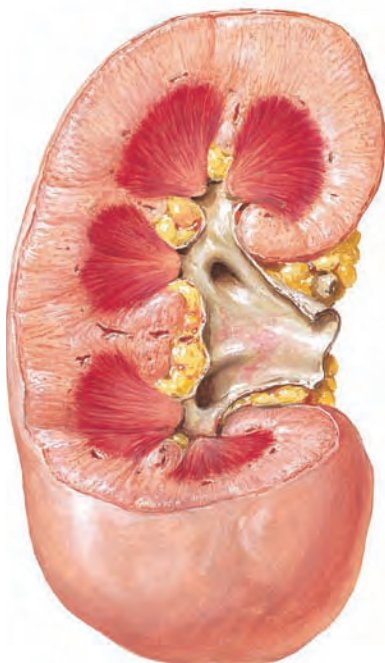


Kidney News

January 2010 | Vol. 2, Number 1

Treatment Guidelines, Early Detection Paramount for Acute Kidney Injury

By Timothy O'Brien



In parenchymatous acute kidney injury, a large pale kidney presents with a thick, pale cortex and hyperemic pyramids.

What common acute medical condition occurs in about 5 percent of all hospitalized patients; has jumped in incidence by about one-third in recent years; is known to be a major risk factor for chronic organ dysfunction and death; and carries costs of about \$10 billion per year? Nephrologists know the answer all too well: acute kidney injury (AKI)—or acute renal failure (ARF), as some call it.

While AKI is hardly a new disease, the past few years have witnessed an explosion of new information on the incidence and consequences of this difficult-to-diagnose, difficult-to-treat condition. Efforts currently underway—including evolving tests for early diagnosis and the development of evidence-based clinical guidelines—promise to answer at least some of the riddles surrounding AKI in the next few years.

We know it when we see it

Acute kidney injury can be defined as “rapid loss of kidney function”... at least, that’s good enough for Wikipedia. Only recently have efforts been made to establish a uniform definition and classification system for AKI. Two systems have now been developed and are turning up more often in research and clinical practice: the RIFLE criteria (Risk, Injury, Failure, Loss and End Stage), developed by the Acute Dialysis Quality Initiative (ADQI) Group, and the Acute Kidney Injury Network (AKIN) criteria.

Although they differ in some ways, both RIFLE and AKIN use changes in serum creatinine and urine output to define and classify AKI. “Previous to that, there was no accepted definition of ARF,” according to Chi-yuan Hsu, MD, division chief and professor of

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Health Care Reform Legislation Nears Final Form

By Eric Seaborg

After dominating the headlines in 2008, the debate over health care culminated in the House and Senate each passing sweeping reform measures. In January, House and Senate negotiators plan to hammer out a final version for the president’s signature.

Congressional leaders and President Obama have so much invested in the issue that a version acceptable to both houses is almost certain to emerge. The bills as

passed diverge from each other in several aspects, but their many areas of agreement provide a snapshot of the myriad ways they will reshape the health insurance system and Medicare.

“I think a lot of people were expecting this bill to do two things, one of them was to expand coverage, and the other was to control costs,” said William Harmon, MD, director of pediatric nephrology at Children’s Hospital Boston and a member

of the American Society of Nephrology’s Public Policy Board. “It is clear that what seems to be coming out is going to expand coverage. The jury is out on whether it is actually going to contain costs.”

The nonpartisan Congressional Budget Office (CBO) estimates that the House bill would insure an additional 36 million people, resulting in coverage for 96 percent of legal residents under 65, and the Senate plan would cover an additional 31 million, or about 94 percent of those under 65, compared with 83 percent now.

Aside from the coverage expansion, Harmon and Thomas Hotstetter, MD, chief of the nephrology division at Albert Einstein College of Medicine in New York City and chair of the ASN Public Policy

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Before you start, stop.

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Not the risks.

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Important Treatment Considerations

Renvela® (sevelamer carbonate) is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis • Renvela is contraindicated in patients with bowel obstruction • Caution should be exercised in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders including severe constipation, or major GI tract surgery • Uncommon cases of bowel obstruction and perforation have been reported • Serum bicarbonate and chloride levels should be monitored • Vitamins D, E, K (coagulation parameters), and folic acid levels should be monitored • The most frequently occurring adverse reactions in a short-term study with sevelamer carbonate tablets were nausea and vomiting • In a short-term study of sevelamer carbonate powder dosed three times daily, adverse events were similar to those reported for sevelamer carbonate tablets • In long-term studies with sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, the most common adverse events included: vomiting, nausea, diarrhea, dyspepsia, abdominal pain, flatulence, and constipation • Cases of fecal impaction and, less commonly, ileus, bowel obstruction, and bowel perforation have been reported • Drug-drug interactions may occur with some medications and should be taken into consideration when instructing patients how to take Renvela • Patients should be informed to take Renvela with meals and to adhere to their prescribed diets

Please see Brief Summary of Prescribing Information on adjacent page.

Reference: 1. Renvela [package insert]. Cambridge, MA: Genzyme Corp; 2009.

Renvela®
sevelamer carbonate

Right from the startSM

Treatment Guidlines

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nephrology at the University of California, San Francisco. “It was kind of ‘I know it when I see it,’ even though we all talked about it a lot.”

The central problem with AKI is that diagnosis is generally delayed until changes in serum creatinine occur—which can be hours to days after the decline in kidney function. To close this gap, a flurry of studies in recent years have evaluated potential new biomarkers—with leading candidates including neutrophil gelatinase-associ-

ated lipocalin (NGAL), kidney injury molecule-1 (KIM-1), and interleukin-18 (IL-18).

“So we have quite a number of markers that make a lot of sense, but it’s not entirely clear how to use them clinically—yet,” said Hsu. Nevertheless, some markers are proceeding to commercial development, with registered patents and even commercially available dipstick tests.

Such applications are “running ahead quite a bit,” in Hsu’s view. “I think the general consensus is that we still don’t know exactly how to use these things. But in the next five years,

I would say that they would, in some fashion, come into clinical practice.”

Even if AKI can be detected early, that information is useful only to the extent that available treatments can improve patient outcomes.

“We really don’t have great methods of reversing AKI, particularly when it’s tubular injury,” said Richard Lafayette, MD, clinical chief, nephrology, and associate professor of medicine at Stanford University Medical Center. “We don’t know what the best support plan is for patients with acute renal failure, including when and how to start them on dialysis.”

Renvela[®] sevelamer carbonate

[se vel' a mer]

See package insert for full prescribing information.

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Renvela[®] (sevelamer carbonate) is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis.

DOSAGE AND ADMINISTRATION

Because of the rapid reaction with the hydrochloric acid in the stomach, the dosing of Renvela powder or tablet is anticipated to be similar to that of the sevelamer hydrochloride salt or tablet.

General Dosing Information

Patients Not Taking a Phosphate Binder. The recommended starting dose of Renvela is 0.8 to 1.6 g, with meals based on serum phosphorus level. Table 1 provides recommended starting doses of Renvela for patients not taking a phosphate binder.

Table 1. Starting Dose for Dialysis Patients Not Taking a Phosphate Binder

SERUM PHOSPHORUS	RENVELA [®] 800 MG	RENVELA POWDER
> 5.5 and < 7.5 mg/dL	1 tablet three times daily with meals	0.8 g three times daily with meals
> 7.5 mg/dL	2 tablets three times daily with meals	1.6 g three times daily with meals

Switching from Sevelamer Hydrochloride Tablets. For patients switching from sevelamer hydrochloride tablets to sevelamer carbonate tablets or powder, use the same dose in grams. Further titration may be necessary to achieve desired phosphorus levels. The highest daily dose of sevelamer carbonate studied was 14 grams in CKD patients on dialysis. **Switching between Sevelamer Carbonate Tablets and Powder.** Use the same dose in grams. Further titration may be necessary to achieve desired phosphorus levels.

Switching from Calcium Acetate. In a study in 84 CKD patients on hemodialysis, a similar reduction in serum phosphorus was seen with equivalent doses (approximately mg for mg) of sevelamer hydrochloride and calcium acetate. Table 2 gives recommended starting doses of Renvela based on a patient's current calcium acetate dose.

Table 2. Starting Dose for Dialysis Patients Switching From Calcium Acetate to Renvela

CALCIUM ACETATE 667 MG (TABLETS PER MEAL)	RENVELA [®] 800 MG (TABLETS PER MEAL)	RENVELA POWDER
1 tablet	1 tablet	0.8 g
2 tablets	2 tablets	1.6 g
3 tablets	3 tablets	2.4 g

Dose Titration for All Patients Taking Renvela. Titrate the Renvela dose by 0.8 g TID with meals at two-week intervals as necessary with the goal of controlling serum phosphorus within the target range.

Sevelamer Carbonate Powder Preparation Instructions

The entire contents of each 0.8 or 2.4 g packet should be placed in a cup and mixed thoroughly with the amount of water described in Table 3.

Table 3. Sevelamer Carbonate Powder Preparation Instructions

RENVELA POWDER PACKET STRENGTH	MINIMUM AMOUNT OF WATER FOR DOSE PREPARATION (EITHER OUNCES, mL, OR TEASPOON/TABLESPOON)		
	ounces	mL	tsp/tbsp
0.8 g	1	30	6 teaspoons/2 tablespoons
2.4 g	2	60	4 tablespoons

Multiple packets may be mixed together with the appropriate amount of water. Patients should be instructed to stir the mixture vigorously (it does not dissolve) and drink the entire preparation within 30 minutes or resuspend the preparation right before drinking.

Based on clinical studies, the average prescribed daily dose of sevelamer carbonate is approximately 7.2 g per day.

DOSAGE FORMS AND STRENGTHS

Tablets: 800 mg white oval, film-coated, compressed tablets imprinted with “RENVELA 800”.

Powder: 0.8 g and 2.4 g pale yellow powder packaged in an opaque, foil lined, heat sealed packet.

CONTRAINDICATIONS

Renvela is contraindicated in patients with bowel obstruction.

WARNINGS AND PRECAUTIONS

Use Caution in Patients with Gastrointestinal Disorders. The safety of Renvela has not been established in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders including severe constipation, or major GI tract surgery. Uncommon cases of bowel obstruction and perforation have been reported.

