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 Health Care Reform Legislation Nears Final Form

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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 Honstetter, MD, chief of the nephrology division at Albert Einstein College of Medicine in New York City and chair of the ASN Public Policy

### Health Care Reform Legislation Nears Final Form

By Eric Seaborg

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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-associated 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.

Questions also remain as to the best method of dialytic support (i.e., continuous renal replacement therapy versus standard dialysis), timing of initiation, and intervals. 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 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 at different rates across the country, and with managed care it's been harder and harder to get into the hospital.

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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 fund- ing 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 immunosuppress- ing 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.

**Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)** requires that Medicare pay- ment 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 prepar- ing 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 in another 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 organi- zations 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 extensions.

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 compara- tive 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, Hostetter 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 manage chronic kidney disease, 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 reim- bursements currently under consideration by CMS.

While more funding for research would be welcome, Hostetter 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 physici- an 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 cov- erage would come through a variety of mechanisms. Medicaid would be expand- ed 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 insur- ance, 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 bill would impose a 5.4 percent income tax on individuals earning more than $250,000 and couples earning more than $1 million. The Senate bill would 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 Hostetter look forward to the expansion of health insurance coverage. “It’s a start,” Hostetter noted, “and 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 subter 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.”
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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.

Happy Birthday, ASN Kidney News!

By Pascale Lane

Renal WeekEnds

The perfect complement to Renal Week

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ASN Renal WeekEnds 2010 at a city near you:
- Dallas, TX, February 6 - 7
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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

Pascale Lane
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, readsies 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 readiness 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 osmolarity is 551 mOsm/kg. The serum osmolarity is 288 mOsm/kg. I even calculated a transtubular potassium gradient (TTKG); it is 4.

**Nephron, looking a bit scared, realizing he has provided more information than requested…**

Good work, Henle! The kidney should be dumping potassium with a TTKG of at least 10, especially with high urine sodium. Urine osmolarity 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…**

**Nephron**

…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).

**Henle, smirking**

Yes, Detective. Her platelet count is less than 500,000/µL. 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 hypercalcaemia, and hypoglycaemia.

**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 hours 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. Hyperkalemia 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 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 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 adenitis 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.

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.
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.
Frankly, we’re flattered!

But it takes more than imitation to become America’s APD leader.

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ASN News

ASN: Moving Forward

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 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 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.

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

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.

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.
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.

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

By Jennifer Nix

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.

The passage of Medicare and Medicaid in 1965 set the stage for the ESRD Program,” 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 chronic dialysis 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-
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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].


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 noncardiovascular 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 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 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** 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** 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.

- **Fellows of the American Society of Nephrology (FASN)**
  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.

Publications and Communications
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.

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The candidate section of the ASN Career Center is open to ASN members only, which makes it a premiere benefit of membership. Job seekers can post anonymous resumes for employer review, search the latest job postings in their field or area of interest, and create personalized job agents that will seek out and notify them of job postings based on the selected criteria.

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To advertise, contact Tammy Zafiros at tammyz@scherago.com or 941/753-3086.
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
• Jula Inrig, MD
• Rajnish Mehrotra, MD, FASN
• Uptal Patel, MD
• Emily Schopick, MD
• William Harmon, MD
• Suzanne Wińnick, 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.

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 payment 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 a Congressional Budget Office, the changes to the SGR formula would increase the fees paid to physicians under Medicare by about $915 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.

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-specific website is a non-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 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 glomerulonephrotic 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 (CTSA), 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 future 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.

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