ASN® The American Society of Nephrology

KidneyNews

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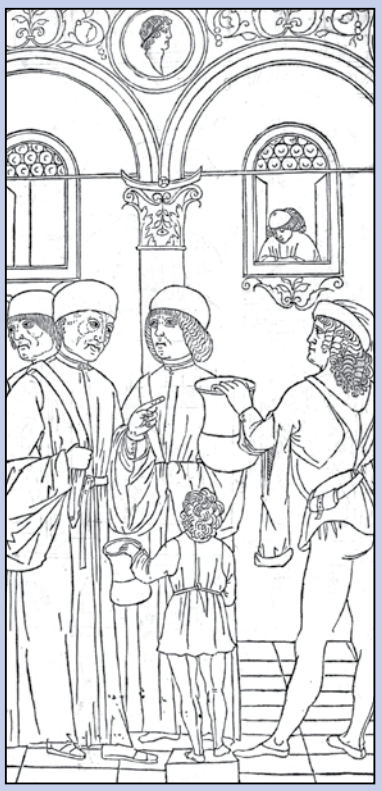

Johannes de Ketham, Fasciculus Medicinae. In comincia el dignissimo Fasciculo de Medicina in Volgare. Venice: Giovanni & Gregorio di Gregorii, 5 Feb. 1493/4.

Two curious youths with urine flasks attend a group of physicians. Sparking curiosity about the kidneys could help spur young people to become nephrologists. See special section, p. 11.

Medicare Policy Could Reduce Dialysis Access for African Americans

Study Raises New Concerns Over Proposed Fixed Payment Bundle

By Timothy O'Brien

The Centers for Medicare & Medicaid Services' (CMS) proposed fixed payment bundle system could have an unintended consequence—reduced access to dialysis for African Americans, suggests a study in the July *Journal of the American Society of Nephrology*.

Racial differences in hemoglobin levels and requirements for erythropoietin-stimulating agents (ESAs) could provide a financial disincentive for dialysis centers to accept African American patients under the coming bundled payment policy, according to Areef Ishani, MD, of the University of Minnesota. "The concern is that when you go into a fixed-bundle payment, where everyone gets paid the same irrespective of race and the influence of race on injectable medications, it could turn out to disadvantage African Americans," said Ishani.

The concerns arise from the recent proposal to alter CMS reimbursement for outpatient hemodialysis. The proposal calls for a "fixed payment bundle" covering both outpatient dialysis and injectable medications. According to the proposal, dialysis facilities "would no longer have an incentive to provide more ESRD drugs than clinically necessary" and clinicians would have "more flexibility in decision making because incentives to prescribe a particular drug or treatment are reduced." (The complete proposal can be downloaded at http://www.gao.gov/new.items/d0777.pdf.)

However, Ishani and colleagues saw cause for concern regarding the policy's potential impact on African-American patients. They noted that African Americans historically start dialysis at lower hemoglobin levels that white pa-

Continued on page 3

Experts Explore Role of ESAs Beyond Making Red Blood Cells

For 20 years, the use of erythropoiesis-stimulating agents (ESAs) has improved the health and quality of life for patients with chronic kidney disease (CKD) while reducing the need for blood transfusions. By replacing erythropoietin, a protein made by the kidneys but deficient when the kidneys fail, ESAs help correct the anemia of CKD by stimulating the bone marrow to produce more red blood cells.

Therapy has always been a balancing act. Physicians must weigh the amount of ESA to use, providing enough iron to meet the body's needs for red blood cell production and setting and achieving hemoglobin goals. Another goal is to balance benefits and risks of ESAs' nonhematologic effects in the body, effects that are increasingly coming into view through clinical experience and research. Recent studies indicate that more is not always better. A higher hemoglobin level can present problems, and negative outcomes may be related to a multitude of factors, possibly including high doses of ESAs themselves.

Besides their use in CKD, ESAs are also approved for treating the anemia related to cancer chemotherapy. Here, too, their optimal use is still being worked out.

"The mechanism of why some patients fare poorly, I don't think we understand very well," said Murat Arcasoy, MD, associate professor of medi-

Continued on page 4

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Please see Brief Summary of full Prescribing Information on adjacent page.

References: **1.** Renvela [package insert]. Cambridge, MA: Genzyme Corp; 2007. **2.** Delmez J, Block G, Robertson J, et al. A randomized, double-blind, crossover design study of sevelamer hydrochloride and sevelamer carbonate in patients on hemodialysis. *Clin Nephrol*. 2007; 68:386-391.

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Medicare Policy

Continued from page 1

tients and are less likely to receive ESA therapy before initiating dialysis.

Using Medicare data, they identified about 12,000 patients starting hemodialysis during 2006. "We were looking primarily at people with the same insurance source—they all had Medicare," said Ishani. "None had been treated with an ESA in the two years prior." All received EPO during their first two months on dialysis. (A small number of patients who received darbepoietin alfa were excluded from the analysis.)

"We looked at initial hemoglobin, and yes, African Americans did come into the program with lower hemoglobins compared to whites," said Ishani. The baseline hemoglobin level in African American patients was 9.9 g/dL, compared to 10.3 mg/dL in white patients. After adjustment for sex and other variables, the racial difference was about 0.35 mg/dL.

African-American patients also had higher initial EPO requirements. "We looked specifically at EPO during the first two months, and it turned out that African Americans used about 10 to 11 percent more, compared to whites." When baseline hemoglobin level was taken into account, the racial difference in EPO narrowed to about 7 percent.

Could Racial Differences Affect Access to Dialysis Care?

It is not clear why African Americans have lower hemoglobin than whites, but there are a lot of possibilities, Ishani said. "It might be poorer care, it might be poorer access to insurance, it might be that sickle-cell trait or thalassemia are more prevalent in African Americans. Even on a population level, African Americans have slightly lower hemoglobin than Caucasians."

In some studies, apparent racial differences in hemoglobin and ESA requirements have disappeared after adjustment for other factors. "Some researchers have looked at this, and they can make this difference go away. But they have to adjust for a lot of things," said Ishani.

"That's well and good from a biological perspective. The concern we have is that Medicare doesn't pay biologically adjusted values. When you go into a fixed-bundle payment, where everyone gets paid the same irrespective of race and the influence of race on the injectable, it could turn out to disadvantage African Americans."

Racial differences in requirements for other injectable drugs could also have an impact. "The other big injectable would be vitamin D, and there are other studies showing that African Americans use more vitamin D as well," Ishani said. "Between EPO and vitamin D, you might have a combined deleterious effect of this new legislation."

One concern is that dialysis centers—most of which are for-profit entities—might find it less profitable to treat African-American patients. "Dialysis providers know what their cost structures are, and they know what their reimbursement rates are, and they can figure this all out—probably more accurately than we can using national data," said Ishani.

Center Characteristics Might Also Have Effects

Bundled payments could also adversely affect dialysis centers with larger African-American patient populations—many of which are not-for-profit. "As you look across the country, you can ask where the for-profit dialysis centers are and what is their case mix for African Americans, compared to the not-for-profit dialysis units associated with inner-city hospitals," said Ishani. "While the fixed payment bundle may be budget neutral overall, it may not be budget neutral to an individual dialysis center."

Other dialysis center characteristics may also affect revenue under the new proposal. In *Nephrology News & Issues*, J.G. Bhat, MD, and colleagues of Atlantic Dialysis Management Services in Ridgewood, NY, found that the new policy would have significant negative cost implications for small to mid-size dialysis providers. "We modeled our patient-level financial and clinical data as per the methodology proposed by CMS," said Bhat. "In our small data set, we found that the case-mix adjusters as currently defined very poorly and inaccurately predict the actual costs of ESRD care. Therefore, we believe that many smaller facilities may be placed at an increased financial risk."

"Based on the findings of Ishani et al, we can extrapolate that costs of care may be higher for African-American

Continued on page 5

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Kidney News

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ESAs

Continued from page 1

cine in hematology and oncology at Duke University Medical Center in Durham, N.C. "My feeling is that it's probably not just the hemoglobin causing adverse effects and potential for decreased tumor responses."

Typical therapeutic doses of ESAs are much higher than the body's natural levels, said Anatole Besarab, MD, director of clinical research in the division of nephrology and hypertension at the Henry Ford Health System in Detroit, Mich. "Pharmacological levels where you reach 1, 2, 3, 4 milliunits per mL are concentrations log orders higher than anything that the body normally sees, but that's part of our problem," he said during the American Society of Nephrology's Renal Week in November 2008.

Erythropoietin (Epo) has a multitude of functions and effects besides red blood cell production, or erythropoiesis. In fetal development, it aids brain development and blood vessel formation. A lack of Epo causes fetal death. In the adult, it has the potential to protect tissues, with possible applications in myocardial ischemia, heart attack, stroke, spinal cord injury, wound healing, other conditions of ischemia (lack of blood flow to a tissue), trauma, toxic exposure, inflammation, pathologic blood vessel formation (angiogenesis), and autoimmunity.

Tissue Protective Mechanisms

Epo may have therapeutic potential as a tissue protective agent, Besarab said. Administration of a single dose of recombinant human Epo decreased the degree of infarction to about one-quarter of that in saline-treated controls, he said. In addition, Epo markedly decreased tissue apoptosis. And even when given to rats three weeks after tying off a coronary artery, it induced VEGF, an angiogenic protein that resulted in capillary growth.

Similar effects can occur in the brain. "I think what's important is what's going on in the vasculature. We don't spend enough time about this particular role of Epo, and it can cause proliferation and migration" of cells, he said. He warned that different ESAs may stimulate vessel cells to different degrees, "and it is dose dependent."

Clinical Implications and Potential

In terms of possible beneficial effects besides red cell production, "the area of research that is most mature at this point in time is the potential neurologic [protective] effect of the medication," Arcasoy said. In a small study of stroke patients conducted by Ehrenreich and colleagues at the Max-Planck-Institute for Experimental Medicine of the Georg-August-University in Goettingen, Germany, recombinant human Epo or saline placebo was administered for three days to 40 patients, beginning within eight hours of an ischemic stroke.

At one month, the patients who received the active drug had greater improvement on neurologic outcome scales and a "strong trend for reduction in infarct size…compared to controls." Patients who received the drug had Epo levels in their cerebrospinal fluid that were 60 to 100 times greater than in the saline control group, indicating that Epo reached the brain, suggesting a possible direct effect of the drug on the brain and not just an increase in red blood cell numbers.

The dilemma is to balance the beneficial effects of ESAs with possible detrimental effects, Arcasoy and Besarab said. In stroke, ESA's tissue protective effects could be offset by increases in red cell mass, increased blood pressure, and an increased propensity for blood clots.

A similar concern exists for the use of ESAs in cancer patients. A side effect of chemotherapy can be anemia, and while giving an ESA may correct the anemia, the potential exists for it to stimulate some tumors.

Another potential concern is stimulating blood vessel formation in the retina of CKD patients with diabetes, a population that often develops retinal problems. Yet in certain situations, Epo can be protective, Arcasoy said.

Lois Smith, MD, PhD, and colleagues at Harvard demonstrated both protective and harmful effects of Epo administration using an animal model and manipulating the amount of oxygen that the retina was exposed to. A critical factor was the timing of Epo administration. So, again, the picture is far from clear, and not only are doses important but so may be the timing of Epo administration.

"Even for the approved indications, we don't really know optimally how to give the drugs, whether we should use hemoglobin as the target [or] whether we should have other outcome measures," Arcasoy said. "Typically hemoglobin has been measured, but at least in the renal literature, higher doesn't necessarily mean better."