Monitor Serum Chemistries. Bicarbonate and chloride levels should be monitored.

Monitor for Reduced Vitamins D, E, K (clotting factors) and Folic Acid Levels. In preclinical studies in rats and dogs, sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, reduced vitamins D, E, and K (coagulation parameters) and folic acid levels at doses of 6–10 times the recommended human dose. In short-term clinical trials, there was no evidence of reduction in serum levels of vitamins. However, in a one-year clinical trial, 25-hydroxyvitamin D (normal range 10 to 55 ng/mL) fell from 39 ± 22 ng/mL to 34 ± 22 ng/mL (p<0.01) with sevelamer hydrochloride treatment. Most (approximately 75%) patients in sevelamer hydrochloride clinical trials received vitamin supplements, which is typical of patients on dialysis.

ADVERSE REACTIONS

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

There are limited data on the safety of Renvela. However, based on the fact that it contains the same active ingredient as the hydrochloride salt, the adverse event profiles of the two salts should be similar. In a cross-over study in hemodialysis patients with treatment durations of eight weeks each and no washout the adverse reactions on sevelamer carbonate tablets were similar to those reported for sevelamer hydrochloride. In another cross-over study in hemodialysis patients, with treatment durations of four weeks each and no washout between treatment periods, the adverse reactions on sevelamer carbonate powder were similar to those reported for sevelamer hydrochloride.

In a parallel design study of sevelamer hydrochloride with treatment duration of 52 weeks, adverse reactions reported for sevelamer hydrochloride (n=99) were similar to those reported for the active-comparator group (n=101). Overall adverse reactions among those treated with sevelamer hydrochloride occurring in > 5% of patients included: vomiting (22%), nausea (20%), diarrhea (19%), dyspepsia (16%), abdominal pain (9%), flatulence (8%), and constipation (8%). A total of 27 patients treated with sevelamer and 10 patients treated with comparator withdrew from the study due to adverse reactions.

Based on studies of 8–52 weeks, the most common reason for withdrawal from sevelamer hydrochloride was gastrointestinal adverse reactions (3–16%).

In one hundred and forty-three peritoneal dialysis patients studied for 12 weeks using sevelamer hydrochloride, most adverse reactions were similar to adverse reactions observed in hemodialysis patients. The most frequently occurring treatment emergent serious adverse reaction was peritonitis (8 reactions in 8 patients [8%] in the sevelamer group and 2 reactions in 2 patients [4%] on active-control). Thirteen patients (14%) in the sevelamer group and 9 patients (20%) in the active-control group discontinued, mostly for gastrointestinal adverse reactions. Patients on peritoneal dialysis should be closely monitored to ensure the reliable use of appropriate aseptic technique with the prompt recognition and management of any signs and symptoms associated with peritonitis.

Postmarketing Experience: Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to drug exposure.

The following adverse reactions have been identified during post-approval use of sevelamer hydrochloride, which has the same active moiety as sevelamer carbonate: pruritus, rash, abdominal pain, fecal impaction, and uncommon cases of ileus, intestinal obstruction, and intestinal perforation. Appropriate medical management should be given to patients who develop constipation or have worsening of existing constipation to avoid severe complications.

DRUG INTERACTIONS

Sevelamer carbonate has been studied in human drug-drug interaction studies with warfarin and digoxin. Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, has been studied in human drug-drug interaction studies with ciprofloxacin, digoxin, warfarin, enalapril, metoprolol, and iron.

Ciprofloxacin: In a study of 15 healthy subjects, a co-administered single dose of 2.8 grams of sevelamer hydrochloride decreased the bioavailability of ciprofloxacin by approximately 50%.

Digoxin: In 19 healthy subjects receiving 2.4 grams of sevelamer hydrochloride three times a day with meals for 2 days, sevelamer did not alter the pharmacokinetics of a single dose of digoxin. In 18 healthy subjects receiving 9.6 grams of sevelamer carbonate once daily, sevelamer did not alter the pharmacokinetics of a single dose of digoxin.

Warfarin: In 14 healthy subjects receiving 2.4 grams of sevelamer hydrochloride three times a day with meals, sevelamer did not alter the pharmacokinetics of a single dose of warfarin. In 14 healthy subjects receiving 9.6 grams of sevelamer carbonate once daily with meal, sevelamer did not alter the pharmacokinetics of a single dose of warfarin.

Enalapril: In 28 healthy subjects a single 2.4 gram dose of sevelamer hydrochloride did not alter the pharmacokinetics of a single dose of enalapril.

Metoprolol: In 31 healthy subjects a single 2.4 gram dose of sevelamer hydrochloride did not alter the pharmacokinetics of a single dose of metoprolol.

Iron: In 23 healthy subjects, a single 2.8 gram dose of sevelamer hydrochloride did not alter the absorption of a single oral dose of iron as 200 mg exsiccated ferrous sulfate tablet.

Other Concomitant Drug Therapy: There are no empirical data on avoiding drug interactions between Renvela and most concomitant drugs. During postmarketing experience, very rare cases of increased thyroid stimulating hormone (TSH) levels have been reported in patients co-administered sevelamer hydrochloride and levothyroxine. Monitor TSH levels and signs of hypothyroidism in patients receiving both medications.

When administering an oral medication where a reduction in the bioavailability of that medication would have a clinically significant effect on its safety or efficacy, there is no information suggesting a dosing regimen that would be universally appropriate for all drugs. One may, however, administer the drug one hour before or three hours after Renvela, and when appropriate, monitor blood levels of the drug. Patients taking anti-arrhythmic medications for the control of arrhythmias and anti-seizure medications for the control of seizure disorders were excluded from the clinical trials.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Sevelamer products should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

The effect of sevelamer hydrochloride on the absorption of vitamins and other nutrients has not been studied in pregnant women. Requirements for vitamins and other nutrients are increased in pregnancy. In pregnant rats given doses of sevelamer hydrochloride during organogenesis, reduced or irregular ossification of fetal bones, probably due to a reduced absorption of fat-soluble vitamin D, occurred at a dose approximately equal to the maximum clinical trial dose of 13 g on a body surface area basis. In pregnant rabbits given oral doses of sevelamer hydrochloride by gavage during organogenesis, an increase of early resorptions occurred at a dose approximately twice the maximum clinical trial dose on a body surface area basis [See *NONCLINICAL TOXICOLOGY* (13.2)].

Labor and Delivery: No sevelamer hydrochloride treatment-related effects on labor and delivery were seen in animal studies [See *NONCLINICAL TOXICOLOGY* (13)]. The effects of sevelamer carbonate on labor and delivery in humans is unknown.

Pediatric use: The safety and efficacy of Renvela has not been established in pediatric patients.

Geriatric use: Clinical studies of Renvela did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

OVERDOSAGE

Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, has been given to normal healthy volunteers in doses of up to 14 grams per day for eight days with no adverse effects. In CKD patients on dialysis, the maximum dose studied was 14 grams of sevelamer carbonate and 13 grams of sevelamer hydrochloride. There are no reports of overdosage with sevelamer carbonate or sevelamer hydrochloride in patients. Since sevelamer is not absorbed, the risk of systemic toxicity is low.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility: Standard lifetime carcinogenicity bioassays were conducted in mice and rats. Rats were given sevelamer hydrochloride by diet at 0.3, 1, or 3 g/kg/day. There was an increased incidence of urinary bladder transitional cell papilloma in male rats of the high dose group (human equivalent dose twice the maximum clinical trial dose of 13 g). Mice received dietary administration of sevelamer hydrochloride at doses of up to 9 g/kg/day (human equivalent dose 3 times the maximum clinical trial dose). There was no increased incidence of tumors observed in mice.

In an *in vitro* mammalian cytogenetic test with metabolic activation, sevelamer hydrochloride caused a statistically significant increase in the number of structural chromosome aberrations. Sevelamer hydrochloride was not mutagenic in the Ames bacterial mutation assay.

Sevelamer hydrochloride did not impair the fertility of male or female rats in a dietary administration study in which the females were treated from 14 days prior to mating through gestation and the males were treated for 28 days prior to mating. The highest dose in this study was 4.5 g/kg/day (human equivalent dose 3 times the maximum clinical trial dose of 13 g).

Developmental Toxicity: In pregnant rats given dietary doses of 0.5, 1.5, or 4.5 g/kg/day of sevelamer hydrochloride during organogenesis, reduced or irregular ossification of fetal bones, probably due to a reduced absorption of fat-soluble vitamin D, occurred in mid- and high-dose groups (human equivalent doses approximately equal to and 3.4 times the maximum clinical trial dose of 13 g). In pregnant rabbits given oral doses of 100, 500, or 1000 mg/kg/day of sevelamer hydrochloride by gavage during organogenesis, an increase of early resorptions occurred in the high-dose group (human equivalent dose twice the maximum clinical trial dose).

HOW SUPPLIED/STORAGE AND HANDLING

Tablets: Renvela[®] 800 mg Tablets are supplied as white oval, film-coated, compressed tablets, imprinted with “RENVELA 800”, containing 800 mg of sevelamer carbonate on an anhydrous basis, microcrystalline cellulose, hypromellose, diacetylated monoglycerides, sodium chloride, and zinc stearate.

1 Bottle of 30 ct 800 mg Tablets (NDC 58468-0130-2)

1 Bottle of 270 ct 800 mg Tablets (NDC 58468-0130-1)

Powder: Renvela[®] for Oral Suspension is supplied as opaque, foil lined, heat sealed, packets containing 0.8 g or 2.4 g of sevelamer carbonate on an anhydrous basis, natural and artificial citrus cream flavor, propylene glycol alginate, sodium chloride, sucralose, and ferric oxide (yellow).

1 Box (NDC 58468-0131-2) of 90 ct 2.4 g packets (NDC 58468-0131-1)

1 Box (NDC 58468-0132-2) of 90 ct 0.8 g packets (NDC 58468-0132-1)

1 Sample Box (NDC 58468-0131-4) of 90 ct 2.4 g packets (NDC 58468-0131-3)

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Questions also remain as to the best method of dialytic support (i.e., continuous renal replacement therapy versus standard dialysis), timing of initiation, and intensity of treatment.

