients experience high rates of hospitalization and transition to assisted nursing facilities after initiation of treatment," Dr. Wong explained. Recent observational studies conducted in European countries have also raised concerns that dialysis may not meaningfully lengthen survival and is associated with poorer quality-of-life compared with more palliative approaches, such as hospice, for older patients with significant comorbidity. "Our findings underscore the importance of shared decision-making for dialysis to ensure that treatment decisions uphold the priorities and preferences of individual patients and are grounded in realistic expectations about prognosis and the expected benefits and harms of this treatment," said Dr. Wong.

Jennifer Scherer, MD, of NYU School of Medicine, and Alvin Moss, MD, of West Virginia University, noted in an accompanying editorial that the study issues a call to action to the nephrology community, stressing that changes are needed concerning dialysis decision-making with older patients who have advanced CKD.

"Despite the integration of palliative care into the care of patients with cancer and other chronic diseases, a national policy shift towards patient-centered care, and recognition by nephrology fellows over a decade ago that more palliative care education is needed in their training, Wong *et al.* have shown that nephrology practice in the United States has not kept pace," Drs. Scherer and Moss wrote. "The leaders in the nephrology interdisciplinary community including nephrologists, nurses, social workers, dietitians, and technicians, in collaboration with palliative care clinicians, need to make the implementation of a comprehensive model of renal supportive care delivery a priority for the growing population of older patients with advanced CKD."

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

2016 Corporate Supporters

The ASN Corporate Support Program recognizes supporters year round for their generous contributions to the Society. Through this program, supporters help ASN lead the fight against kidney disease. ASN gratefully acknowledges the following companies for their contributions in 2016.

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as of September 7, 2016

ABIM Releases New "Blueprint" for Maintenance of Certification Exam

Based on input from more than 400 nephrologists, the American Board of Internal Medicine (ABIM) revised the specifications for its maintenance of certification (MOC) exam. Effective for the fall 2016 exams, the changes are more of a recalibration of attention to certain topics than a significant shift of focus.

"The previous MOC exam blueprint was set primarily by the exam committee based on their best estimate of what was seen by the 'typical' nephrologist," said Jeffrey S. Berns, MD, FASN, chair of the ABIM nephrology board. The exam outline, or "blueprint," was updated "in response to information from a large group of diverse nephrologists regarding what they saw frequently in practice and what they thought was important for the practicing nephrologist to know even if not seen frequently."

ABIM board-certified nephrologists were asked to fill out a detailed survey rating the frequency and importance of a large variety of conditions and topics in their practices. The ABIM committee also determined the relative frequency of patient conditions by analyzing documented national health care data, such as that of Medicare patients.

Berns said that the comment process revealed that the previous blueprint was not far off the mark, so the changes in the percentages of questions on certain topics are not great. The 10 subject areas remain the same.

"The new blueprint increases the percentage of the MOC exam questions in the content area of chronic kidney disease (from 20% to 23%) and acute kidney injury/ICU nephrology (from 14% to 15%). There are small decreases in the percentage of questions related to acid-base and potassium disorders, glomerular and vascular disorders, and pharmacology," said Berns, who is professor of medicine and pediatrics at the University of Pennsylvania.

Survey participants were also asked to rate topics on a three-point scale of low, medium, and high importance. "The new MOC exam will have no questions on topics of low importance, no more than 25% will be on topics of medium importance, and at least 75% will be on topics of high importance," Berns said.

ABIM began the revision process because of feedback from physicians that MOC assessments should better reflect what they see in practice. The revision "is part of the larger effort by the ABIM to modify the current MOC process and make it more relevant to practicing nephrologists," according to Mark Perazella, MD, FASN, professor of medicine at Yale University school of medicine who served a six-year term on the ABIM nephrology exam committee that ended in 2013. He helped design the former MOC blueprint (the one that was revised), but was not involved in this new redesign. "The blueprint represents a roadmap that diplomates can use to focus their attention when preparing for the MOC exam," he said.

Designing a good roadmap and exam is a careful balancing act, according to Melanie Hoenig, MD, an assistant professor at Harvard Medical School who heads the ASN Kidney Self-Assessment Program: "If rare diagnoses are not considered at all, individuals studying for the certification exam may limit their studies and avoid consideration of these topics. This has the potential to result in an inability to recognize clinical syndromes which represent rare diseases. The blueprint does not appear to exclude rare disorders, but instead seems to seek to reassure participants that the rare disorders will represent a small percentage of the examination. In addition, the emphasis is on the recognition—diagnosis and testing—rather than items easily identified with a Google search, such as epidemiology of rare conditions and prognosis."

"The new blueprint has the potential to be more practical and allow the traditional 'zebras' to receive less attention. For example, topics considered of 'low importance' in the blueprint will not be on the examination. There are very few topics in this category, but examinees can be certain that there will be no questions on the pathophysiology of Fabry's disease (though there could be a question on diagnosis) and no questions regarding 'the pathophysiology of desensitization' in the setting of a renal transplant," Hoenig said.