In one trial, Linda Szczech and coworkers at Duke University Medical Center found that significantly more patients randomized to a higher hemoglobin target group were unable to achieve the higher target level and required high-dose Epo compared with patients randomized

ASN Kidney News Podcast: Nephrology Fellowship

In this month's _ASN Kidney News_ Podcast, Steven Darrow, MD, discusses resident choices for nephrology fellowships, factors that may prevent them from pursuing this training, and his own quest for dual fellowship in pediatric and adult nephrology. See Darrow's article on p. 16 and download the podcast at www.asn-online.org or through Itunes.

to a low hemoglobin target. They were also at greater risk of death, heart attack, congestive heart failure, or stroke. However, those patients who did achieve the target level had better outcomes than those who did not, and there was no increased risk associated with the higher hemoglobin goal. The work was conducted as part of a secondary analysis of the Correction of Hemoglobin in the Outcomes in Renal Insufficiency (CHOIR) trial.

The mechanisms of harm with more intensive ESA treatment are not clear. But one approach is to correct the factors that may limit responsiveness to ESAs, possibly allowing lower doses to be used to achieve target hemoglobin levels. Steven Fishbane of the department of neurology at Winthrop University Hospital in Mineola, N.Y., reported on the experience of a group of dialysis clinics in Berlin that "achieved outstanding patient outcomes" while targeting normal hemoglobin levels.

The study addressed ancillary factors such as intensive cardiovascular and antihypertensive treatment, treatments to optimize oxygen utilization (e.g., correction of metabolic acidosis, supplementation with L-carnitine, folic acid, and vitamins B6 and B12), maintainence of sufficient iron stores, and avoidance of excessively high ESA doses. Patients required considerably lower doses of ESA in the Berlin centers than what is typical in the United States, Fishbane said. "This is likely a result of intensive iron treatment and improved ESA responsiveness," he said. "The reduced ESA dose requirement could relate to the excellent patient outcomes."

Support for this idea comes from a study by Zhang and colleagues at the Medical Technology and Practice Patterns Institute in Bethesda, MD. Zhang's group found that ESA dose was an independent predictor of mortality in their study of more than 90,000 hemodialysis patients.

The Berlin results are in contrast to large randomized clinical trials (RCTs) that found trends toward worse outcomes with higher hemoglobin targets. Given the sample sizes, the RCTs carry more weight, Fishbane said. Nonetheless, the Berlin experience demonstrated the possibility of achieving excellent clinical outcomes while maintaining full hemoglobin correction (13.5–14.5 g/dL), he noted. In addition, patients had significant improvements in several measures of cardiac function.

More work is needed to understand the mechanisms of ESA resistance in CKD patients that lead to the need for higher doses associated with adverse effects, Arcasoy said. "We can think about ways to avoid causing problems for our patients if we understand the mechanisms."

Arcasoy suggested that discovering parameters that predict ESA resistance would be helpful. As in the Berlin experience, correcting the factors that are modifiable could increase patients' responsiveness to ESAs. For those factors that are not modifiable, "can we select patients who will fare better with ESA therapy?" he asked. The final question would be whether that approach would translate into a patient benefit.

Medicare Policy

Continued from page 3

patients," Bhat said. "Therefore, under the proposed bundle, dialysis facilities that serve a higher proportion of African-American patients may be at higher financial risk, and consequently African-American patients may be at risk for decreased access to care."

The study by Ishani et al. had some important limitations: it included only patients over age 67 with Medicare as their main insurance source, limiting generalizability. Also, ESA requirements may change after the first two months on dialysis.

The Medicare Improvements for Patients and Providers Act (MIPPA), passed last summer, calls for a bundled payment system to be implemented by 2011. To adjust for differences between patients, basic case-mix information would be used to modify the monthly captitated payment. The text of MIPPA mentions race/ethnicity as one possible factor to be considered as a payment adjuster, along with other case mix factors such as body mass index, comorbidities, and time on dialysis.

So as it stands, race may be included as a payment adjuster—but it might not, according to Ishani. "It's at a point where it's unclear whether this will make the final cut for what's included as an adjustment."

Said Bhat: "The expanded bundle needs to be re-examined prior to implementation, and the inclusion of race as an additional case-mix adjuster needs to be strongly considered."

That won't be decided until CMS issues its bundling rule, which will likely occur sometime this summer, according to Jonathan Himmelfarb, MD, director of the Kidney Research Institute and professor of medicine at the University of Washington. "Until then, it's unknown whether or not CMS will view the potential impact of race and gender as an important component for case mix adjustment for the ESRD expanded payment bundle," said Himmelfarb, who is chair of ASN's Public Policy Board.

He expects there will likely be a 60- to 90-day public comment period, during which nephrologists, dialysis center operators, and other interested parties will have a chance for input. "When the CMS rule comes out, I think it's fair to say that ASN will be paying close attention, and may or may not comment, depending on what it looks like," Himmelfarb said. "Our goal will be to see that the final decisions on these critical issues are shaped by scientific data—the more science that is available, the more evidence-based the final rules can be."

Industry Spotlight

Asian Fusion—Asahi and NxStage Partner in Dialyzers

Asahi (Japan-based Asahi Kasei Kuraray Medical) has agreed to partner with NxStage Medical to take advantage of their joint expertise and resources as makers of dialyzers. Asahi will deliver a better loan rate to NxStage, while NxStage will deliver manufacturing and business expertise to the Asian manufacturer of dialyzers. Dialyzers are part of dialysis machines that act as the filters, with patient's blood in one compartment and dialysate in the neighboring compartment.

Asahi will provide Lawrence, Mass.–based NxStage with $40 million of debt financing to pay off its entire $28 million debt obligation owed under its GE credit facility and infuse the U.S. company with funding. Asahi's $40 million loan is being delivered as a four-year term loan at 8 percent. NxStage's former loan carried 11 percent annual interest.

NxStage plans to give Asahi a license to its production technology (without royalties) to make and sell NxStage's current dialyzer. Asahi will sell this design exclusively in Asia and nonexclusively in other places.

NxStage's dialyzers will be manufactured and sold under the Asahi brand at NxStage's facilities in Germany. NxStage will license its blood tubing technology to Asahi. In return, Asahi will supply its polysulfone hollow-fiber membrane to NxStage.

Looking forward, the companies will operate with more potential capacity. Asahi has agreed to pay for a new NxStage facility if the Asian dialyzer firm sees more demand. The new facility would provide more production resources and potential cost savings for both companies.

NxStage announced net revenue for the first quarter of 2009 of $33.7 million, a 9 percent increase from last year's first quarter.

The company was fourth in line as the business with the largest revenue gain in Massachusetts during a challenging year for nearly every industry. The *Boston Business Journal* listed Massachusetts-based companies on percent change in revenue, and NxStage jumped nearly 115 percent to $128.8 million in 2008. In 2007, the company had revenues of $60 million.

NxStage CEO Jeffrey Burbank noted that revenues grew robustly because of the company's drive to encourage daily home hemodialysis with the NxStage System One. In addition, NxStage acquired Medisystems, which makes dialysis supplies like tubing and needles, and expanded its critical care customer base.

A return to PD?

The United States could save more than $1 billion in five years if just 15 percent of all dialysis patients used peritoneal dialysis (PD), according to a study published in *Clinical Therapeutics* (2009; 31:880–888). PD is an alternative to hemodialysis that uses the peritoneal membrane around the stomach to filter the patient's blood with the help of dialysate that is infused and drained by catheter.

The study was supported by a grant from Baxter Healthcare, which makes a PD system called Homechoice Pro. The researchers performed a five-year budget-impact analysis using data from the 2007 U.S. Renal Data System report.

The study concluded that PD has better survival rates than in-center hemodialysis. PD is also less expensive than hemodialysis by thousands per year per patient. The authors found that if PD use decreased to 5 percent of dialyzing patients over the next five years, Medicare spending on end stage renal disease patients would jump by about $401 million.

However, if the percentage of PD patients increased to 13 percent over the next five years, then Medicare would save nearly $826 million. And if its use increased to 15 percent by the end of five years, Medicare could see savings of more than $1.1 billion, according to the study. Savings would come from fewer hospitalizations and lower drug spending levels for the overall younger patients who undergo PD, the authors noted.

One blogger in the dialysis world took issue with the study findings about the actual cost savings: "Providing PD to people in SNF (skilled nursing facilities) is highly problematic, so you have to assume that growing the percent of people who use PD would create savings from switching people who are not in an SNF and who would have otherwise used HD. This would suggest $11,400 in savings rather than the $18,900 the authors use to get their savings of one billion dollars over five years. More on dialysis observer Bill Peckham's arguments can be found at http://www.billpeckham.com/from_the_sharp_end_of_the/2009/05/fail-clinical-therapeutics-paper-gets-the-math-wrong-and-misses-the-point.html.

Fiction Benefits Real Kidney Patients

The season finale of NBC's "30 Rock" highlighted a familiar scenario – the problem of a relative (Alec Baldwin) who was striving to find a matched kidney donor, in this case for his TV father. A chorus of popular musicians gathered at a benefit written into the show to sing "We Need a Kidney." Reality enters and takes over because the TV shows' producers actually teamed with Apple's iTunes Store to distribute a music video of the star-studded song. The video is available on iTunes' "30 Rock" page, and all proceeds from purchasing and downloading the video will benefit the National Kidney Foundation, according to its web site.

Letters

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

Iron Replacement Roundup

In Corona, Calif., Watson Pharmaceuticals announced it would continue to sell its iron deficiency treatment, Ferrlecit, in the United States until the end of the year. A Swiss arbiter ruled in favor of Watson. In March 2008, Ferrlecit's maker, Sanofi-Aventis, let Watson know that their joint agreement for supply and distribution of Ferrlecit would expire on Feb. 18, 2009, according to a filing with the U.S. Securities and Exchange Commission. Sanofi-Aventis noted it would expect damages if any sales occur after that date.

In a decision favoring Watson, the Swiss Chambers of Commerce Court of Arbitration ruled that the Ferrlecit supply and distribution agreement between Watson and Sanofi-Aventis would expire on Dec. 31. As a result, Watson officials announced the company would continue to market and sell Ferrlecit until year-end. Watson reports it is still in talks with Sanofi-Aventis in an effort to extend the agreement into 2010. If the two companies cannot agree by the Dec. 31 deadline, Watson must stop selling the drug.

According to a new report, "Global Intravenous (IV) Iron Drugs Market: Potential Opportunities," Watson is second only to Galenica Limited in terms of IV iron drug market share. The report said that Venofer—from Galenica Limited—has emerged as the undisputed leader in the IV iron drugs market and has overtaken the market share of Watson's Ferrlecit and InFed. The global market for IV iron drugs is growing, mainly in the hemodialysis setting, and IV iron could be used in many other therapeutic areas that are "highly under-penetrated," according to the report. The chronic kidney disease (CKD) population is growing outside the United States, and pricing of such drugs is lower. The market in countries like China is still developing and "growing rapidly, with tremendous potential."

Two new iron drugs are on the horizon. The U.S. Food and Drug Administration was expected to complete its review of AMAG Pharmaceuticals' anemia drug Feraheme by June 29, the company announced. AMAG would like marketing approval for Feraheme (ferumoxytol injection), an iron replacement therapy to treat iron deficiency anemia in CKD patients.

In addition, the FDA accepted Lexington, Massachusetts–based AMAG's resubmission of Feraheme's New Drug Application. The FDA had requested more information last December.

Rockwell Medical Technologies (RMTI) is testing a water-soluble iron replacement therapy for dialysis patients called SFP (soluble ferric pyrophosphate). The firm recently completed enrollment for a Phase 2b study of SFP, which is a six-month, dose-ranging study. About 130 hemodialysis patients are participating as the company determines safety parameters and optimal SFP concentration to maintain normal levels of iron and hemoglobin. The Phase 2b trial should be available for release in late November or early December, after the clinical trial ends in September.

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1. Create a Twitter account, if you don't already have one. It's free and requires very little information other than a valid email.
2. Go to http://twitter.com/RenalWeek and click on the button to request to follow. This is a closed group, so the general public will not be able to see what we say.
3. Send an email (tweet@asn-online.org) when you make the follow request. I need to know your status (practicing nephrologist, fellow, research scientist, professor, etc) and your screen name. I will then OK your membership in the group and follow your updates.