Evaluation of new approaches to prevention and treatment will require accurate approaches to measuring efficacy. A study in the November 2009 *Clinical Journal of the American Society of Nephrology* showed that the results of AKI treatment trials are affected by the outcome measures used (*Clin J Am Soc Nephrol* 2009; 4:1705–1715). Led by John Pickering, PhD, of the University of Otago, Christchurch, New Zealand, the researchers found that continuous measures of creatinine change provided the best estimates of treatment efficacy. By comparison, categorical metrics tended to underestimate the effect of treatment when efficacy was low, and overestimate it when efficacy was high.

The study suggested that using an estimated baseline creatinine tends to overestimate AKI prevalence, compared to a measured baseline. “Clinical trials of AKI should utilize a continuous outcome metric, a measured baseline, and report baseline median and interquartile range,” Pickering and colleagues concluded. They also proposed some new, continuous outcome metrics incorporating information on the extent, rate, and duration of change in creatinine.

As AKI incidence rises, new data on long-term health effects

Establishing the incidence of AKI poses special challenges. “Most previous studies of the epidemiology of AKI looked at how many cases per hospitalization,” said Hsu. “The problem is that hospitalization is not an unchanging thing—people get hospitalized at different rates across the country, and with managed care it’s been harder and harder to get into the hospital.”

Only recently have studies focused on quantifying the incidence of AKI on the population level. “That’s an important advance, and it’s clearly shown that the incidence of AKI is going up over time,” Hsu said. “The incidence of dialysis-requiring AKI, for example, has gone from 19.5 to 29.5 per 100,000 person-years over about an eight-year period—1996 to 2003. That’s a 33 percent increase.”

While the focus has been on CKD and ESRD in recent years, AKI is the real “epidemic” of kidney disease, Hsu said. “It’s actually going up faster than the incidence of ESRD and CKD— not a widely known fact.”

Today’s high-tech medical procedures contribute to the increase in AKI incidence. “I think it’s because we’re doing more and more invasive procedures,” Hsu said. “More people getting cardiac catheterization. More people getting CT scans with nephrotoxic agents. More people getting bone marrow transplants. More people getting

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Health Care Reform

Continued from page 1

Board, pointed out two provisions in the bills of particular interest to nephrologists: Medicare payment related to end stage renal disease (ESRD) and increased funding for comparative effectiveness research. The reform momentum is likely to also lead to another key action within the next two months—a reconfiguration of the Medicare reimbursement scheme that avoids scheduled cuts.

ESRD payment

A proposal for funding the extension of Medicare coverage for immunosuppressant drugs for transplant patients beyond the current 36-month limit has sparked controversy, and even caused a rift between the dialysis community and the transplant community. Both sides support extending the coverage, but the proposal is perceived by some as coming at the expense of dialysis patients.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires that Medicare payment for dialysis services be bundled to include the patient's drugs as well, and the Centers for Medicare and Medicaid Services (CMS) is in the midst of preparing its final rule on the bundling. Many in the dialysis community have objected to CMS' proposal to include oral drugs as part of the bundle, but the CBO calculates that this bundling would save Medicare some \$100 million over the next 10 years. A provision in the House bill included at the behest of Rep. Pete Stark (D-Calif.) would extend Medicare payment for immunosuppressive drugs for life, noting that the increased cost would be offset by the savings in dialysis payments.

Supporters of this approach say that it creates no actual tie between the dialysis and immunosuppressant payments, but is only a nod to Congress' pay-as-you-go rules, which require that before increasing spending in any area, one must identify a reduction or new revenue source to offset it. And the bundling is already set in law. Opponents of the approach complain that it appears to pit funding for one group of patients against another, that proposed dialysis payments are already inadequate, and that further cuts could compromise care.

When Sen. Richard Durbin (D-Ill.) proposed a similar amendment for the Senate bill, the move was opposed by Kidney Care Partners, a coalition that includes dialysis centers, several drug manufacturers, and nonprofit organizations including the National Kidney Foundation. The group advocates that private insurance coverage for dialysis be extended to cover one more year before Medicare takes over, using this cost-shift to pay for the immunosuppressive drug extension.

Organizations including the American Society of Transplantation, American Society of Transplant Surgeons, Transplant Recipients International Organization, and United Network for Organ Sharing went on record backing the Durbin amendment.

The Durbin amendment was not included in the final Senate bill, but given his prominence as the second-ranking Senate Democrat and the inclusion of the provision in the House bill, the proposal is certain to receive close consideration in the conference committee that reconciles the two bills.

Comparative effectiveness research

Both bills contain provisions for a greater federal commitment to comparative effectiveness research. The House bill would establish a Center for Comparative Effectiveness Research within the Agency for Healthcare Research and Quality whereas the Senate would create a non-profit Patient-Centered Outcomes Research Institute.

Nephrology could particularly benefit from comparative effectiveness research, Hotstetter said: "Nephrology is certainly a place where we just don't know which treatments are best for a lot of conditions. There are big issues in nephrology where comparative effectiveness research could be very useful: what's the best way to lower phosphate, what's the best real target range for parathyroid hormone, and what's the best vitamin D preparation to use." All of these relate particularly to the end stage renal disease and dialysis treatment reimbursements currently under consideration by CMS.

While more funding for research would be welcome, Hotstetter noted most scientists prefer that such research be performed in the peer-reviewed context of the National Institutes of Health instead of an agency that could be more subject to political pressure.

Medicare reimbursement schedule

For the past several years, Medicare physician reimbursements have been scheduled to be reduced annually. Congress has voted at the last minute to postpone the cuts, until their cumulative effect would be a 21 percent reduction if they were allowed to take effect.

The House has already passed a bill that repeals the 21 percent cuts and institutes a new reimbursement formula, and Senate leaders say they plan to pass a companion measure in the first two months of 2010.

Coverage expansion

The expansion in health insurance coverage would come through a variety of mechanisms. Medicaid would be expanded to cover those whose incomes exceed the federal poverty level by 150 percent (House bill) or 133 percent (Senate bill), resulting in about 15 million additional recipients. Those with incomes up to 400 percent of the federal poverty level would be eligible for subsidies to buy insurance. The House bill would require employers with payrolls over \$500,000 to provide employee health insurance. The Senate bill includes no such mandate, but would require large employers to pay fees to the government if their employees qualify for federal subsidies. Small employers would not be required to provide health insurance, but would receive tax credits to buy it for employees.

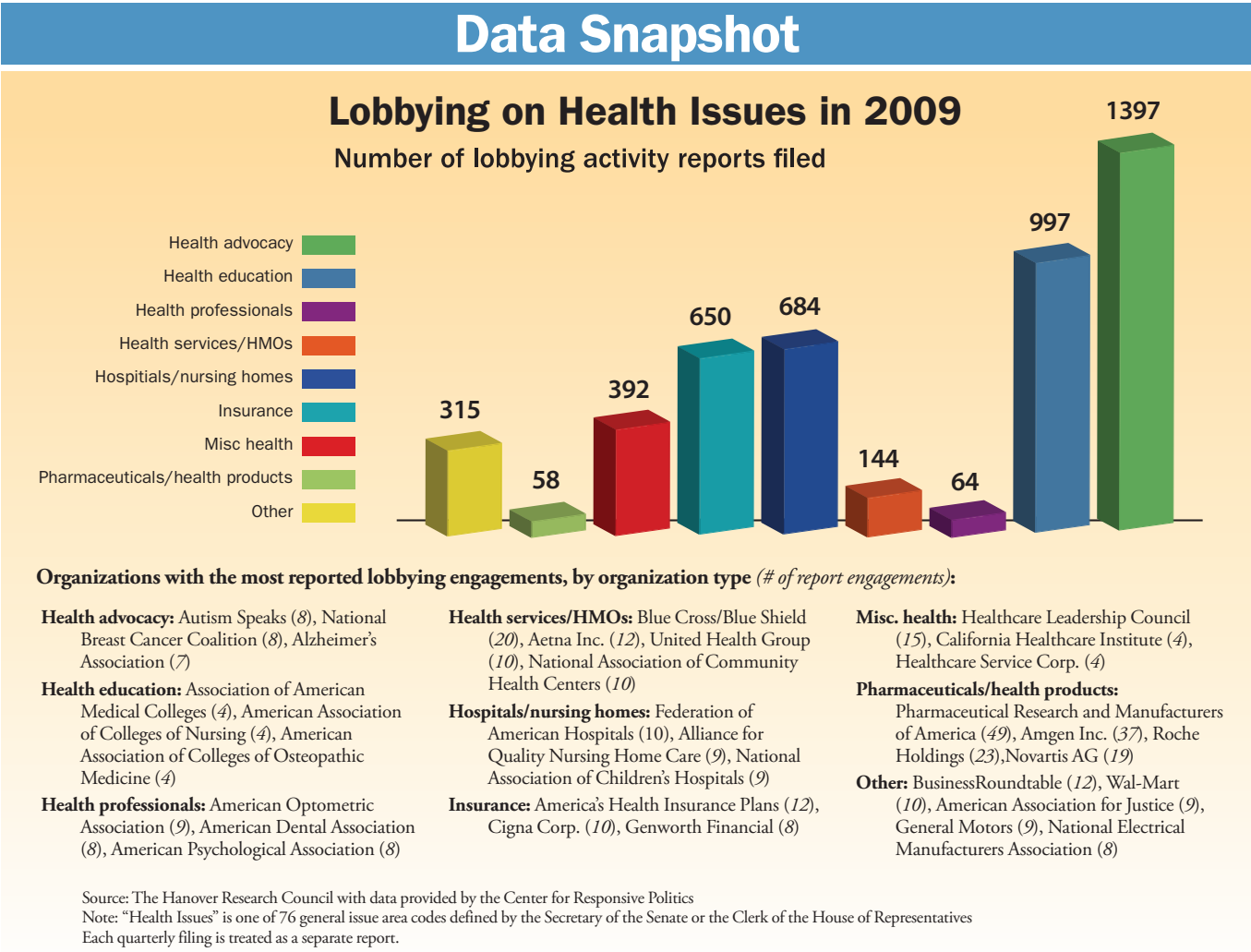
One of the most contentious issues is a publicly run health insurance option, which is included in the House bill but not in the Senate bill. How that issue will be worked out is anyone's guess at this point.