According to the ABIM website, the more than 400 nephrologists who contributed to the survey with topic ratings provided a representative sample of nephrologists in terms of age, gender, time spent in direct patient care, and geographic region. In rating the importance of conditions, they considered factors that included the risk of a significant adverse outcome; cost of care and stewardship of resources; common errors in diagnosis or management; effect on population health; effect on quality of life; and when failure to intervene could deprive a patient of significant benefit.

The overall structure of the exam is unchanged. It is composed of 240 single-best-answer multiple-choice questions, of which a small number are new questions being tested for use in future exams that do not count in the examinee's score.

Although many ASN members participated, ASN did not participate formally in the revision of the blueprint. A full explanation of the new roadmap can be found at http://www.abim.org/~/media/ABIM%20Public/Files/pdf/exam-blueprints/maintenance-of-certification/nephrology.pdf.

KIDNEYWEEK 2016

Career Fair

November 17-19, 2016
9:30 am – 2:30 pm
McCormick Place • Chicago, IL

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

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Division of Nephrology and Hypertension

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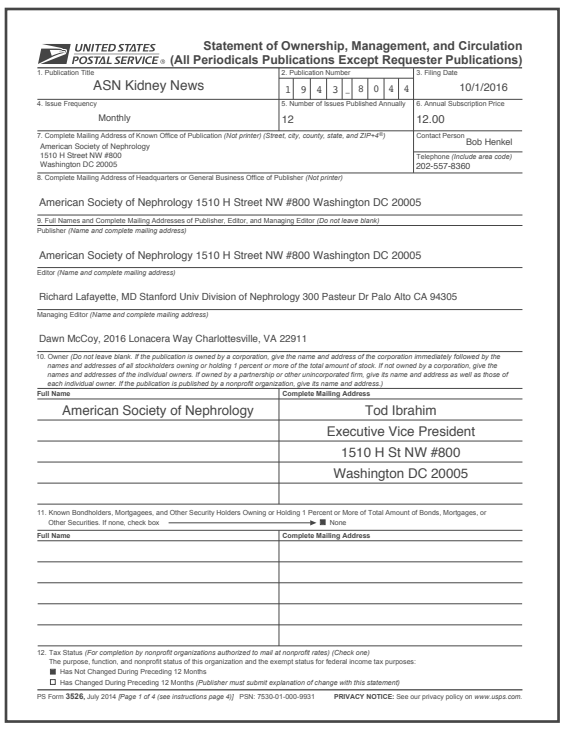

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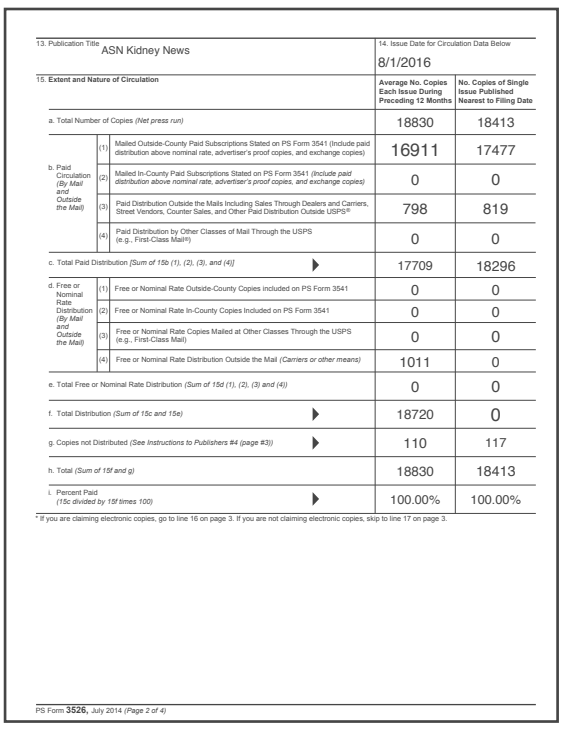

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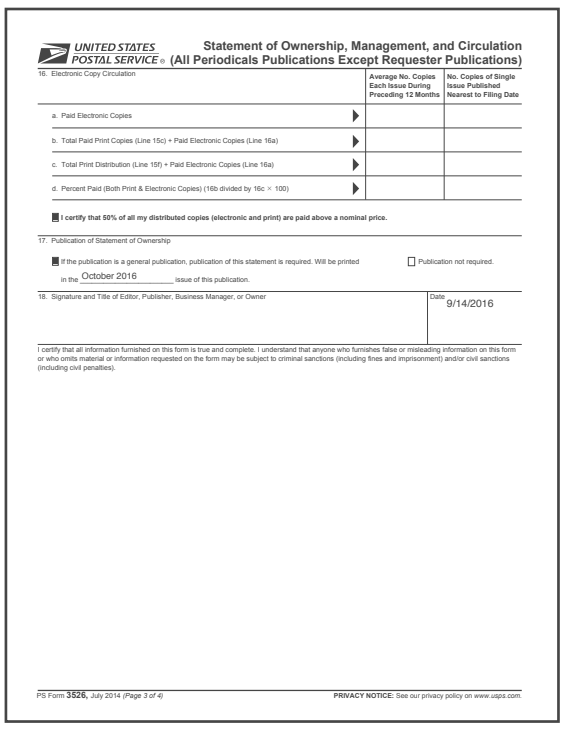

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