Journal View

More Preventive Care Lowers Cardiovascular Risk in CKD Patients

Among patients with chonic kidney disease (CKD), those receiving more recommended preventive care measures have lower rates of cardiovascular events and death, reports a study in the *Journal of the American Society of Nephrology*.

The analysis used three-year rolling cohorts of Medicare patients, including approximately 1.2 million patients per year. In year 1, CKD and diabetes status was assessed. Adherence to preventive health-care recommendations (based on Kidney Disease Outcomes Quality Initiative guidelines) was assessed in year 2 and atherosclerotic heart disease outcomes in year 3.

Eighty percent of CKD patients received at least two serum creatinine measurements, but only 11 percent underwent recommended parathyroid hormone testing. Cumulative incidence of any atherosclerotic heart disease event was 11 percent for patients without pre-existing cardiovascular disease and 25 percent for those with prevalent disease.

For most measures, meeting preventive care recommendations was linked to a lower risk of atherosclerotic heart disease outcomes the following year. Undergoing calcium-phosphorus assessment was associated with a 43 percent reduction in risk the following year. For patients undergoing influenza vaccination and two or more A1c measurements, risk decreased by 13 percent. The exception was serum creatinine measurement—patients undergoing two or more tests were at 13 percent higher risk the next year.

The greater the number of preventive measures in patients with CKD, the lower the risk of atherosclerotic heart disease outcomes. In the full study sample, receiving most or all preventive measures would avoid about 75,000 events per year [Snyder JJ, Collins AJ: Association of preventive health care with atherosclerotic heart disease and all-cause mortality in CKD. *J Am Soc Nephrol* 2009; 20: 1614–1622].

Many Missed Dialysis Sessions after Katrina, Study Finds

More than 40 percent of New Orleans hemodialysis patients missed one or more dialysis sessions in the wake of Hurricane Katrina, suggests a study in *Kidney International*.

The researchers performed phone interviews with 386 patients from nine New Orleans dialysis units regarding their Katrina experiences, including how the disaster affected their dialysis schedule. Forty-four percent of patients said they missed at least one dialysis session, while 17 percent missed three or more sessions.

Multiple missed sessions were more likely for patients with certain characteristics: being on dialysis for less than two years (compared to five years or longer); having 38 or fewer billed dialysis sessions; and being unaware of their dialysis center's emergency plan. Risk was also higher for patients who lived alone before Katrina, who did not evacuate before the storm made landfall, and who were placed in a shelter. For patients missing three or more sessions, the adjusted odds ratio for hospitalization was 2.16, compared to those who did not miss any sessions.

The results show the high rate and serious consequences of missed dialysis sessions for victims of a natural disaster. The findings help to identify groups at particularly high risk. Disaster preparedness plans should emphasize patient awareness of their dialysis center's emergency plan, as well as early activation of the plan [Anderson AH, Cohen AJ, Kutner NG, Kopp JB, Kimmel PL, Muntner P: Missed dialysis sessions and hospitalization in hemodialysis patients after Hurricane Katrina. *Kidney Int* 2009; 75:1202–1208].

Risk of VTE Increases with Microalbuminuria

Microalbuminuria is an independent risk factor for venous thromboembolism (VTE), reports a study in *The Journal of the American Medical Association*.

The investigators analyzed data on 8574 Dutch adults participating in a community cohort study. Microalbuminuria, defined as albumin level of 30 to 300 mg per 24-h urine collection, was assessed as a risk factor for deep vein thrombosis and/or pulmonary embolism. At an average follow-up of 8.6 years, the annual incidence of VTE was 0.14 percent.

As urinary albumin excretion (UAE) increased, so did the incidence of VTE: 0.12 percent at UAE under 15 mg/24 h, 0.20 percent at 15 to 29 mg/24 h, 0.40 percent at 30 to 300 mg/24 h, and 0.56 percent at more than 300 mg/24 h. On adjusted analysis, hazard ratios for VTE at the different levels of UAE were 1.40 at 15 to 29 mg/24 h, 2.20 at 30 to 300 mg/24 h, and 2.82 at more than 300 mg/24 h. The hazard ratio for VTE among patients with microalbuminuria was 2.00. One additional case of VTE would occur each year for each 388 people with microalbuminuria.

The results suggest that microalbuminuria is associated not only with arterial thromboembolism, but also with VTE. Risk of VTE increases at higher UAE levels, even short of microalbuminuria. More study will be needed to determine whether treatment for microalbuminuria can influence VTE risk [Mahmoodi BKJ, Gansevoort RT, Veeger NJGM, Matthews AG, Navis G, Hillege HL, van der Meer J, for the Prevention of Renal and Vascular End-stage Disease (PREVEND) Study Group. *J Am Med Assoc* 2009; 301:1790–1797].

For Older Adults, High Risk of Death While Waiting for a Kidney

Projections suggest that close to half of patients aged 60 or older currently on the waiting list for kidney transplantation will die before receiving a cadaver organ, according to a study in the *Clinical Journal of the American Society of Nephrology*.

The investigators reviewed national registry data on transplant patients including nearly 55,000 patients over age 60 who were listed for a single-kidney transplant from 1995 to 2007. Survival models suggested that 46 percent of over-60 patients wait-listed in 2006 or 2007 would die before undergoing deceased donor kidney transplantation.

For certain groups of patients, the risks of dying without a transplant were even higher, including rates of 62 percent for African Americans, 61 percent for diabetics, and 52 percent for patients aged 70 or older. Risk was 71 percent for patients with blood type B and 60 percent for those with type O, 68 percent for highly sensitized patients, and 52 percent for those on dialysis at wait-listing. By UNOS region, the risk of dying on the waiting list varied from 6 percent (region 6) to 81 percent (region 5).

The increase in waiting times to deceased donor transplantation has a particularly large impact on older patients. The risk of dying before receiving a kidney transplant is high for patients over 60 and varies between regions. Disseminated to patients, this information could have an important impact on decision-making, including the decision to seek a living donor [Schold JD, Srinivas TR, Sehgal AR, Meier-Kreische HU: Half of kidney transplant candidates over the age of sixty now wait listed will die prior to receiving a deceased donor transplant. *Clin J Am Soc Nephrology* 2009; 4:1239–1245].

New Insights into Effects of Dual RAAS Blockade in CKD

In patients with chronic kidney disease (CKD), the acute response to a potassium challenge may predict chronic changes in potassium level while receiving dual renin-angiotensin-aldosterone (RAAS) blockade, reports a study in *Hypertension*.

The randomized, crossover trial included 18 patients with hypertension and CKD with a glomerular filtration rate of 25 to 65 mL/min. In random order, the patients received four weeks of treatment with dual RAAS blockade, consisting of lisinopril 40 mg/dL and spironolactone 25 mg/dL, and four weeks of placebo. After each treatment, dynamic renal potassium excretion and serum potassium were assessed after a 35 mmol oral potassium challenge.

Ambulatory potassium concentrations were 4.87 mmol/L after four weeks on lisinopril/spironolactone versus 4.37 mmol/L after four weeks on placebo. After lisinopril/spironolactone treatment, a small 0.44 mmol/h drop in potassium excretion was accompanied by a 0.67 mmol/L increase in serum potassium, suggesting impairment of extrarenal/transcellular potassium disposition. The increase in serum potassium after potassium challenge was a significant predictor of the increase in ambulatory potassium on lisinopril/spironolactone.

Dual RAAS blockade can improve cardiovascular and renal outcomes in patients with hypertension. However, in patients with CKD, it can lead to hyperkalemia. In this trial, lisinopril/spironolactone increases serum potassium concentration not only through reduced potassium excretion, but also through impairment of extrarenal potassium disposition. Changes in dynamic potassium handling may become useful in predicting changes in ambulatory potassium concentration in response to this drug treatment strategy [Preston RA, Afshartous D, Garg D, Medrano S, Alonso AB, Rodriguez R: Mechanisms of impaired potassium handling with dual renin-angiotensin-aldosterone blockade in chronic kidney disease. *Hypertension* 2009; 53:754–760].

Rare Genetic Disease Lends Insights into Renal Salt Handling

Studies of a rare mutation of the potassium-channel gene *KCNJ10* suggest that this gene may play an important role in renal salt handling and blood pressure regulation, according to a study in *The New England Journal of Medicine*.

The report describes five children from two consanguineous families with a syndrome of epilepsy, ataxia, sensor neural deafness, and tubulopathy, which the authors designate "EAST syndrome." The salt-losing tubulopathy was associated with a hypokalemic metabolic alkalosis, without high blood pressure. Genetic studies traced the autosomal recessive disorder to two mutations of *KCNJ10*, which encodes a potassium channel expressed in the brain, inner ear, and kidney.

Further studies linked the mutations to significant and specific reductions in potassium currents. In mice with deletions of the gene *Kcnj10*, dehydration and renal salt wasting were observed.

Studies of rare inherited renal tubular diseases have provided new insights into renal salt and water handling, with implications for the management of hypertension. The new findings suggest that *KCNJ10* could play a key role in renal salt handling, and thus in maintenance and regulation of blood pressure. The authors suggest re-evaluating data from genome-wide association studies to examine this possibility [Bockenhauer D, Feather S, Stanescu HC, Bandulik S, et al.: Epilepsy, ataxia, sensorineural deafness, tubulopathy, and *KCNJ10* mutations. *N Engl J Med* 2009; 360:1960–1970].

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47% of CKD Stage 5 patients failed to meet serum phosphorus targets (DOPPS).[1] When you're forced to switch this summer, choose FOSRENOL®.

Don't just switch. Change — to FOSRENOL.

FOSRENOL is indicated to reduce serum phosphate in patients with end stage renal disease.

Important Safety Information

• The most common adverse events were gastrointestinal, such as nausea and vomiting, and generally abated over time with continued dosing • The most common side effects leading to discontinuation in clinical trials were gastrointestinal events (nausea, vomiting, and diarrhea) • Other side effects reported in trials included dialysis graft complications, headache, abdominal pain, and hypotension • Although studies were not designed to detect differences in risk of fracture and mortality, there were no differences demonstrated in patients treated with FOSRENOL® compared to alternative therapy for up to 3 years • The duration of treatment exposure and time of observation in the clinical program were too short to conclude that FOSRENOL® does not affect the risk of fracture or mortality beyond 3 years • While lanthanum has been shown to accumulate in the GI tract, liver, and bone in animals, the clinical significance in humans is unknown • Patients with acute peptic ulcer, ulcerative colitis, Crohn's disease, or bowel obstruction were not included in FOSRENOL® clinical studies. Caution should be used in patients with these conditions • FOSRENOL® should not be taken by patients who are nursing or pregnant • FOSRENOL® should not be taken by patients who are under 18 years of age

Reference: 1. Tentori F, Blayney MJ, Albert JM, et al. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and PTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis.* 2008;52(3):519-530.

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Please see brief summary of Full Prescribing Information on adjacent page.

www.fosrenol.com

FOSRENOL® (lanthanum carbonate)

Shire

BRIEF SUMMARY: Consult the Full Prescribing Information for complete product information.

FOSRENOL® (foss-wren-all)
(Lanthanum Carbonate) 500, 750, and 1000 mg Chewable Tablets.

INDICATIONS AND USAGE
FOSRENOL® is indicated to reduce serum phosphate in patients with end stage renal disease.

CONTRAINDICATIONS
None known.

PRECAUTIONS
General:
Patients with acute peptic ulcer, ulcerative colitis, Crohn's disease or bowel obstruction were not included in FOSRENOL® clinical studies. Caution should be used in patients with these conditions.

Diagnostic Tests:
Abdominal x-rays of patients taking lanthanum carbonate may have a radio-opaque appearance typical of an imaging agent.

Long-term Effects:
There were no differences in the rates of fracture or mortality in patients treated with FOSRENOL® compared to alternative therapy for up to 3 years. The duration of treatment exposure and time of observation in the clinical program are too short to conclude that FOSRENOL® does not affect the risk of fracture or mortality beyond 3 years.