Both bills would create a Health Insurance Exchange where companies and individuals could comparison shop among insurers, with the government defining a minimally acceptable benefit package. Insurance companies would no longer be permitted to deny coverage based on pre-existing conditions, but until that measure takes effect in future years, the bills would establish high-risk pools with caps on the premiums that can be charged. (Many of the provisions phase in from 2013 to 2016, to allow consumers and insurers time to adjust.) In response to complaints about insurers canceling coverage when a patient becomes ill, the bills would prohibit insurers from rescinding coverage except in cases of fraud. The bills cap annual out-of-pocket spending and remove limits on lifetime benefits.

Paying for change

Individuals would be required to obtain qualifying health coverage or pay a penalty, with exceptions allowed for religious objections or financial hardship. The House bill would impose a fee on those who do not obtain coverage of 2.5 percent of their income, with a similar penalty in the Senate bill.

To fund the subsidies and other costs, each bill would impose new taxes, and the bills differ greatly in their approaches. The House would impose a 5.4 percent income surtax on individuals who earn more than \$500,000 and couples who earn more than \$1 million. The Senate bill would increase the Medicare payroll tax on individuals earning more than \$200,000 and couples earning more than \$250,000 and impose a tax on high-priced health insurance policies, the so-called Cadillac plans.



The CBO estimates that the net effect of both versions would be to reduce the federal deficit by an average of about \$13 billion a year for the next 10 years.

Medicare adjustments

Much of the federal budget cost savings come through squeezing more than \$400 billion out of the growth of Medicare and related programs over 10 years. A large portion of the cuts would be to Medicare Advantage plans, bringing their reimbursements in line with regular Medicare payments.

The House bill would direct CMS to negotiate drug prices with pharmaceutical

manufacturers for Part D plans. Both bills contain provisions to close or reduce over several years the "doughnut hole," in which Medicare does not cover drug expenses between \$2,700 and \$6,154. The House plan would shrink it by \$500 a year, and for most people in the doughnut hole, drug manufacturers have agreed to provide brand-name drugs at half price.

Whatever the impact of the many provisions of the legislation, Harmon and Hotstetter look forward to the expansion of health insurance coverage. Hotstetter noted that increased early treatment of the two most common causes of renal failure,

hypertension and diabetes, in a primary care environment could prevent the need for many patients to ever see a nephrologist.

"If we really can have 94 percent of the population covered, hopefully that would mean that people with chronic kidney disease could be treated earlier and effectively, and their need for dialysis or transplantation prevented or forestalled. If more people get treatment at early enough stages, that could save money and would be good from a nephrology standpoint, but that's years down the line to see if that really happens," he said.

Treatment Guidelines

Continued from page 3

a lot of things which are nephrotoxic." An increased rate of sepsis is another likely factor.

So AKI is a hospital-acquired disease? "It is. Most people who have AKI got it in the hospital," said Hsu. He sees the kidney as an innocent bystander in many of today's high-tech, lifesaving interventions. "A lot of the modern-day AKI is created by doctors, usually in pursuit of something good, of course! But it's an iatrogenic side effect."

Meanwhile, there's a growing appreciation of the adverse consequences of AKI in the long term—after the patient goes home from the hospital. "Almost all the previous studies of AKI have been limited to hospital stay," said Hsu. "They generally haven't asked what happens to patients when they leave the hospital, because studies are just not set up to do that."

Studying the post-hospital course of patients with AKI poses numerous difficulties. In the past, when a patient with AKI came off dialysis—as most do—they were considered to have recovered. "Ten years ago, most of the nephrologist's attention was on ESRD," said Hsu. "So if a patient had some decrease in renal function, but didn't have ESRD, people didn't pay that much attention to it."

When later problems developed—including CKD—the history of acute renal failure often wasn't considered as a contributing factor. "When we see someone with CKD, we ask, do you have diabetes, hypertension?" said Hsu. "We never ask, have you had AKI?"

"First of all, patients don't remember. Too, it's kind of hard to get the records from a while ago. Patients know if they have diabetes, they can tell you, whereas having AKI, people may not remember." The fact that AKI often occurs during hospitalization for some

other serious illness is another contributing factor.

A growing body of research clarifies the aftermath of AKI. In one large analysis by Hsu's group (*Kidney Int* 2009; 76:893–899), patients with dialysis-requiring AKI were 28 times more likely to develop stage 4 or 5 CKD at follow-up. There was also more than a twofold increase in the risk of death. Further studies will be needed to clarify the long-term health effects of AKI—not only dialysis-requiring AKI, but also subtler decrements in renal function.

Clinical practice guidelines coming soon

As the new decade begins, there has been major progress in developing standardized definitions and classification systems, research into new diagnostic and treatment approaches, and understanding the risk factors, incidence, and sequelae of AKI. The obvious next step is the development of a

unifying approach to the diagnosis and management of AKI worldwide—a goal best met through the development of evidence-based clinical practice guidelines.

That challenge has been taken on by a Work Group of Kidney Disease: Improving Global Outcomes (KDIGO). The Work Group's task is to develop clinical practice guidelines for the diagnosis, evaluation, classification, prevention, and management of AKI. Publication of the guidelines is anticipated in the first half of 2010.

Stay tuned for more coverage of AKI in February as *KN* presents a special issue on "Acute Kidney Injury: The Road to Recovery."

CORPORATE SUPPORTERS

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DIAMOND LEVEL



PLATINUM LEVEL



Happy Birthday, ASN Kidney News!

By Pascale Lane



Pascale Lane

One year ago, this magazine appeared in mailboxes across America. After that auspicious birth, five subsequent issues of the publication appeared at somewhat irregular intervals. I feel we have completed our toddlerhood and now move into a more mature, civilized period of development.

With this anniversary issue, *ASN Kidney News* becomes a monthly periodical. Monthly issues mean not only more work but also better coverage. More frequent publication allows us to truly cover breaking news in the world of kidneys.

We will continue to publish special sections devoted to topics in nephrology, some extensive and some smaller. Regular features and columns will continue as well. One new column debuts in this issue—*Detective Nephron*. This Holmes-like nephrologist, the creation of Kenar Jhaveri, starts with a single abnormal laboratory value and generates the diagnosis with some help from the trainee, L.O. Henle. Their caffeine-fueled adventures will appear quarterly.

A number of other features will appear regularly. The Fellows' Corner debuts next month. This column will alternate with Trends in Medical Education. We will explore all aspects of nephrology training, from increasing trainee recruitment to Maintenance of Certification. Expansion of policy coverage is in the works as well, given the volatile health care and research funding environments today.

ASN Kidney News also plans to expand its online presence. Our podcasts were accessed more than 70,000 times in the first six months after their May debut; more of these audio files will be available in 2010. An interactive comments section with a user-friendly interface is also in the works.

The ASN has rolled out its new logo, necessitating a change in our masthead. Just as the organization changes over time to serve its members, so does this magazine. If you have a great idea for *ASN Kidney News*, drop us a line (KidneyNews@asn-online.org). Your idea may be our next Big Thing.

Pascale Lane, MD, editor-in-chief of ASN Kidney News, is the Helen Freytag Distinguished Professor of Pediatrics at the University of Nebraska Medical Center.

Renal WeekEnds

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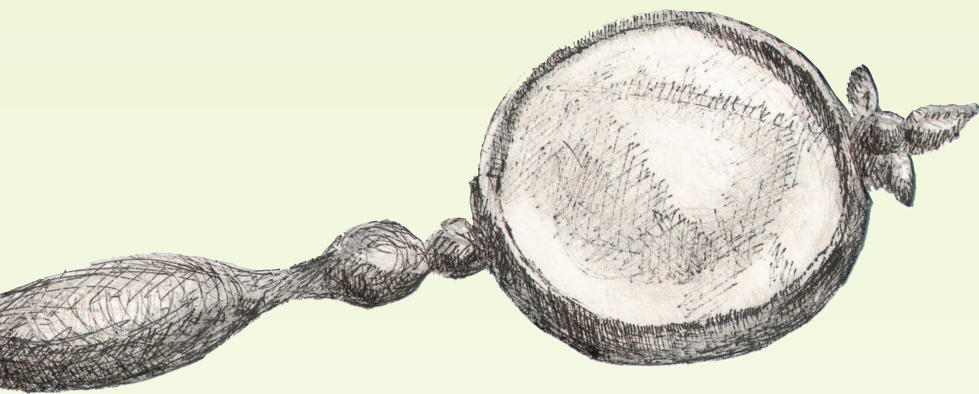
ASN Renal WeekEnds 2010 at a city near you:

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- **Washington, DC**, February 13 - 14
- **Atlanta, GA**, February 27 - 28
- **Chicago, IL**, March 6 - 7
- **New York, NY**, March 13 - 14
- **Los Angeles, CA**, March 20 - 21

Expert faculty summarize, critique, and integrate all key lectures, symposia, and abstract presentations from Renal Week 2009.

Program information is available online at www.asn-online.org

Detective Nephron



Detective Nephron, world-renowned for expert analytical skills, trains budding physician-detectives on the diagnosis and treatment of kidney diseases. L.O. Henle, a budding nephrologist, readies himself to present another case to the master consultant.

Henle enters Detective Nephron's brightly lit office, fidgeting nervously.

Henle, with excitement Dr. Nephron, we have a case!

Nephron Fantastic! I hope it proves challenging this time.

Detective Nephron places ASN Kidney News on the table and readies himself to take notes.

Nephron What do you have for me, Henle?

Henle A 56-year-old female with hyperkalemia of 6.5 mEq/L who presents with...

Nephron, interrupting impatiently Stop right there! You have a lot to learn, Henle. A potassium value alone can be quite enlightening.

After a pause for deep contemplation, Nephron continues...

Nephron Hyperkalemia would not produce consternation in a patient with abnormal kidney function. High potassium is exciting when the GFR is normal. Since my expertise is requested, I conclude the renal function is normal.

Henle Correct again, Dr. Nephron! She has human immunodeficiency virus (HIV) as well...

Nephron, with some anger Remember: no more information until I ask for it!

After a pause...

Nephron Let us begin with hyperkalemia. Most of the potassium in our body is intracellular. The Na-K ATPase pump tightly regulates the ratio of intracellular and extracellular potassium. Minute changes in intracellular potassium can cause profound changes in cardiac and neurological status. Was she symptomatic?