Information for the Patient:
FOSRENOL® tablets should be taken with or immediately after meals. Tablets should be chewed completely before swallowing. To aid in chewing, tablets may be crushed. Intact tablets should not be swallowed.

Notify your physician that you are taking FOSRENOL® prior to an abdominal x-ray (see **PRECAUTIONS, Diagnostic Tests**).

Drug Interactions:
FOSRENOL® is not metabolized.

Studies in healthy subjects have shown that FOSRENOL® does not adversely affect the pharmacokinetics of warfarin, digoxin or metoprolol. The absorption and pharmacokinetics of FOSRENOL® are unaffected by co-administration with citrate-containing compounds (see **CLINICAL PHARMACOLOGY: In Vitro/In Vivo Drug Interactions**).

An *in vitro* study showed no evidence that FOSRENOL® forms insoluble complexes with warfarin, digoxin, furosemide, phenytoin, metoprolol and enalapril in simulated gastric fluid. However, it is recommended that compounds known to interact with antacids should not be taken within 2 hours of dosing with FOSRENOL®.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
Oral administration of lanthanum carbonate to rats for up to 104 weeks, at doses up to 1500 mg of the salt per kg/day [2.5 times the maximum recommended daily human dose (MRHD) of 5725 mg, on a mg/m^2 basis, assuming a 60-kg patient] revealed no evidence of carcinogenic potential. In the mouse, oral administration of lanthanum carbonate for up to 99 weeks, at a dose of 1500 mg/kg/day (1.3 times the MRHD) was associated with an increased incidence of glandular stomach adenomas in male mice.

Lanthanum carbonate tested negative for mutagenic activity in an *in vitro* Ames assay using *Salmonella typhimurium* and *Escherichia coli* strains and *in vitro* HGPRT gene mutation and chromosomal aberration assays in Chinese hamster ovary cells. Lanthanum carbonate also tested negative in an oral mouse micronucleus assay at doses up to 2000 mg/kg (1.7 times the MRHD), and in micronucleus and unscheduled DNA synthesis assays in rats given IV lanthanum chloride at doses up to 0.1 mg/kg, a dose that produced plasma lanthanum concentrations >2000 times the peak human plasma concentration.

Lanthanum carbonate, at doses up to 2000 mg/kg/day (3.4 times the MRHD), did not affect fertility or mating performance of male or female rats.

Pregnancy:
Pregnancy Category C. No adequate and well-controlled studies have been conducted in pregnant women. The effect of FOSRENOL® on the absorption of vitamins and other nutrients has not been studied in pregnant women. FOSRENOL® is not recommended for use during pregnancy.

In pregnant rats, oral administration of lanthanum carbonate at doses as high as 2000 mg/kg/day (3.4 times the MRHD) resulted in no evidence of harm to the fetus. In pregnant rabbits, oral administration of lanthanum carbonate at 1500 mg/kg/day (5 times the MRHD) was associated with a reduction in maternal body weight gain and food consumption, increased post-implantation loss, reduced fetal weights, and delayed fetal ossification. Lanthanum carbonate administered to rats from implantation through lactation at 2000 mg/kg/day (3.4 times the MRHD) caused delayed eye opening, reduction in body weight gain, and delayed sexual development (preputial separation and vaginal opening) of the offspring.

Labor and Delivery
No lanthanum carbonate treatment-related effects on labor and delivery were seen in animal studies. The effects of lanthanum carbonate on labor and delivery in humans is unknown.

Nursing Mothers:
It is not known whether lanthanum carbonate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FOSRENOL® is administered to a nursing woman.

Geriatric Use:
Of the total number of patients in clinical studies of FOSRENOL®, 32% (538) were ≥ 65, while 9.3% (159) were ≥ 75. No overall differences in safety or effectiveness were observed between patients ≥ 65 years of age and younger patients.

Pediatric Use:
While growth abnormalities were not identified in long-term animal studies, lanthanum was deposited into developing bone including growth plate. The consequences of such deposition in developing bone in pediatric patients are unknown. Therefore, the use of FOSRENOL® in this population is not recommended.

ADVERSE REACTIONS
The most common adverse events for FOSRENOL® were gastrointestinal events, such as nausea and vomiting and they generally abated over time with continued dosing.

In double-blind, placebo-controlled studies where a total of 180 and 95 ESRD patients were randomized to FOSRENOL® and placebo, respectively, for 4-6 weeks of treatment, the most common events that were more frequent (≥5% difference) in the FOSRENOL® group were nausea, vomiting, dialysis graft occlusion, and abdominal pain (Table 1).

Table 1. Adverse Events That Were More Common on FOSRENOL® in Placebo-Controlled, Double-Blind Studies with Treatment Periods of 4-6 Weeks.

	FOSRENOL® % (N=180)	Placebo % (N=95)
Nausea	11	5
Vomiting	9	4
Dialysis graft occlusion	8	1
Abdominal pain	5	0

The safety of FOSRENOL® was studied in two long-term clinical trials, which included 1215 patients treated with FOSRENOL® and 943 with alternative therapy. Fourteen percent (14%) of patients in these comparative, open-label studies discontinued in the FOSRENOL®-treated group due to adverse events. Gastrointestinal adverse events, such as nausea, diarrhea and vomiting were the most common type of event leading to discontinuation.

The most common adverse events (≥5% in either treatment group) in both the long-term (2 year), open-label, active controlled, study of FOSRENOL® vs. alternative therapy (Study A) and the 6-month, comparative study of FOSRENOL® vs. calcium carbonate (Study B) are shown in Table 2. In Table 2, Study A events have been adjusted for mean exposure differences between treatment groups (with a mean exposure of 0.9 years on lanthanum and 1.3 years on alternative therapy). The adjustment for mean exposure was achieved by multiplying the observed adverse event rates in the alternative therapy group by 0.71.

Table 2. Incidence of Treatment-Emergent Adverse Events that Occurred in ≥ 5% of Patients (in Either Treatment Group) and in Both Comparative Studies A and B

	Study A %		Study B %	
	FOSRENOL® (N = 682)	Alternative Therapy Adjusted Rates (N=676)	FOSRENOL® (N=533)	Calcium Carbonate (N=267)
Nausea	36	28	16	13
Vomiting	26	21	18	11
Dialysis graft complication	26	25	3	5
Diarrhea	23	22	13	10
Headache	21	20	5	6
Dialysis graft occlusion	21	20	4	6
Abdominal pain	17	17	5	3
Hypotension	16	17	8	9
Constipation	14	13	6	7
Bronchitis	5	6	5	6
Rhinitis	5	7	7	6
Hypercalcemia	4	8	0	20

OVERDOSAGE
There is no experience with FOSRENOL® overdosage. Lanthanum carbonate was not acutely toxic in animals by the oral route. No deaths and no adverse effects occurred in mice, rats or dogs after single oral doses of 2000 mg/kg. In clinical trials, daily doses up to 4718 mg/day of lanthanum were well tolerated in healthy adults when administered with food, with the exception of GI symptoms. Given the topical activity of lanthanum in the gut, and the excretion in feces of the majority of the dose, supportive therapy is recommended for overdosage.

DOSAGE AND ADMINISTRATION
The total daily dose of FOSRENOL® should be divided and taken with meals. The recommended initial total daily dose of FOSRENOL® is 1500 mg. The dose should be titrated every 2-3 weeks until an acceptable serum phosphate level is reached. Serum phosphate levels should be monitored as needed during dose titration and on a regular basis thereafter.

In clinical studies of ESRD patients, FOSRENOL® doses up to 3750 mg were evaluated. Most patients required a total daily dose between 1500 mg and 3000 mg to reduce plasma phosphate levels to less than 6.0 mg/dL. Doses were generally titrated in increments of 750 mg/day.

Tablets should be chewed completely before swallowing. To aid in chewing, tablets may be crushed. Intact tablets should not be swallowed.

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The Changing Nephrology Workforce

These are certainly interesting times for nephrology education. As the number of patients with chronic kidney disease increases, the number of trainees seeking careers in nephrology is not keeping pace. The nephrology workforce forms the ASN, so this month we examine personnel issues, including changes in the education of nephrologists-to-be and those maintaining certification. Other topics of interest include international medical graduates, women, transplant nephrologists, and pediatric nephrologists.

We started with a curse; let's end with a wish: "May you find this an interesting section."

—*Pascale Lane, editor in chief,* ASN Kidney News

The Impending Workforce Crisis in Nephrology

By Susan Owens

The United States will face a shortage of nephrologists during the next decade. This shortfall will occur despite the fact that the number of nephrology fellows nearly doubled during the past 20 years, from 460 in 1987 to 863 in 2008 (1,2). The current disparities—by ethnicity, socioeconomic status, and geographical location—among patients with kidney disease will worsen as a result of this shortage.

At least three simultaneous trends are conspiring to fuel this crisis: Nephrology is not an appealing career option for the majority of U.S. medical school graduates (USMGs), the graduates of international medical schools are facing pressures not to seek additional training or to practice in this country, and the prevalence of chronic kidney disease (CKD) and end stage renal disease (ESRD) is rising dramatically.

Nephrology is not an appealing career option for the majority of USMGs

Today's medical students are fundamentally different from their predecessors. As has been well documented, they value a controllable work-life balance, define success within the context of their personal lives instead of professional accomplishments, sacrifice salaries and career advancement for time with families, and characterize professionalism differently.

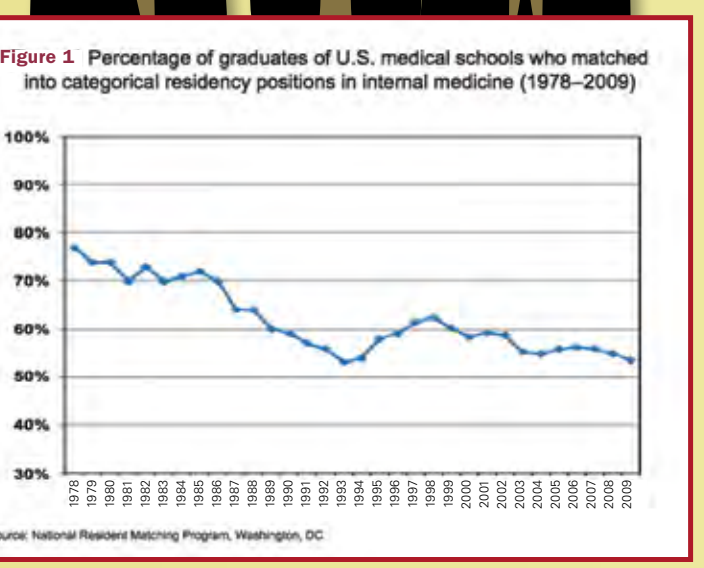
Medical students also face staggering debt. According to a recent report from the Government Accountability Office (GAO), "The median amount of educational debt for indebted medical students graduating in 2008 was $155,000—a 53 percent increase since 1998, controlling for inflation" (3). GAO calculated that the monthly loan payment for a resident or fellow with a $155,000 debt "could reach over $1700 (about 48 percent of pretax income)." Given this financial situation, it is not surprising that medical students want to complete their training and start generating salaries high enough to pay down their debt.

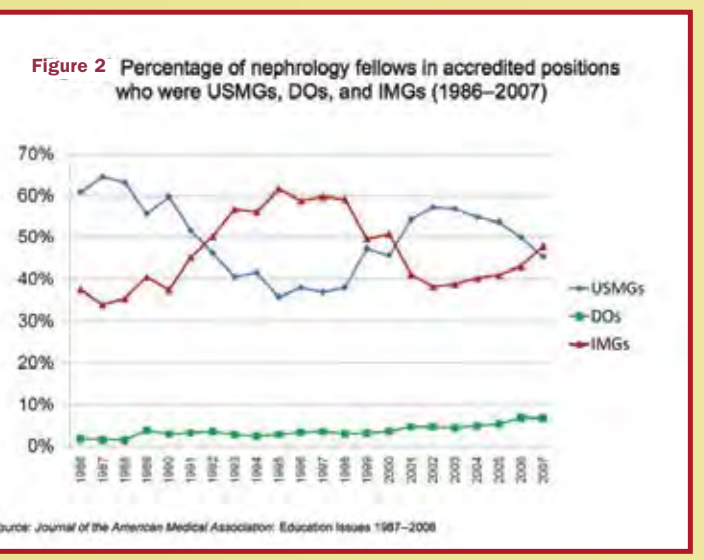
These factors—combined with more career options (due to new specialties, such as sleep medicine)—have decreased the interest of USMGs in internal medicine residency positions, which are the pathway to nephrology fellowships. In 2009, 1196 fewer graduates of U.S. medical schools selected categorical residency programs in internal medicine than in 1985 (Figure 1). Many have commented that today's students see radiology, ophthalmology, anesthesiology, and dermatology as the "ROAD" to successful careers in medicine.

In addition to selecting from an already diminished pool of USMGs, nephrology is further challenged by the fact that students have little exposure to kidney disease before they must choose a career path. For most medical students, the first exposure to nephrology is during their third-year internal medicine clerkship, which in U.S. medical schools lasts on average 10.5 weeks.

Although internal medicine residency programs are required to include a "clinical experience" in each of the subspecialties of internal medicine, it is "not necessary that each resident be assigned to a dedicated rotation in every subspecialty" (4). Given the breadth and depth of internal medicine—let alone nephrology—it is not surprising that the exposure of medical students and residents to career options in nephrology is limited.

Continued on page 13





International Medical Graduates in Nephrology: Benefit, Challenge, or Both?

By Allison Haupt

For years, international medical graduates (IMGs) have comprised a significant percentage of the fellows in nephrology training programs who prepare to provide treatment to the rapidly growing population of patients suffering from kidney disease. In the 2006–2007 school year, physicians trained in foreign institutions constituted 47 percent of the fellowship class, an increase over the historic low of 38 percent in 2002–2003, and a return to the high percentages posted in the late 1990s. IMGS comprised 59 percent of all nephrology fellows in 1997–1998 (Table 1).

While IMG interest is vital to the success of nephrology training programs and the nephrology field as a whole, their high concentration in the nephrology arena portends a number of potential challenges.

Compared with other internal medicine specialties, nephrology programs attract a higher proportion of IMGs. Of internal medicine specialties with a comparative number of participating programs in the 2009 Match, nephrology programs matched the greatest percentage of IMGs (49 percent), according to Donald Kohan, MD, PhD, director of the nephrology training program and assistant dean of graduate medical education at the University of Utah School of Medicine, and Mark Rosenberg, MD, director of the division of renal diseases and hypertension at the University of Minnesota School of Medicine. Gastroenterology programs matched the fewest (19 percent), while rheumatology, endocrinology, and hematology/oncology were closest with 36 percent.

Many in academic medicine fear that the declining interest in primary care—and the disinterest among medical school graduates in internal medicine residencies—is the culprit behind declining numbers of U.S. graduates specializing in nephrology. Although that must play a significant role, why are other internal medicine specialties bearing less of the impact? If specialties that offer similar compensation are better able to attract U.S. medical graduates, members of the nephrology community should consider how to better market the specialty to physicians-in-training.

IMGs supplement the overall physician workforces of various medical specialties and historically have provided necessary care in medically underserved areas that are unable to attract U.S. physicians. Due to restrictions associated with the J-1 visa—a cultural exchange visa historically used by most IMGs—IMGs must return to their home countries for two years after the completion of training. To circumvent the return requirement, IMGs can apply for the Conrad 30 waiver program. This federal program allows each state to hire up to 30 foreign-trained physicians to practice in rural and inner-city areas in need of primary and specialty care.

According to *American Medical News* (March 10, 2008), 10,901 IMGs entered the United States on J-1 visas in 1995–96. That number has significantly declined. In 2006–07, only 6033 IMGs entered on J-1 visas. However, the net number of IMGs has significantly increased. Since 1978, the IMG workforce has more than doubled, and now IMGs comprise approximately 25 percent of all practicing physicians.

Rather than entering on the J-1 visa, IMGs are selecting the more expensive, yet less restrictive, H-1B visa. This change in immigration practice has led to a depletion of physicians interested in serving in medically underserved areas. In 1995, 1374 IMGs requested a J-1 visa waiver. In 2006, that number declined to 903. Ironically, a greater percentage of J-1 visa holders are applying for the waiver program (12.6 percent of J-1 visa holders in 1995 versus 15.0 percent in 2006).

Concerns about U.S. medical graduate interest in nephrology as well as geographic distribution are magnified when compared with data illustrating the impact of kidney disease across the United States. According to a state-by-state analysis of the Conrad 30 program, 10 states histori-

Table 1. Comparison of states with high kidney disease prevalence and those filling J-1 visa waiver positions

Year	Number of programs	Fellows	USMGs*	%USMGs	DOs	%DOs	IMGs	%IMGs
1986	149	240	146	60.83%	4	1.67%	90	37.50%
1987	152	460	297	64.57%	7	1.52%	156	33.91%
1988	153	486	307	63.17%	7	1.44%	172	35.39%
1989	150	212	118	55.66%	8	3.77%	86	40.57%
1990	146	417	249	59.71%	12	2.88%	156	37.41%
1991	149	482	249	51.66%	15	3.11%	218	45.23%
1992	143	544	252	46.32%	19	3.49%	273	50.18%
1993	141	628	255	40.61%	17	2.71%	356	56.69%
1994	142	637	265	41.60%	15	2.35%	357	56.04%
1995	139	580	207	35.69%	16	2.76%	357	61.55%
1996	137	609	231	37.93%	20	3.28%	358	58.78%
1997	135	635	234	36.85%	22	3.46%	379	59.69%
1998	129	638	242	37.93%	19	2.98%	377	59.09%
1999	127	678	321	47.35%	21	3.10%	336	49.56%
2000	127	626	286	45.69%	22	3.51%	318	50.80%
2001	128	649	352	54.24%	30	4.62%	267	41.14%
2002	128	711	407	57.24%	33	4.64%	271	38.12%
2003	128	772	439	56.87%	34	4.40%	299	38.73%
2004	130	772	423	54.79%	38	4.92%	311	40.28%
2005	135	822	441	53.65%	44	5.35%	337	41.00%
2006	136	802	401	50.00%	55	6.86%	346	43.14%
2007	139	808	367	45.42%	54	6.68%	387	47.90%
1986–2007	-10	568	221		50		297	
1986–2007 (percent change)	-6.71%	236.67%	151.37%		1250.00%		330.00%	

Table 2. Changes in numbers of training programs, fellows, and type of graduates, 1986–2007.

States with top ten highest kidney disease prevalence rates, 2008 USRDS	States that traditionally fill all J-1 visa waiver positions
California	*California*
Texas	Texas
New York	*New York*
Florida	*Florida*
Illinois	*Illinois*
Ohio	*Ohio*
Pennsylvania	Arizona
Michigan	Massachusetts
Georgia	Rhode Island
North Carolina	Missouri

*USMGs includes graduates of Canadian medical schools

cally use all 30 of their available waiver slots. A review of the 10 states with the highest end stage renal disease (ESRD) prevalence rates identifies six states cross-referenced on both lists (Table 2).

The states that need and use the waiver program are the same states that are in the greatest need of nephrologists to care for their large populations of kidney disease patients. If use of the J-1 waiver program continues to decline, many states may face serious physician shortfalls in medically underserved areas (not to mention that states that already have difficulty luring J-1 visa waiver applicants will face a virtual drought).

The problem is further exacerbated when reviewing the pediatric nephrology workforce. Nationwide, we face a significant workforce problem, with only one pediatric physician for every 167,000 children. In Georgia, where ESRD prevalence rates are the ninth highest in the nation, there is only one pediatric nephrologist for every 410,000 children. Yet many children's hospitals are not included as "underserved areas," even though they may require more subspecialty support.

Although many states allow IMGs to practice their designated specialties in underserved areas, some require they only practice primary care, even if the state illustrates growing specialty needs. California, Idaho, Nevada, North Dakota, and Utah all do not accept specialists into the Conrad-30 program. Considering California posted the highest ESRD incidence rates in 2008, according to the U.S. Renal Data System, it might be to the nephrology community's benefit to encourage broader support for specialty care when the Conrad-30 program is up for extension in September 2009. According to Sen. Kent Conrad (D-N.D.), the original sponsor of the program, he plans "to expand and improve Conrad 30 through further legislation."

By depending on IMGs to fill gaps in kidney care, the nephrology community must also consider medical challenges that extend beyond the United States. Some critics argue that an influx of IMGs into U.S. medical programs leads to a deplorable "brain drain" in which talented physicians are removed from nations in desperate need of skilled medical labor.

"There are always costs to the source country in terms of financial resources (investment in education) and human capital (gifted, ambitious people)," said Fitzhugh Mullan, MD, professor of medicine and health policy at George Washington University School of Public Health and Health Services in Washington, DC. "Moreover, many medical schools in source nations are influenced by the 'Western aspirations' of their students, so that their training programs are not well aligned with local patterns of disease and levels of technology."

While attempting to distribute IMG physicians to underserved areas in the United States, we may be adding to the list of underserved areas worldwide in need of appropriate care. Does the nephrology community need to consider the international implications of the IMG influx, or should it encourage anyone willing to practice in the United States to flock to our medical schools, teaching hospitals, and community centers?

Without IMGs, the nephrology workforce would likely be in serious decline. IMGs supplement the general workforce and provide additional care in medically underserved areas. While not suggesting that IMGs interested in the profession should be discouraged or underappreciated, the nephrology community should assess why the specialty is less appealing to U.S. medical graduates and consider ways to encourage greater attention to diseases affecting the kidney.

Allison Haupt was ASN research policy coordinator until June 2009, when she left the Society to attend the New York University School of Law.

Workforce

Continued from page 11

IMGs face pressures not to seek additional training or to practice in this country

Approximately 25 percent of U.S. physicians hold J-1 visas (and remain in the United States as part of a waiver program that requires them to work in an underserved area for three years), hold H1-B visas, have become naturalized U.S. citizens, or are U.S. citizens who traveled abroad for medical school. An estimated 40 percent of nephrologists in the United States graduated from an international medical school, making nephrology more dependent on international medical graduates (IMGs) than any other specialty, except geriatrics (5).

A "convergence of technology" and other factors (such as global supply chains) is causing the developing world—particularly India and China—to provide opportunities for well educated people to work in efficient systems. A reduction in IMGs from these countries could have long-term consequences on the nephrology workforce. Together, India and China account for more than 20 percent of IMGs in the United States (6).

Complicating matters, the immigration process became more restrictive with its move, after September 11, 2001, from the Department of State to the Department of Homeland Security. The number of IMGs entering the country on J-1 visas dropped from 11,471 in 1996 to 6033 in 2006. As a result, underserved rural and urban communities must meet workforce needs with a smaller pool of J-1 visa holders.

At the same time, the number of H1-B visa holders—who have no requirement for working in underserved areas—is increasing. These trends (fewer J-1 and more H1-B visa holders) have several implications for nephrology. Fellowship program directors need to rely more on IMGs with H1-B visas, IMGs who are U.S. citizens, and graduates of osteopathic medical schools to fill training positions. The number of DOs in nephrology fellowships increased from seven in 1987 to 54 in 2007 (Figure 2).

The prevalence of CKD is rising dramatically

An estimated 31 million adults in the United States (or 16 percent of the population) currently have some form of CKD, and another 20 million are at risk for developing it. As the U.S. population ages—and a greater number of individuals suffer from diabetes, hypertension, and obesity—the prevalence of CKD rises. For the first time, the United States Renal Data System (USRDS) in 2008 included a separate volume focusing solely on CKD in its Annual Data Report.