Henle She described no cardiac or neurologic symptoms. Her electrocardiogram showed peaked T waves in lateral and inferior leads.

Nephron, patting Henle's back You are giving me more information than requested! Nevertheless, she has no known renal injury and hyperkalemia with ECG changes. You checked her urine potassium?

Henle It is 44 mEq/L. The urine sodium is 102 mEq/L, and urine osmolality is 551 mOsm/kg. The serum osmolality is 288 mOsm/kg. I even calculated a transtubular potassium gradient (TTKG); it is 4.

Henle looks a bit scared, realizing he has provided more information than requested...

Nephron Good work, Henle! The kidney should be dumping potassium with a TTKG of at least 10, especially with high urine sodium. Urine osmolality is not low enough to affect tubular flow and potassium excretion. Is she orthostatic?

Henle, with a curious look A tad; no change in heart rate, but a 10 mm Hg drop in systolic blood pressure.

Nephron, confidently You shall see! Is the patient on HIV retroviral medications?

Henle She has been stable for 10 years on lamivudine, stavudine, and nevirapin. She also takes...

The detective listens carefully as his assistant reads out a long list of medications...

Henle ...besides those, she takes multivitamins once a day.

She is not on digoxin or nonsteroidal anti-inflammatory medications (NSAIDs), sulfamethoxazole-trimethoprim, an angiotensin converting enzyme inhibitor (ACEI), or angiotensin receptor blocker (ARB).

Nephron Great work, my protégé. At this time, you can rule out acute kidney injury, medications, and hyperosmolality. Did you consider pseudohyperkalemia?

Henle, smirking Yes, Detective. Her platelet count is less than 500,000/ μ L. Hemolysis, leukocytosis, and severe thrombocytosis have been associated with hyperkalemia. Her complete blood counts were all within the normal ranges.

Nephron What is her urine pH?

Henle 5.5

Nephron Let me complete your laboratory data for you. She also has hyponatremia, a normal gap metabolic acidosis, mild hypercalcemia, and hypoglycemia.

Henle You are correct! What...how...why...?

Nephron, very excited You mentioned she was orthostatic. Is she craving salt?

Henle As a matter of fact, she mentioned that!

Nephron Is she having night sweats, weight loss, or fatigue? Any abdominal pain?

Henle, astounded Yes! All of those!

Nephron, calm My dear apprentice, she has a systemic disorder that needs your attention as soon as possible. Before I elucidate, please admit her to the hospital for intravenous hydration.

Henle exits and Detective Nephron resumes his readings.

A few hour pass, and Henle returns to the office for discussion. The detective sets his work aside and looks into the eyes of his junior colleague before speaking...

Nephron You worked well, but you missed a major diagnosis that will make the patient critically ill in a few hours.

She has Addison's disease.

Henle, frightened How did you conclude this?

Nephron Patients with Addison's disease can present with profound electrolyte findings. Ninety percent have hyponatremia, reflecting both sodium loss and volume depletion caused by mineralocorticoid deficiency, plus increased vasopressin secretion caused by cortisol

deficiency. Recall the diagram in every textbook that shows the breakdown of euvolemic hyposmolar hyponatremia. Remember, we always rule out adrenal insufficiency and hypothyroidism before we label someone with syndrome of inappropriate antidiuretic hormone (SIADH). Here we are, now rule it out.

Henle listens intently and takes notes.

Nephron

Hyperkalemia, often associated with a mild hyperchloremic acidosis, occurs in 60–65 percent of patients due to mineralocorticoid deficiency. Hypercalcemia occurs rarely; increased calcium input into the extracellular space and reduced renal clearance may account for this phenomenon. Slightly reduced GFR or increased tubular calcium reabsorption are candidate mechanisms. Measurement of blood or urine aldosterone levels will indicate whether the adrenal gland is producing aldosterone. Low levels support the diagnosis of primary adrenal insufficiency.

Henle

I see!

Nephron, with confidence

Loss of mineralocorticoid activity in this woman led to salt dumping, which explains her elevated urine sodium and decreased aldosterone activity that produced her hyperkalemia. Her peripheral hypoglycemia can also be explained by this disorder. I deduce her urine glucose was negative.

Henle

Correct.

Nephron

Good. I like it when you hide information from me.

They both chuckle...

Nephron

Did you obtain a plasma renin activity and a serum aldosterone level? What results do you predict for these assays?

Henle, confidently

I ordered those tests. I expect the aldosterone to be low and the renin high as a secondary response.

Nephron

Correct again, Henle!

They pause...

Henle

Detective Nephron, is this a type IV renal tubular acidosis?

Nephron, with a smirk Almost all states of primary hypoaldosteronism generate a chronic normal-gap metabolic acidosis. Inhibition of any step from the production of renin to angiotensin II formation, from aldosterone production to cortical collecting duct response, will promote hyperkalemia. No matter what the cause of hypoaldosteronism, distal tubule sodium reabsorption and proton secretion will be slowed. Hyperkalemia can also inhibit ammonia production which will reduce acid secretion. You can give this patient a diagnosis of renal tubular acidosis, but it is meaningless until you identify the cause. In this case, adrenal insufficiency is the cause. In other cases, it could occur from drugs such as NSAIDs, ACEIs or ARBs, chronic heparin, spironolactone, amiloride, or trimethoprim. Anything that affects any step in this endocrine pathway can result in hyperkalemia and a normal-gap metabolic acidosis.

The detective pauses to sip his coffee...

Nephron

I would ask the primary physician to perform a morning cortisol level, corticotrophin stimulation test, and radiological examination of the adrenal glands.

She could be suffering from adrenal tuberculosis or a lymphoma and might need urgent attention. Endocrine abnormalities are common in asymptomatic patients with HIV infection and those with acquired immunodeficiency syndrome. The adrenal glands may show a necrotizing adrenalitis caused by cytomegalovirus infection, but infection with *Mycobacterium avium-intracellulare* or cryptococci and infiltration by metastatic Kaposi's sarcoma are also possible.

One week later, Henle returns to present results.

Henle

Her serum aldosterone level was less than 4.1 ng/dL, and her plasma renin was 5 ng/mL. Aldosterone was low and renin elevated appropriately. Cortisol level was also low, and she failed the corticotrophin stimulation test. These results confirm your diagnosis of primary adrenal insufficiency.

Her CD4 count was decreased to 300/μL. Her doctors eventually diagnosed adrenal tuberculosis, and therapy was begun. Mineralocorticoid replacement was begun, but corticosteroids were not, in fear of worsening her tuberculosis.

Nephron, pleased

Excellent!

Henle

She is doing relatively well now, and her electrolyte abnormalities are correcting.

Nephron

I just want to point out to you that from a single electrolyte disturbance we diagnosed a life-threatening systemic disorder. Always be a good detective. Observe, think, read, and apply! If it doesn't cross your mind, you will never diagnosis it.

Great case, Henle! Now let's go get some real coffee. ●

Detective Nephron was developed by Kenar Jhaveri, MD, an assistant attending in nephrology at North Shore University and Long Island Jewish Medical Center in Great Neck, N.Y. Detective Nephron was inspired by Mitch Halperin, MD, and Muthukumar Thangamani, MD, both of the University of Toronto, and Alan Weinstein, MD, of Cornell University.





Research Excellence, Clinical Leadership and a Commitment to Our Patients

Kidney disease affects one out of every nine adults. If kidney disease is detected and treated early, kidney function can be preserved. At Yale-New Haven Hospital we are dedicated to delivering compassionate, high-quality care for people with kidney conditions. We provide the latest therapies to minimize the impact of kidney disease and allow our patients to lead healthy and fulfilling lives.

Our doctors have particular expertise in treating kidney stones, hypertension, pregnancy-associated kidney problems, polycystic kidney disease, glomerulonephritis and inflammation of the kidney. For advanced kidney disease we offer a wide range of care options including transplantation and all forms of dialysis.

Our researchers are internationally recognized leaders in the study of acute kidney injury, kidney stones, and inherited kidney diseases including polycystic kidney disease. We are home to two Kidney Centers funded by the National Institutes of Health and numerous clinical trials for kidney patients.

Being on the forefront of the clinical research and treatment means our physicians and surgeons are considered national leaders in the current understanding of kidney disease, and most importantly, are positioned to provide the best care possible to our patients.



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ASN News



In 2008, ASN leaders hired a leading health care communications firm, GYMR, to survey members, external partners, and other stakeholders to understand how the society is perceived by kidney professionals. Responses to the survey and numerous interviews indicated that ASN was widely regarded as the premier professional society promoting intellectually rigorous kidney education and research and holding the world's most essential meeting focused on kidney disease (ASN Renal Week).

Many respondents, however, were unaware of the active role ASN plays in advancing clinical care and science worldwide and in addressing current concerns in kidney disease and policy. ASN leaders began to evaluate how the Society presents its goals and achievements and contracted with a leading design firm, Informatics Studio, to develop a new logo and visual identity that would embody ASN's ever more active role in the kidney community.

The society tagline, "Leading the fight against kidney disease," introduced

ASN: Moving Forward

in 2009, reflects the evolution of ASN and recognizes the effort, drive, and results ASN members bring to the kidney community. The new logo, introduced January 1, 2010, builds on that tagline to highlight the dynamic role ASN and its members play providing high-quality care to patients, conducting cutting-edge research, educating the next generation of kidney care professionals, and

shaping policy.

Founded in 1966, ASN has evolved from holding an annual meeting to publishing two scientific journals (starting with the *Journal of the American Society of Nephrology* in 1990) to establishing a freestanding office in 2000 to producing myriad educational offerings (such as the Nephrology Self-Assessment Program, or NephSAP, which started in 2002) to

expanding its efforts related to advocacy, policy, and public affairs in 2008.

The logo serves as a tangible symbol of ASN's evolution in the global kidney community and the society's commitment to improving lives through kidney care, research, and education. The new logo is but one of many steps ASN will take between now and its 50th anniversary in 2016 to celebrate this ascension. ●



ASN Student Scholar Grant

ASN supports medical students with an interest in either basic or clinical research to spend 10-52 weeks engaged in continuous full-time research.