Some of the data for this report were collected from the National Health and Nutritional Examination Surveys (NHANES). These surveys, conducted by the National Center for Health Statistics (part of the Centers for Disease Control and Prevention), indicate that the prevalence of CKD has increased by 20 to 25 percent during the past decade. Josef Coresh, MD, and colleagues evaluated the same data for a study published in the *Journal of the American Medical Association* in 2007. Their study found that the prevalence of CKD rose from 10 percent of the population in 1988–1994 to 13 percent in 1999–2004 (7).

The increasing prevalence of CKD also threatens to multiply the number of patients with ESRD. In 2005, 484,995 U.S. adults had ESRD. USRDS estimates that this number will increase by 60 percent by 2020, to nearly 785,000. The incidence rate of ESRD is expected to increase by 41 percent to 151,000 new cases in 2020 (8).

With 7550 active physicians, nephrology currently ranks 22nd among 36 physician specialties in the United States. The nephrology workforce is larger than that of child and adolescent psychiatry but smaller than the physical and rehabilitation medicine workforce.

At this time, there are 39,950 people per nephrologist in the United States. As the prevalence of CKD and ESRD escalates—and the gap widens between the number of people and the number of nephrologists to treat them—who is going to care for all the patients with kidney disease? If fewer IMGs train or practice in the United States, who will care for poor patients as well as patients in underserved rural and urban communities? If USMGs continue to pursue other career pathways, who will care for underrepresented populations, such as African Americans, who already have a disproportionate share of kidney disease?

Susan Owens is senior policy coordinator at ASN and works to address all issues related to nephrology training programs.

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Identifying optimal predictive markers

Better predictors of long-term outcomes are needed in renal transplantation

Treatment advances have resulted in improved short-term posttransplant outcomes.[1] Clinical endpoints have evolved along with these improvements.[1] For years, acute rejection was the standard endpoint used in clinical trials to evaluate immunosuppressants and assess posttransplant outcomes.[1] Data suggest that decreasing acute rejection rates, however, have not led to an increase in long-term graft survival.[2] Therefore, acute rejection may not be considered a reliable predictor of long-term outcomes.[1]

Alternative short-term surrogate markers, such as renal function, histologic findings, and immunologic markers, have been assessed.[1] Markers that reliably predict long-term graft and patient survival in renal transplantation are needed to better assess therapeutic success.[1,3]

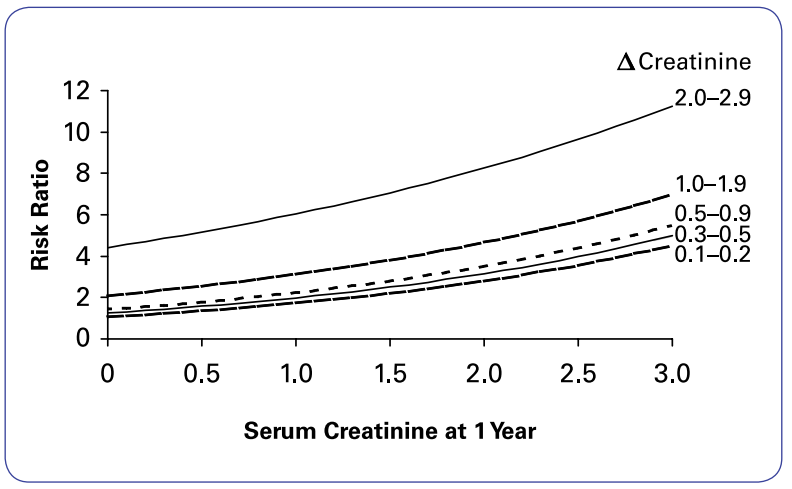
Is renal function a better predictor of long-term outcomes?

Renal function has emerged as a better marker than acute rejection in predicting long-term patient and graft survival.[4-6] Studies demonstrate that preservation of renal function is critical for long-term graft survival.[2,4]

Hariharan et al conducted a retrospective study in 105,742 adult renal transplants performed between 1988 and 1998, examining renal function 1 year posttransplant to determine long-term renal graft survival.[4] Results demonstrated a statistically significant link between renal function and long-term graft survival: elevations in 1-year serum creatinine and change in serum creatinine from 6 to 12 months increase the relative hazard for graft failure (Figure 1).[4]

When assessing the impact of posttransplant variables on long-term outcomes, 1-year serum creatinine and change in serum creatinine from 6 to 12 months had a significant effect ($P<.0001$) on graft failure.[4] Acute rejection within 1 year, however, did not reach significance ($P=.8853$).[4]

Figure 1. Relative hazard for graft failure according to 1-year creatinine and Δ creatinine values.[4]



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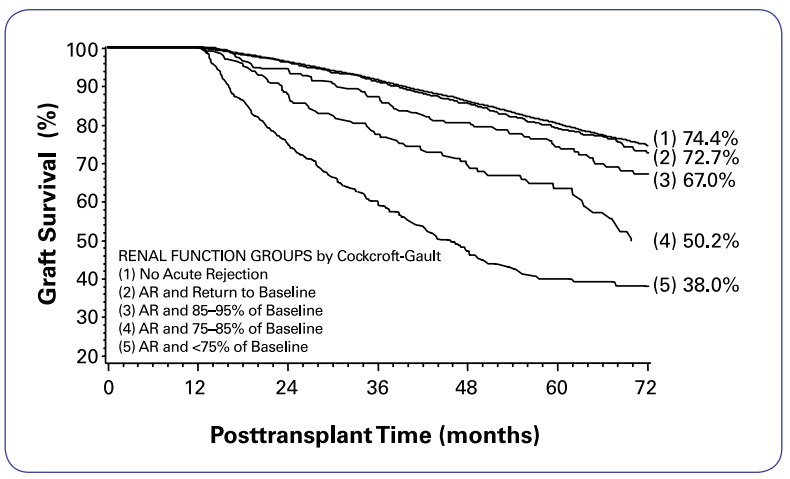
To evaluate the impact of renal function on long-term graft survival in the absence or presence of acute rejection, Meier-Kriesche et al retrospectively studied 38,426 adult renal transplants performed between 1995 and 2001.[2] This study reported that only those acute rejection episodes that impair renal function negatively affect long-term graft survival.[2] Three- and 6-year graft survival rates were comparable among patients who had an acute rejection episode with renal function returning to baseline and those who had no acute rejection episodes (Figure 2).[2] The data showed that in the presence of acute rejection episodes, renal function is the better predictor of long-term outcomes.[2]

Figure 2. Kaplan-Meier graph of overall graft survival by acute rejection/GFR grouping levels.[2]



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in solid organ transplantation

GFR: An important marker of renal function

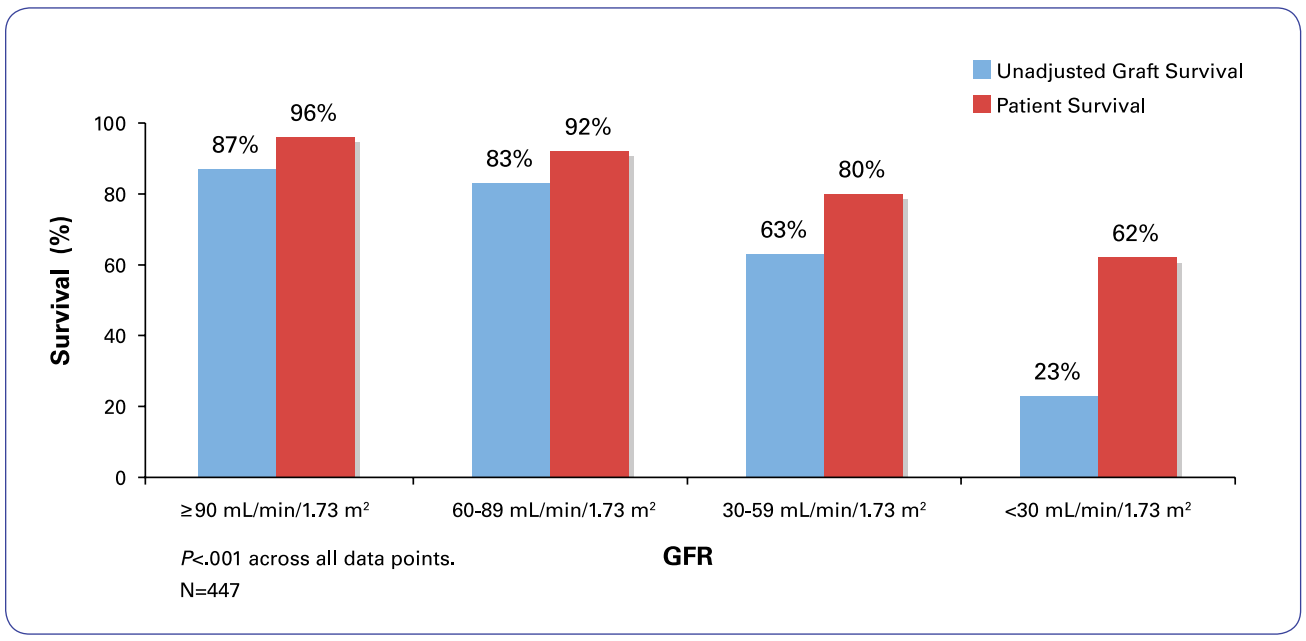
Glomerular filtration rate (GFR), measured through clearance assays, may be a more accurate method of estimating renal function versus serum creatinine, by avoiding the dependence on age, gender, race, and body weight.[3]

In a retrospective study of 447 renal transplant recipients who received organs from deceased donors between 1980 and 1994, Marcén et al examined whether calculated GFR at 12 months posttransplant was predictive of 10-year, long-term graft and patient survival (Figure 3).[7] Results from this study are consistent with the findings from Hariharan et al, demonstrating renal function, as measured by GFR, to be an important marker of long-term graft survival.[7] In addition, this research shows GFR at 12 months also correlates to long-term patient survival.[7]

Signaling the future: Using renal function to predict long-term outcomes

Short-term, surrogate endpoints that predict long-term renal transplant survival are needed to better evaluate success in renal transplantation.[1,3] Research findings demonstrate renal function may be the best predictor of long-term outcomes.[6,7] Renal function should therefore be incorporated into clinical studies as a clinical endpoint to assess posttransplant success.[1]

Figure 3. 10-year graft and patient survival by GFR levels at 12 months posttransplant.[7]



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CHOOSING NEPHROLOGY: The View From Fellows

By Stephen Darrow

As the new academic year begins, nephrology fellows beginning their adult nephrology training can look back at the application process with a unique perspective compared with previous years' fellows. They are the first class to enter the fellowship through the National Resident Match Program. The match has been considered a success in the fellowship community (Kohan and Rosenberg, 2009).

As one applicant cycle has closed, however, fellowship directors begin thinking about the recruitment process for future years. Given the projected shortage of nephrologists (Rosenberg, 2007), fellowship directors wonder if the pool of high-quality applicants will continue to grow. Pediatric nephrology fellowship directors face the same concern about the number of high-quality applicants.

Resident physicians are influenced by many factors as they consider whether to enter nephrology: developing a good understanding of the kidney's complexities, being exposed to the field early in their educational training, and addressing the personal challenges of balancing family versus fellowship.

Why nephrology?

If you are reading this article, you will most likely agree that nephrology is the best organ system to study. What is the thought process that leads to this conclusion? Simple: "The kidney is the smartest organ in the body," says Abha Harish, MD, a first-year nephrology fellow at the University of Alabama, summarizing the general consensus among recent graduates of internal medicine and/or pediatric residency.

This love for the intricacies of the kidney is what inspires many to study nephrology. For these individuals, the cerebral side of nephrology—the complexities of acid/base disorders, electrolyte abnormalities, and the clinical problem-solving—needed in the profession is a larger draw to the field than procedures.

When do residents decide?

Thinking about recruiting a resident into applying for nephrology? Start early! Most physicians interviewed for this article made their decision to enter fellowship early in medical school. All decided by the time their intern year was ending. Perhaps this early decision-making is due to the time constraints of the application process. Residents wishing to enter fellowship immediately upon graduating from residency must start applying by the first half of their second year of residency.

More often, however, a nephrology faculty member gave a medical school lecture, sparking interest in an aspiring internist or pediatrician. Melanie Lind-Ayres, who is starting her pediatric nephrology fellowship at the University of Minnesota, said the renal pathophysiology lectures at her medical school captured her interest.

Don't give up on trying to recruit a resident if they are considering another field. Durgalakshmi Duraikannan, MD, a fourth-year internal medicine-pediatric resident at Creighton University/University of Nebraska, was set on endocrinology until she began a nephrology elective at the start of her second year of residency. Seeing the management of electrolyte disorders handled so well is what swayed Duraikannan to study nephrons as a career.

If the curriculum at a residency program is not designed to offer a nephrology elective during an intern year, don't fret. Even other rotations can convert interns into seeking nephrology. Kevin Heath, MD, a first-year nephrology fellow at Stanford University, was considering cardiology, but switched his career preference to nephrology during his intern night float month. He felt the repetitive–routine chest pain–rule out myocardial infarction-admitting diagnoses were not providing the intellectual stimulation he was seeking in a career. "I enjoyed the mystery of trying to figure out the cause of someone's abnormal lab values," Heath said.

Challenges of entering fellowship

Even if nephrology is a resident physician's top choice for a subspecialty, there is one more challenge that must be worked through before he or she decides to enter a nephrology fellowship—balancing family and fellowship.

Rugmini Warrier, MD, and Anna Lavedan, MD, are two recent graduates from Creighton University's internal medicine and med-peds residency program, respectively. Both enjoy nephrology immensely. They differ in their approach to balancing family and fellowship, and the two approaches are used by many women physicians today. Lavedan, who is also married to a physician, decided to put a fellowship quest on hold so she could spend more time with her husband and three children. She satisfies her love for nephrology by trying to thoroughly work up some of the acute renal failure patients or electrolyte abnormality patients before referring them to a consultant.

Like Lavedan, Warrier also entered primary care upon completion of residency. She knew having children during fellowship would be challenging. Now that her twins are toddlers, she is entering the applicant pool for the entering nephrology class of 2010. Being a wife and mother is one reason Duraikannan, a med-peds resident, chose adult nephrology over pediatric nephrology. "It's one less year," she said. "With a family, I want to be done sooner."

The decision to choose nephrology as a fellowship is complex. Inspiring students early on is one of the best ways to ensure a future generation of top kidney specialists. Students and residents need to be exposed to the wonderful world of nephrons early in their medical education through mentors or lecturers. Lavedan summarized her general passion for nephrology: "It [the kidney] makes sense!"

Sharing this love for nephrology, I invite you to recruit the next generation of nephrologists by helping medical students and residents feel that the kidney "makes sense."

Stephen Darrow, MD, is a graduate of Loyola University Chicago medical school and Creighton University/University of Nebraska's internal medicine-pediatric residency. He is beginning a four-year combined medicine-pediatric joint nephrology fellowship at the University of Minnesota.

Nephrology Training Program Directors Join Forces with ASN Training Program Director Executive Committee

By Donald Kohan

U.S. nephrology training program directors (TPDs) are increasingly joining forces to meet many of today's current challenges. These efforts are spearheaded by the American Society of Nephrology's (ASN) TPD executive committee. The committee consists of members elected by the TPD community to serve three-year terms, and is led by the ASN Education Director for Nephrology Fellowships.

TPDs and the TPD executive committee have been involved in several important issues of late, including participation in the national residency matching program and establishment of the in-training examination and geriatric nephrology curriculum.

National Residency Matching Program

The first nephrology match took place in 2008 for nephrology applicants starting their nephrology training in July 2009. The decision to join the Match was made possible by extensive education of nephrology TPDs and other faculty about the match, followed by careful attention to any problems during the match process.

Approximately 90 percent of training programs and 90 percent of positions were filled by applicants through the match process. This year, about 91 percent of positions and applicants are anticipated to participate in the match. Although the match process has entailed most programs interviewing more applicants, in general, the match has been met with enthusiasm by both programs and applicants.

In-training examination

In response to the perceived need by TPDs for a standardized instrument to assist in the formative evaluation of trainees, and to help meet Residency Review Committee-Internal Medicine (RRC-IM) requirements, the ASN TPDs, under the leadership of Mark Rosenberg initially and then Mitch Rosner, developed an in-training examination in conjunction with the National Board of Medical Examiners (NBME). The examination was written by ASN volunteers who were trained by the board in writing questions.

The first version of the test was taken in April 2009. As of this writing, 693 fellows had registered to take the test, representing more than 80 percent of nephrology fellows. According to the NBME, this is the highest percentage of fellow participation in an in-training examination given for the first time by any internal medicine subspecialty.

The TPDs will be analyzing results of the first examination and making appropriate modifications for future tests. Finally, it should be emphasized that the in-training examination is intended as a tool only for internal use by TPDs to identify areas presenting challenges to fellows or to their entire training program.

Accreditation Council for Graduate Medical Education nephrology program requirements

The RRC-IM is in the process of revising the program requirements for nephrology training and has solicited input from all TPDs. The TPD executive committee and the nephrology TPD community have met with members of the RRC-IM and have submitted recommendations to the RRC-IM for changes in the current program requirements. These recommendations have undergone numerous revisions by the TPDs in response to reviews by the RRC-IM and are currently in the final phases of RRC-IM evaluation. The new regulations will be reviewed by the American Council of Graduate Medical Education (ACGME) Board of Directors in September 2009, and, if approved, will become effective in July 2010.

A variety of changes in the regulations are being proposed. Details on such changes can be obtained by contacting any TPD. In general, the changes are intended to give programs more latitude in their approach to training nephrology fellows, with the caveat that programs are being increasingly required to document and diversify their teaching and evaluation processes in accordance with the ACGME core competencies.

Geriatric nephrology curriculum

The ASN received a T. Franklin Williams grant through the Association of Specialty Professors to develop a curriculum in geriatric nephrology. Dimitrios Oreopoulos assumed leadership of this group and recruited a group of outstanding geriatricians and nephrologists to write the curriculum. Jocelyn Wiggins has joined as a co-leader of the group. A curriculum consisting of 35 modules of about five pages each has been developed and will be placed on the ASN website in the near future. It will be freely available to everyone.

Increased focus on education during Renal Week

The TPD executive committee, working together with the ASN Council and the Renal Week program committee, has created a new education "area" for which individuals may submit abstracts to ASN Renal Week. This area encompasses education of fellows, faculty, or program directors. The first such abstracts were presented at ASN Renal Week 2008 and were met with much enthusiasm by program directors and other teachers. We strongly encourage individuals to consider submission of abstracts dealing with educational topics for the upcoming 2009 Renal Week.

TPD retreats

The first nephrology TPD retreat was held in May 2007. Key issues discussed at this retreat were the match, the in-training examination, and the pending changes to the ACGME-RRC-IM requirements. At the second nephrology TPD retreat, held in May 2009, six small groups each addressed an area of major relevance to training programs and fellows:

- *Interest in nephrology as a career.* While international medical graduates constitute a valued and important contingent of trainees, there is relatively low interest in nephrology as a career among U.S. medical graduates. The goals of this group are to identify target groups (likely medical students and residents), to identify methods to attract their interest (e.g., mentoring, conferences, research, and clinical exposure), and to increase the effectiveness of recruiting through training mentors and professional faculty development.
- *Evaluation tools.* The goals are to identify, create, deliver, and validate formative and summative tools to assist core competency compliance. Programs are free to use whatever tools they wish; however, the goal is to provide them with a variety of options so each program does not have to develop its own tools.
- *Peritoneal dialysis training.* A number of training programs struggle to achieve adequate peritoneal dialysis (PD) training, in large part due to the small numbers of patients receiving PD. A PD working group, whose primary goal is initially to develop a PD curriculum, has been formed. This group will work closely with TPDs to identify barriers to adequate PD training and to develop methods for fellows to achieve competency in PD. Joni Hansson has taken a leadership role in this group.
- *Curriculum development.* This group will focus on areas of the nephrology training curricula that are in special need of development. Such areas include ethical aspects of renal care and transition of patients from pediatric to adult nephrology care. The groups will identify curricula needing special development and then work to create subgroups to define and develop the curricula content.
- *Teaching toolkit development.* This group will develop teaching tools that programs can use to help implement curricular goals and objectives. They will identify areas in need of tool development, identify methods to effectively teach these areas, and help align the teaching methods with core competencies. Examples include the development of standardized patients and simulators.
- *New TPD training course and work group.* This group is in the process of developing a course designed to help train new TPDs. They will work to develop ways to provide TPDs with ongoing education about all aspects of being a TPD.

These activities of the TPD executive committee and nephrology TPDs reflect the collective efforts of nephrology educators. It is heartening to witness nephrology TPDs emerge as one of the most proactive groups of TPDs among internal medicine subspecialties.

It is clear that nephrology TPDs are individuals dedicated to helping recruit high quality trainees, to making their educational experience as valuable as possible, and to making the process of their education (including obtaining ACGME accreditation) as easy as possible. The extensive duties required of a TPD are not always recognized nor adequately compensated. It is hoped that with increasing visibility and recognition of their critically important role, nephrology TPDs will be given the full modicum of credit and support that is essential to their role in training future generations of nephrologists.

Donald Kohan, MD, PhD, is director of the nephrology training program and assistant dean of graduate medical education at the University of Utah Health Sciences Center in Salt Lake City.

Women IN NEPHROLOGY

In 2007, only 21 percent of practicing nephrologists were women, and females filled 36 percent of nephrology training slots. We asked three women to talk about gender issues in the profession.

Sharon Anderson, MD, is professor of medicine and vice chair for Veteran Administration Affairs at Oregon Health & Sciences University (OHSU), and chief, medical service, Portland Veterans Administration Medical Center. She is president-elect of the American Society of Nephrology. Lynda Szczech, MD, is an associate professor of medicine and medical director of the clinical research support office at Duke University. She is president-elect of the National Kidney Foundation (NKF). Sharon Silbiger, MD, is currently professor of clinical medicine at the Albert Einstein College of Medicine/Montefiore Medical Center and director of the internal medicine residency program. In July, she will become the associate chair for undergraduate medical education and the site director for the nephrology division at Einstein. Dr. Silbiger currently serves as president of Women in Nephrology.

Why do you think so few women pursue careers in nephrology?

Anderson: The intellectual aspects of nephrology appeal to many women, but the lifestyle looks onerous. Medical students and residents see the renal fellows working long hours and then coming back into the hospital in the middle of the night to perform emergent dialyses, and that does not look like a family-friendly lifestyle.

Furthermore, while about a third of current fellows are women, the percentages of practicing nephrologists and more senior academic faculty who are female are much lower (Figures 1 and 2)—and so there is a dearth of role models for young women in training. When I started my internship at OHSU, there were two women on the nephrology faculty: Marsha Wolfson and Susan Bagby. Given the relatively small size of the division, it probably didn't occur to me to consider women to be a minority in nephrology, and I didn't see that as any sort of barrier; both were wonderful role models for me. Maybe naivete helps!

Szczech: I agree that good mentors are essential in the development of a physician. If we all think back to the first day of medical school and how we have developed and changed since that time, the path that most of us has taken is seemingly long and quite torturous but also amazing. So many people helped us along the way. Some helped us directly by providing advice and including us in projects. Some helped us indirectly by providing examples of the physicians that we wanted to become. Whether we got direct advice from these people or merely tried to pattern ourselves after them, their presence motivated us.

These role models certainly motivated me to continue down the path that I am currently on. From that perspective, in retrospect, I think it was very helpful to see people with whom I could truly identify succeeding in the way that I wanted to succeed. Whether that is based on gender or age or other demographic factors is probably not as material as the fact that at some level I thought they were like me.