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Friday, March 5, 2010

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Grants and Funding Opportunities

ASN funds clinical and basic research, and provides grant support to members at various points in their careers.

Career Development Grants for New Investigators –

Advancing the independent careers of young investigators in biomedical research, ASN awards these grants to applicants within seven years of initial faculty appointment.

Next application deadline: Friday, January 29, 2010

Interim Funding Grants for Established Investigators –

ASN provides bridge grant support to investigators who have submitted a competitive renewal R01 application, but were not funded.

Upcoming application deadlines: Friday, November 13, 2009; Friday, March 5, 2010; Friday, June 4, 2010

Grants for Medical Student Research – ASN enables selected medical students with an interest in either basic or clinical research to spend time engaged in work on a kidney research project.

Upcoming application deadlines: Friday, March 5, 2010; Friday, October 1, 2010

Travel Support Opportunities – Various travel support opportunities are available to ASN members to attend Renal Week 2010.

Next application deadline: Friday, July 30, 2010

For more information regarding ASN Grants and Funding, please contact grants@asn-online.org or visit www.asn-online.org.

Industry Spotlight

Dialysis Companies Report 3Q 2009 Results

The dialysis services sector of the health care industry grew in nearly every major financial category in the third quarter of 2009 and for the first nine months of 2009 compared with the previous year. Results for DaVita, Dialysis Corporation of America (DCA), and Fresenius North America are given in the chart.

2009 Dialysis financials, to date	Net 3Q revenue 2009	Net 3Q revenue 2008	Net revenue first 9 months 2009	Net revenue first 9 months 2008	Revenue per treatment, 3Q 2009	Revenue per treatment, 3Q 2008
DaVita	\$110 million	\$93.9 million	\$313.0 million	\$275.8 million	\$343	\$336
Dialysis Corporation of America	\$25.1 million	\$21.9 million	\$73.3 million (operating revenue)	\$63.2 million	\$326	\$313
Fresenius North America, dialysis market	\$1.74 billion dialysis services/ medical care \$209 million, dialysis drugs/ products	\$1.59 billion for medical care \$180 million, drugs/ products	\$5.60 billion total dialysis market, incl drugs/ products	\$5.15 billion total dialysis market, incl drugs/products	\$348	\$333

In its 3Q report, Fresenius North America reported that its revenue per treatment rose because of a combination of commercial payer revenue, higher Medicare reimbursement, and increased use of EPO pharmaceuticals related to dialysis. The number of patients in Fresenius North America rose to 130,522, an increase of 4 percent from Sept. 30, 2008. Fresenius North America has 1749 clinics in North America, and 1780 total, including clinics it manages, an increase of 5 percent over 2008.

DaVita operated or provided support to 1513 outpatient dialysis centers as of Sept. 30, 2009, and served about 117,000 patients. A total of 1481 centers were consolidated in the company's financial reports. During 3Q, the firm acquired four centers, opened 21 new centers, merged five centers, and closed one center.

DCA, which operates 35 dialysis centers, reported that same-center treatment growth rose to 6 percent for the quarter compared with 2 percent growth in the previous quarter. ●

Pharmaceutical News

Genzyme reported results of a phase II/III study of its advanced phosphate binder (APB), which was to be a more potent version of its existing drug Renvela® (sevelamer carbonate). Renvela treats hyperphosphatemia, a risk factor for heart disease in patients with chronic kidney disease.

The trial met its primary endpoint, which was to show that the APB lowered phosphate levels effectively compared to placebo, but the advanced drug did not show a significant improvement compared to the original drug. Thus, the company will not pursue further clinical development of the APB. Genzyme had hoped to develop a product with higher potency that would more effectively bind phosphate, while maintaining all the benefits of Renvela, according to a Reuters report.

In other news, the U.S. Food and Drug Administration recently announced new labeling for the diabetes drug Byetta, made by Eli Lilly and Amylin Pharmaceuticals, because of reports of kidney problems.

In three and a half years of data, the FDA received 78 reports of patients taking Byetta who had altered kidney function, including 62 cases of renal failure and 16 of renal insufficiency, according to an alert the agency sent to physicians. The FDA told physicians that some of the reports of kidney malfunction were in patients who had pre-existing kidney disease or one or more risk factors for developing kidney problems.

Information for health professionals was posted to the FDA's Web site: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformation->

[forPatientsandProviders/ucm113705.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformation-).

A few days earlier, the FDA had approved the drug Byetta as a standalone treatment for controlling sugar levels in patients with Type 2 diabetes, along with a regimen of diet and exercise. The drug was previously approved only in patients taking other diabetes medications.

"Health care professionals and patients taking Byetta should pay close attention to any signs or symptoms of kidney problems," said Amy Egan, MD, of the Division of Metabolism and Endocrinology Products at the FDA's Center for Drug Evaluation and Research. "Patients also should be aware that problems with kidney function could lead to changes in urine color, frequency of urination or the amount of urine, unexplained swelling of the hands or feet, fatigue, changes in appetite or digestion, or dull ache in the mid- to lower back." ●

Letters

ASN Kidney News accepts letters to the editor in response to published articles. Please submit all correspondence to kidneynews@asn-online.org

My Father's Gift

Navigating the American health-care system as a kidney disease patient

By Jennifer Nix

For 17 years, I watched my father run on a hemodialysis machine in our living room, and never believed my kidneys would also fail me. As an adult, I checked my blood pressure, never took ibuprofen, ate organic, and trusted the medical opinion, given to my parents in the 1970s, that my dad's renal disease was not hereditary.

In November 2008, however, I very eerily found myself at age 42 sitting across from my father's former internist in Ann Arbor, Mich., as he delivered the news that not only had I inherited a rare form of cystic kidney disease—but I was already in renal failure. Perhaps because of his friendship with my late father (who died in 1999), this

doctor was moved to rush me immediately into a transplant evaluation that very day, and within a week, I knew that three members of my immediate circle of friends and family were blood and tissue matches. The goal was to schedule a preemptive transplant from a living donor as quickly as possible.

In those first, foggy days, beyond the devastation and despair I felt over the expectation that my life as well as my husband's would be consumed by this disease, my greatest fear was one that haunts millions of Americans. I was more terrified of being denied treatment or dropped altogether by my private insurer over a technicality in my records or some heartless decision that I should have known about and reported my "pre-existing condition."

A few weeks into my ordeal, though, I learned that my end stage renal disease (ESRD) diagnosis qualified me for a government health insurance plan. I knew this same program had saved my father's life in its first year back in 1973, but I was frankly surprised to learn it still existed despite numerous legislative changes through the decades. My family history now mirrors exactly the period from 1973 to 2009, during which this entitlement program has allowed access to life-saving dialysis and kidney transplants for more than a million Americans—treatments previously denied to all but a very privileged few.

It was the summer of 1972 when my 30-year-old father, Wayne Nix, learned his kidneys were failing. As a high school teacher, with a wife and two little girls to support, his only two choices were death or financial ruin. Doctors estimated he had six months to live without beginning dialysis.

Back then, dialysis costs ran between \$10,000 and \$15,000 a year, well beyond my father's means. He was on short-term disability leave from work, with no savings to speak of and a brand new mortgage. He was also in possession of an employer-provided insurance policy with a high deductible and a low lifetime cap on payments for

medical care and prescription drugs. With hospital stays, doctor visits, and medicine and dialysis costs, my parents quickly approached bankruptcy. To help make ends meet during those initial months, my parents' friends held parties at which there would always be a "money tree," a small tree branch set in a pot with \$10 and \$20 bills fastened with twist-ties, like so many leaves. Even as my father hoped for a transplant, though, he knew there would be no money to pay for it.

By the 1960s, dialysis and transplantation were established as effective treatments for kidney failure, but with no funding for long-term, chronic dialysis, hospital committees decided who would live and die. These committees looked at age, complicating health concerns, psychological well-being, and a patient's "social worth," but because the wealthy could afford to pay for their treatments outright, they were the people most often treated.

"At that time, simply put, there were no private insurers willing to cover ESRD patients," according to Richard Rettig, an adjunct social scientist with the Rand Corporation and a leading authority on the history of the Medicare ESRD Program. "I have a letter from [dialysis pioneer and physician] Belding Scribner to Met Life, imploring that company to initiate coverage for life-saving medical treatments for chronic kidney failure patients. Scribner and others went to all the big insurers at the time, and not one answered the call to cover chronic ESRD treatments."

My father didn't know it in the summer of 1972, but he had reason to be hopeful. By then, after years of activism by advocacy groups, pioneering dialysis and transplant physicians, a growing community of nephrologists, patients, elected officials, and Congressional staffers, the stars were aligning for the coverage of ESRD under the Medicare program.

The passage of Medicare and Med-



icaid in 1965 had opened a legislative door, and in the fall of 1971, Congress held hearings on the idea of national health insurance for all. Advocates for ESRD's inclusion in any proposed legislation were well represented, particularly by dramatic testimony from Shep Glazer, then the vice president of the National Association of Patients on Hemodialysis (today the American Association of Kidney Patients), who shared his story while dialyzing right there on the chamber floor.

"I am 43 years old, married for 20 years, with two children ages 14 and 10. I was a salesman until a couple of months ago, when it became necessary for me to supplement my income to pay for the dialysis supplies. I tried to sell a noncompetitive line, was found out, and was fired," he said. As his blood pumped through the artificial kidney for all to see, Glazer asked the House members: "Gentlemen, what should I do? End it all and die? Sell my house for which I worked so hard, and go on welfare? Should I go into the hospital under my hospitalization policy? Then I cannot work. Please tell me. If your kidneys failed tomorrow, wouldn't you want the opportunity to live? Wouldn't you want to see your children grow up?"

While it's impossible to determine the deciding factor, eventually Democrats and Republicans in both the House and Senate agreed nearly unanimously that the plight of ESRD patients constituted a moral imperative to provide access to health care through government insurance. A Democratic Congress passed the Medicare ESRD Act in October 1972, for the first time singling out a specific disease for Medicare coverage without requiring beneficiaries to be age 65 or older. (Lou Gehrig's disease is also covered similarly under Social Security, but patients generally live only two years after diagnosis.) A Republican president, Richard M. Nixon, signed the act into law, and by July 1973, the entitlement was paying for my father's dialysis, along with that of about 7000 other kidney patients.

Medicare ESRD would pay for my father's home-based dialysis for 17 years. It also paid for an unsuccessful transplant attempt in 1975 and a successful cadaveric transplant in 1991, as well as hospital stays and some of his prescription immunosuppressant drugs,

which kept his body from rejecting the new kidney. Without passage of this landmark legislation, those doctors who first told my dad he had six months to live would have been right. Instead, he lived another 27 years—teaching, coaching, and creating the National Kidney Foundation's RISE Program, a vocational rehabilitation course for kidney "consumers" (he hated being called a patient). Wayne Nix also became a nationally known activist and testified before Congress about the need for better regulation of for-profit dialysis centers.

I had my own transplant on May 22, 2009, with a kidney miraculously and graciously donated to me by my friend James. We ended up having the surgeries at the University of California—San

qualify for, and ends up costing taxpayers more money because Medicare ESRD must pay roughly \$74,000 a year to keep a dialysis patient alive, while it only costs about \$24,000 a year for the medications to keep a transplanted organ from being rejected. Legislation is currently pending to correct these problems. Because there are too few living donors and not enough cadaveric kidneys available, as many as 14 kidney patients die each day as they wait for a transplant.

I know how lucky I am regarding how quickly my kidney failure was successfully addressed, but I'm lucky in another way too. I'd always admired the way my dad rose above his disease and accomplished so much, but some part

his experience with kidney disease. Most of all, I'm grateful I had Wayne Nix for a dad. ●

Jennifer Nix is a former producer for National Public Radio's "On the Media." She writes frequently about media and politics, and is currently at work on a memoir about her family's history of disease and activism.

Kidney disease ended up providing me with a tremendous gift, by helping me to see my childhood in a different light, and seeing how it prepared me to face a difficult challenge in adulthood.

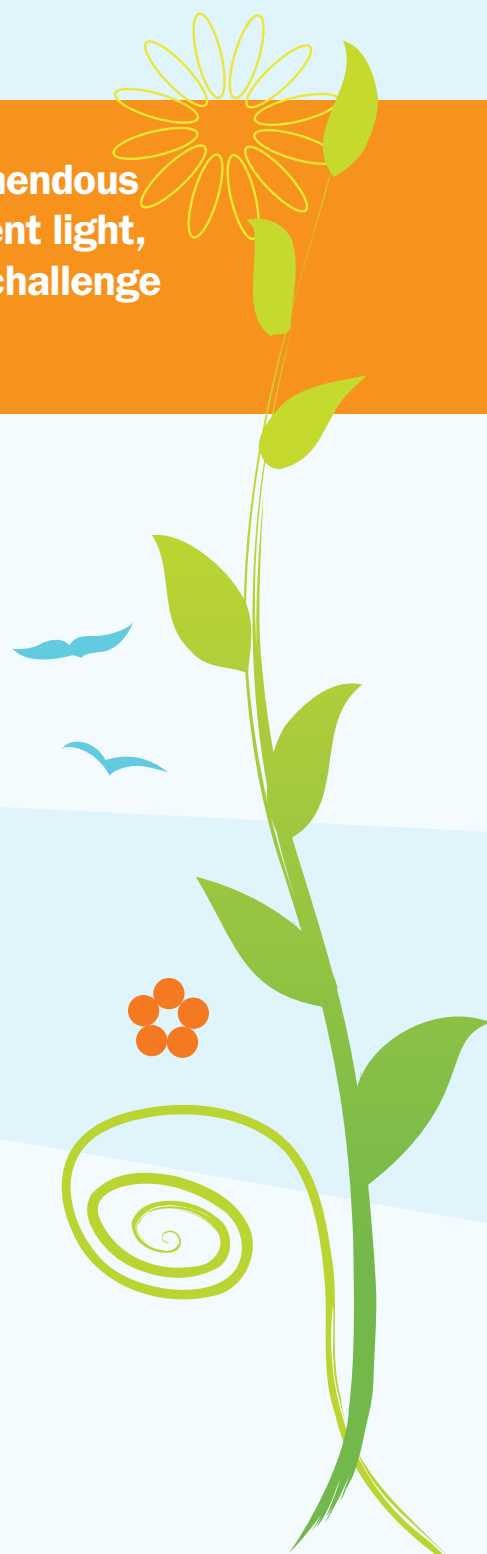
Francisco (it was close to my home and a leader in living donor transplantation), and we both recovered quickly. Because of changes made to Medicare ESRD in the 1980s and '90s, my private insurance is mandated to help cover ESRD costs—a very clear example of what President Obama has called "a public health insurance option keeping private insurance honest." Between Aetna and Medicare ESRD, nearly all of the bills associated with James's surgery and all of my treatment and medicines arrive saying "paid in full."

Going from diagnosis to live-donor transplant in under six months, with treatment paid for by both private insurance and Medicare, puts me in a rarefied group. Approximately 75 percent of ESRD patients are covered by only Medicare, which pays 100 percent of dialysis costs, but only 80 percent of transplant costs and currently stops paying for prohibitively expensive immunosuppressant drugs after three years.

The inability to pay for medications prevents many ESRD patients from getting transplants they would otherwise

of me had resented the ways in which I thought his disease cast a shadow over our family life. After my own diagnosis, though, I saw very clearly how well my father had prepared me to face the disease. Through his brave example, willingness to be included in research studies, and all the hard work he did on behalf of future kidney patients, my own experience has been surprisingly smooth. I knew where to get information and how to go about getting treatment. I knew that should I need dialysis, home-based dialysis would be my best option for long-term survival, and that if I had to be in a for-profit dialysis center, to make sure a new artificial kidney was always used for each run. I knew how to speak up for myself, but at the same time, I felt like my dad was there with me every second helping me navigate the system.

Kidney disease ended up providing me with a tremendous gift, by helping me to see my childhood in a different light, and seeing how it prepared me to face a difficult challenge in adulthood. I'm now so grateful for everything I learned while watching my dad tackle



Journal View

Sharp Drops in GFR Linked to Increased Cardiovascular Disease and Mortality

Compared to medical therapy alone, percutaneous revascularization does not improve clinical outcomes—and may increase risks—for patients with renal artery stenosis, concludes a trial in *The New England Journal of Medicine*.

The randomized, unblinded trial included 806 patients with atherosclerotic renovascular disease at 57 hospitals, most in the United Kingdom. One group received medical therapy alone, while the other group received medical therapy plus percutaneous revascularization, performed by local practitioners.

At five years' follow-up, the two groups were similar in terms of progression of renal dysfunction, assessed using the reciprocal of the serum creatinine level. Mean serum creatinine level was 1.6 μmol lower in the revascularization group. Most secondary outcomes were also similar between groups, including systolic blood pressure, renal and cardiovascular events, and mortality.

At the same time there was evidence of “substantial” risks associated with revascularization. Twenty-three patients in the revascularization group had serious

complications, including two deaths and three amputations of toes or limbs.

Percutaneous revascularization improves renal artery patency in patients with atherosclerotic renovascular disease. However, it remains unclear whether this procedure improves clinical outcomes, compared to medical therapy.

The new trial finds comparable rates of progressive renal impairment and other clinical outcomes for patients undergoing revascularization versus medical therapy alone. “Revascularization carried substantial risk but was not associated with any benefit with respect to renal function, blood pressure, renal or cardiovascular events, or mortality,” the researchers write. They also note a lack of benefit on post hoc analysis of a subgroup for whom revascularization is often recommended: patients with either bilateral renal-artery stenosis of more than 70 percent or renal-artery stenosis of more than 70 percent in a single functioning kidney [The ASTRAL Investigators: Revascularization versus medical therapy for renal-artery stenosis. *N Engl J Med* 2009; 361:1953–1962]. ●

Increased Mortality after Starting Dialysis Isn't Specifically Cardiovascular

The sharp increase in mortality among patients starting dialysis reflects increases in noncardiovascular as well as cardiovascular causes of death, according to a study in the *Journal of the American Medical Association*.

A large European registry was used to identify 123,407 adults starting dialysis from 1994 to 2007, including average follow-up of nearly two years. The data confirmed the high overall risk of death among dialysis patients: 192 per 1000 person-years, compared to about 12 per 1000 person-years in the European general population.

There was no major difference, however, in the percentage of deaths from cardiovascular causes: 39 percent in the dialysis cohort versus 40 percent in the general population. Standardized cardiovascular mortality was 8.8 times higher in the dialysis group than in the general population, while noncardiovascular mortality was 8.1 times higher.

Although all-cause mortality was higher compared to the general population, among dialysis patients, the non-

cardiovascular mortality rate exceeded the cardiovascular mortality rate. “These results suggest that excess mortality in patients receiving dialysis is not specifically the result of increased cardiovascular deaths,” the researchers said.

Dialysis is associated with a 10- to 20-fold increase in cardiovascular mortality, compared to the general population. But the new results challenge current thinking that cardiovascular disease explains most of the high overall mortality in dialysis patients.

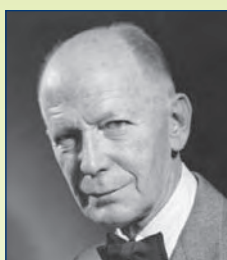
Instead, the results suggest similar increases in cardiovascular and noncardiovascular mortality during the first few years on dialysis. “This implies that the importance of noncardiovascular mortality in patients receiving dialysis has generally been underestimated,” the investigators wrote. “Therefore, research should focus more on methods to prevent noncardiovascular mortality.” [de Jager DJ, et al. Cardiovascular and noncardiovascular mortality among patients starting dialysis. *J Am Med Assoc* 2009; 302:1782–1789]. ●

ASN Awards Deadline Nears

ASN annually presents five awards to individuals who have made important contributions to nephrology in areas ranging from education, teaching, research, clinical care, and beyond. The nominations cycle for awards to be presented at Renal Week 2010 ends this month.



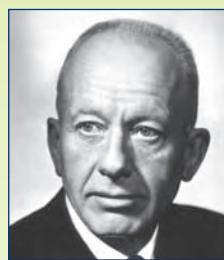
The Robert G. Narins Award honors individuals who have made substantial and meritorious contributions in education and teaching.



The John P. Peters Award recognizes individuals who have made substantial research contributions to nephrology and have sustained achievements in one or more domains of academic medicine, including clinical care, education, and leadership.



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.



The Homer W. Smith Award is presented annually to an individual who has made outstanding contributions that 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.



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.

The deadline for all ASN awards nominations is Friday, January 29, 2010. Nomination letters should be emailed to ASN Operations Coordinator Laura McCann at lmccann@asn-online.org. Please note:

- To nominate a candidate, please submit a letter of nomination and the nominee's curriculum vitae.
- Nominations submitted in 2009 do not need to be resubmitted in 2010. Past nominees will be reconsidered in 2010.
- ASN understands the importance of having its awards recognize the diversity of the Society's members as well as the renal community.

Please visit www.asn-online.org/awards for more information about the awards.

Member Benefits

Education

ASN provides member discounts for a variety of exceptional educational activities:

- **Renal WeekEnds 2010** summarize, critique, and integrate key Renal Week 2009 presentations in powerful two-day courses (presented in six locations across the United States).
- **15th Annual Board Review Course and Update** prepares nephrologists for the ABIM initial certification and maintenance of certification examinations and provides a comprehensive update for the practicing nephrologist.
- **ASN Renal Week 2010** remains the world's premier gathering of kidney professionals presenting advances in treatment, research, and education.

Abstract Submission allows members to submit and sponsor abstracts for oral and poster presentation at ASN Renal Week.

ASN In-Training Examination for Nephrology Fellows helps identify gaps in training and is similar in design to the ABIM certifying examination.

Online Geriatric Nephrology Curriculum provides essential education in geriatric nephrology.

Grants & Funding

ASN funds more than \$3 million annually for research and travel grants.

Member Services

ASN supports several initiatives to enhance members' careers:

Membership Directory

Access ASN member contact information through a searchable online directory.

ASN Committees and Advisory Groups

Volunteer to serve on an ASN committee and help guide the future direction of the society.

ASN Career Center

Advertise jobs, review candidates, post resumes, apply for positions, and reach employers and recruiters—all through one website.

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Achieve FASN status and have your outstanding credentials, achievements, and scholarship recognized.

Policy and Public Affairs

Stay informed about how current and future legislation affects nephrology and improve treatment, research, and education by volunteering to help ASN advocate on behalf of members and their patients.

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Receive all ASN publications and communications in print and online:

Journal of the American Society of Nephrology (JASN)

The leading kidney journal in the world.

Clinical Journal of the American Society of Nephrology (CJASN)

The primary resource for cutting edge clinical research in nephrology.

Nephrology Self-Assessment Program (NephSAP)

An essential tool for earning continuing medical education credits and maintenance of certification points.

ASN Kidney News

A news magazine offering exceptional coverage of current issues of interest to kidney professionals.

ASN Kidney News Podcasts

A bi-monthly audio program providing in-depth discussions of topics that interest and challenge the global kidney community.

ASN Kidney Daily

A daily email collating kidney-related news from medical journals, newspapers, and other media.

Renal Express

The ASN newsletter keeping members current on society programs and news.

Member Categories

Active Member (\$275)

An individual who holds an MD, a PhD, or the equivalent, resides in North or Central America, and fulfills at least one of the following criteria:

- Completion of research or clinical training in nephrology.
- Specialized training in nephrology during residency or other relevant postgraduate education.
- Publication of at least one peer-reviewed paper in nephrology.
- Experience as a specialist in kidney disease and related conditions.

Corresponding Member (\$275)

An individual who meets the criteria for active membership but resides outside North or Central America.

Affiliate Member (\$275)

An individual in nephrology or allied fields who is not eligible for Active or Corresponding membership.

Fellow-in-Training Member (FREE) *VERIFICATION REQUIRED*

A nephrology fellow or postdoctoral student who resides in North or Central America.

Retired Member (FREE)

A senior member retired from clinical, research, and teaching activities who wants to receive print and online subscriptions to ASN publications.

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Policy Update

ASN to CMS: Protect Nephrologist Autonomy and Quality of Care for Patients with ESRD

ASN Advises CMS as it Moves Toward a New Bundled Payment System

This past December, ASN submitted an extensive comment letter to the Centers for Medicare and Medicaid Services (CMS) on the End Stage Renal Disease (ESRD) bundled payment system Proposed Rule. This letter represented nearly three months of intensive analysis and discussion by the ASN ESRD Task Force, the ASN Public Policy Board, and ASN policy staff.

In September 2009, the Centers for Medicare and Medicaid Services (CMS) released the much anticipated End Stage Renal Disease (ESRD) bundled payment system Proposed Rule. The bundled payment system, mandated by the Medicare Improvements for Patients and Providers Act of 2008, will provide a single payment for all drugs and services related to dialysis care—including medications that are separately billable under the current payment system—beginning January 1, 2011. Prior to issuing a final rule, CMS solicits commentary from the medical community on the Proposed Rule.

Given the Rule's monumental impact on patients with kidney disease and the practice of nephrology nationwide, ASN formed an ESRD Bundling Task Force to analyze and provide comment on the 547-page document. The Task Force, comprised of eight members from a diverse range of clinical and research backgrounds, scrutinized the Rule during numerous conference calls as well as a full-day retreat. In its deliberations, the group focused primarily on the Rule's potential influence on patient care and physician autonomy. ASN also worked closely with the American Society of Pediatric Nephrology (ASPN) to present a unified message to CMS on the potential ramifications of the Proposed Rule

on the pediatric population.

In late October, ASN presented comments on the bundled payment system at a CMS town hall meeting at the agency's headquarters in Baltimore to the entire CMS ESRD staff and much of the kidney care community. More than 300 applicants requested the opportunity to comment, and ASN was one of the few organizations to earn a spot. Read a transcript of the speech at CMS headquarters, presented by ASN Director of Policy and Public Affairs Paul Smedberg, at ASN's patient care policy page (www.asn-online.org).

Upon drafting a comment letter, the Task Force sought review and feedback from the Members of the Public Policy Board, Practicing Nephrologists Advisory Group (PNAG), Dialysis Advisory Group (DAG), and the ASN Council. Suggestions from these groups were incorporated into the final comment letter submitted to CMS; ASN encourages members to read this letter on ASN's patient care policy page.

ASN thanks the following members for dedicating their time and expertise to the ESRD Task Force:

- Alfred Cheung, MD
- William Harmon, MD
- Julia Inrig, MD
- Rajnish Mehrotra, MD, FASN
- Uptal Patel, MD
- Emily Schopick, MD
- John Sedor, MD
- Suzanne Watnick, MD

Moving forward, the ASN Policy Board and Policy staff look forward to further communications with the Agency on this important issue. For additional information about the Proposed Rule or ASN's patient care policy efforts, please contact ASN Policy Associate Rachel Shaffer at rshaffer@asn-online.org or Paul Smedberg at psmedberg@asn-online.org.

NIH Announces National Research Study Recruitment Registry

On November 10, 2009, the NIH announced the first national research study recruitment registry to match volunteers with researchers. Individuals who want to participate in research studies can go to ResearchMatch.org and connect online with researchers nationwide. The disease-neutral website is a not-for-profit, secure site designed to help volunteers gain access to studies that are recruiting participants.

"This registry provides obvious benefits for nephrology researchers, but the role it could play for clinicians providing care to patients with rare diseases, for which there is not an effective treatment to offer, should not be overlooked," said ASN Clinical Science Committee Member Rajnish Mehrotra, MD, FASN. "One suggestion could very well be to register on such a website. All primary glomerular diseases are infrequent enough such that patients, clinicians, and researchers

working on such disease could benefit from using this registry."

The site is the result of a collaborative effort of the national network of medical research institutions affiliated with the Clinical and Translational Science Awards (CTSAs), which focuses on enhancing the translation of basic science research discoveries into new treatments for patients. The CTSA program is led by the National Center for Research Resources at NIH. The Vanderbilt CTSA hosts the registry.

After a volunteer has self-registered on ResearchMatch.org, they are notified electronically if they are a possible match and must then make the decision to release their contact information. Those behind the development of ResearchMatch hope the site will provide a convenient solution to the challenge of enrolling an adequate number of participants to complete research and advance health care.

Federal Budget Process Begins

President Obama has started developing the budget for the fiscal year that begins October 1, 2010.

ASN has joined forces with advocates across the nation to urge President Obama to continue to strengthen the scientific and economic momentum generated by the American Recovery and Reinvestment Act (ARRA). ARRA has invigorated the research community after years of diminishing budgets for the National Institutes of Health (NIH), but substantial, sustainable funding is necessary to make medical research a priority.

On Monday, February 1, 2010, President Obama will submit his budget to

Congress, including proposed funding at agency and department levels and justification for cuts or increases to programs. Six weeks after the budget is released, the House and Senate authorizing committees will hold hearings on the president's proposed budget. ASN will recommend particular budget allocations and advocate on behalf of research programs and agencies to promote the best outcomes for kidney research and treatment.

To learn more about ASN's actions on the Hill and to advocate on behalf of the Society, visit ASN's Legislative Action Center at <http://capwiz.com/asn/home>.

Advocacy Efforts Help Drive Medicare Physician Payment Reform

In recent months, ASN has been pressing lawmakers to reform the flawed sustainable growth rate (SGR) formula with a new Medicare physician payment system. These efforts came to fruition on November 19, 2009, when the U.S. House of Representatives passed HR 3961, "The Medicare Physician Payment Reform Act of 2009." If passed by the Senate, this bill would permanently restructure the SGR formula, which determines the annual updates to payment rates for physician services.

HR 3961 would eliminate the 21 percent reduction in Medicare payments that was scheduled to go into effect this month. It would also prevent future pay-

ment cuts, projected to be about 2 percent annually for several years. The bill would put in place a new payment formula to provide positive payment updates, using an update adjustment factor based on actual physician expenditures. According to the Congressional Budget Office, the changes to the SGR formula would increase the fees paid to physicians under Medicare by about \$195 billion over the 10-year budget projection window.

ASN will continue to advocate for HR 3961 as it moves through the Senate, working closely with partner medical professional societies to advance this important measure.

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Reference: 1. Nagel, M., et al., *Hum Mutat.* 2005 Jul; 26(1):60.

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