Silbiger: Young trainees are encouraged to enter specific fields in medicine by their direct mentors and role models. Until approximately 25 years ago, there were few female nephrologists to fill those mentorship roles. Therefore, female trainees rarely saw women practicing nephrology, doing research in the field, or creating flexible career tracks for themselves. This situation is changing, and the increase of female nephrologists in practice and in academic roles now gives female trainees the role models they need to envision themselves in a career in nephrology.

What barriers do you see for women entering nephrology?

Szczech: I think the greatest issue for women in academic medicine is related to issues of personal negotiation. In the past, it may not have been possible to explain why attending morning or late evening meetings on a regular basis was onerous due to issues such as child care. In years where this explanation was not possible, women may have merely opted out of an academic career path. Thankfully, for those women who would like to opt into this career path, discussions regarding how to balance both home and career responsibilities are more frequent and comfortable.

Silbiger: I agree that balancing child-rearing and home responsibilities with a rewarding medical career can be challenging. In order to accommodate these responsibilities, some women decelerate from the standard academic career trajectory early in their careers and miss career advancing opportunities. Then they lag behind their male peers in career advancement. As families begin to distribute the "work of home" more equitably, and women who have not followed the traditional career trajectory assume more leadership roles, this situation may change.

Anderson: Another important issue is the perception that academic medicine is a full-time job. I suspect that nephrology lags behind other disciplines in finding ways to create part-time positions, but that doesn't make any sense. Given our considerable outpatient duties (e.g., clinics, rounding in dialysis units), part-time positions should not be difficult to create. At OHSU, we have been very successful in recruiting some of the very best female fellows into part-time positions, which allow them to be full participants in division activities while having more time at home with their young children, and fewer night and weekend calls. In that respect, I'm not sure issues are all that much different between genders—look at all the males seeking careers in dermatology.

What will be the impact of women in leadership roles in nephrology, and what goals do each of you have for yourselves?

Silbiger: As women take on more leadership roles, they will be available to serve as role models for young female physicians in the field and also have an impact on the traditional medical career structure. There is an opportunity to change the current paradigm. More flexibility in academic medicine tracks is warranted, and women in leadership roles can help to move this agenda forward.

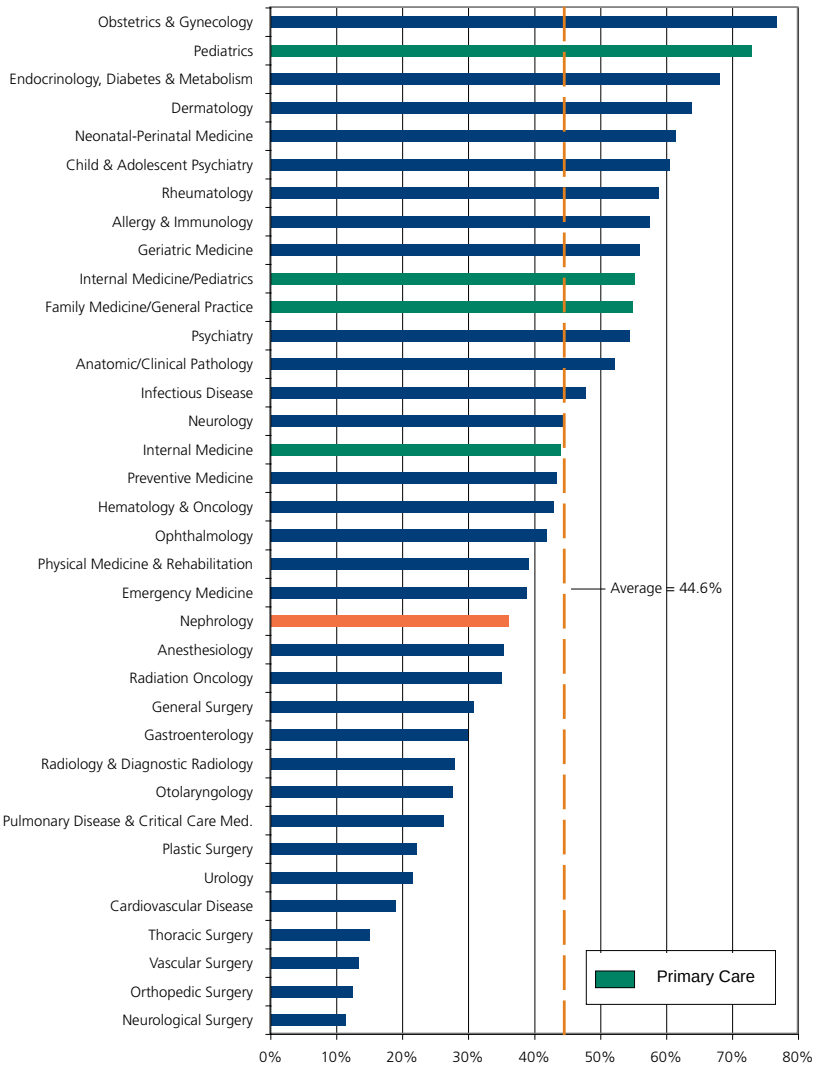
Anderson: You cannot underestimate the importance of visible role models. Again, looking at the example of OHSU, we currently have seven women on the nephrology faculty. Several of us serve in a number of leadership roles both locally and nationally. For students and residents, it looks "normal" for women to be academic nephrologists, and that cannot help but send the message that it can be done. And I think nationally, having more women in leadership roles is serving to change the culture for the better.

Szczech: As president of the NKF, my goals are largely focused on helping everyone who cares for kidney disease patients to see that we are not really in silos. With our focus firmly on providing the best possible care and quality for our patients, it is my desire to discuss and demonstrate that supporting all subgroups of health-care providers—regardless of demographics such as gender—will provide more satisfied practitioners and productive researchers ultimately benefiting patients. In realizing that medicine is truly a team sport, we need to learn how to support all our individual players so that we can accomplish what we set out to do.

Anderson: I believe the ASN has traditionally been viewed by many of its members as having just two goals: increasing NIH funding for research and putting on a spectacular annual scientific meeting. Over the past few years, ASN has dramatically increased its portfolio of activities, from greatly expanding its educational activities and publications portfolio, to taking an active role in public advocacy far beyond research funding. I would hope to see ASN continue to work to understand the needs of all its members and develop career development tools and public advocacy mechanisms to both improve our performance in our various missions, and to help improve and sustain job satisfaction for members.

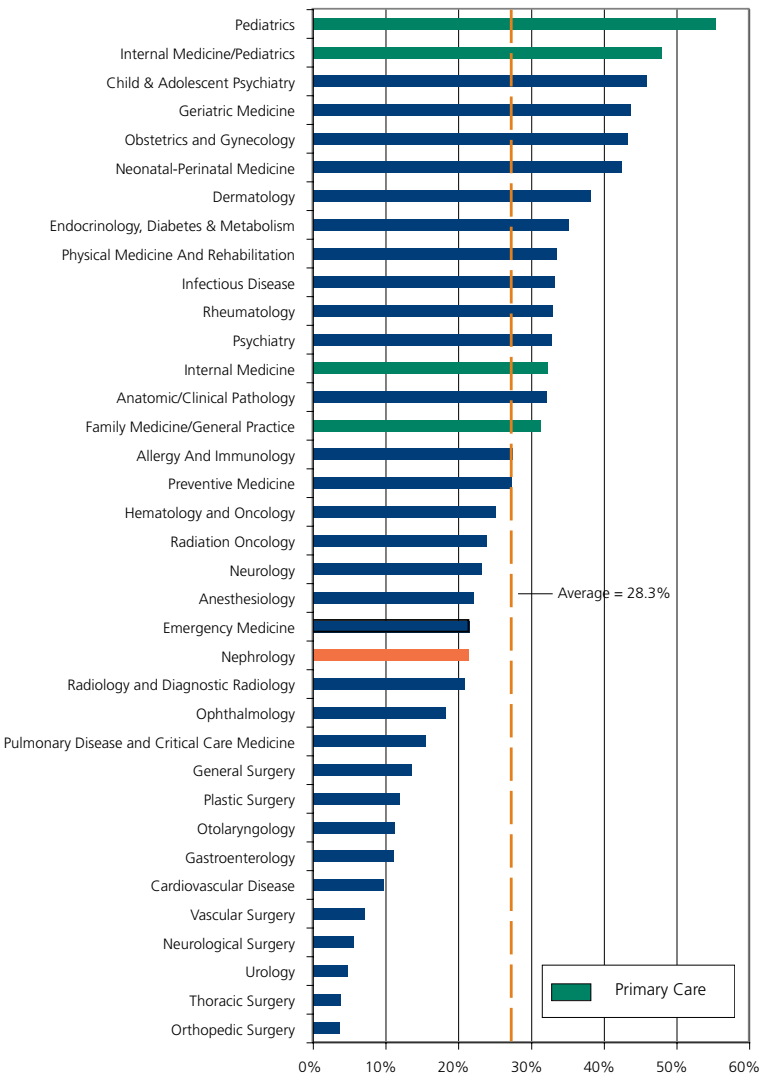
Silbiger: As president of Women in Nephrology, I hope to continue the commitment of the organization to mentoring young trainees and faculty, to advocate for education and research relevant to women, and to work toward increasing the diversity of our nephrology community.

Figure 1. **Percentage of ACGME resident/fellows who are female by specialty, August 2007**



Source: American Association of Medical Colleges/AMA National GME census as of October 14, 2008

Figure 2. **Percentage of active physicians who are female by specialty, 2007**



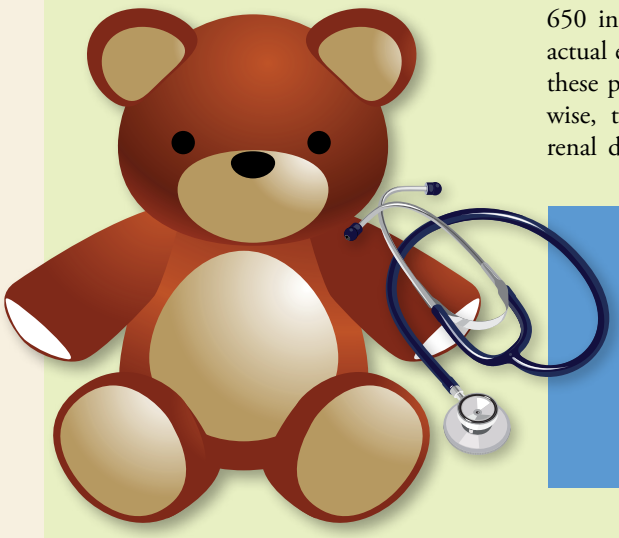
Source: AMA Physician Masterfile (January 2008)

Creating Future Pediatric Nephrologists: *Progress and Challenges Ahead*

By Victoria Norwood

The work lives of most pediatric nephrologists differ significantly from those of our internal medicine colleagues in all aspects of the career pathway. Changing patient and trainee demographics and expectations have spurred a renewed interest in evaluation of our current training processes with an eye toward the future.

Pediatric nephrology patient volumes are increasing. Improved survival of children with a wide variety of congenital or acquired diseases that were routinely fatal in the past is contributing to a higher number of patients with CKD associated with other complex medical needs. At the other end of the spectrum, the nation's obesity crisis is dramatically increasing the incidence of hypertension in the pediatric age range. And many general practice pediatricians have less time to manage children with chronic disease of any form, driving larger numbers of patients with relatively mild disease into ongoing follow-up with pediatric specialists.



Training future pediatric nephrologists

In contrast to our internal medicine colleagues, pediatric nephrology fellowship is mandated to be three years in length. Although there are variations among the 38 current ACGME-accredited programs, most fellows spend approximately one year heavily devoted to clinical training and two years dedicated to research or other scholarly activities. This focus on academic pursuits is driven by the fact that pediatric nephrology practice is almost exclusively performed in academic medical centers or children's hospitals in which teaching and research are expected roles.

Recently, the Training and Certification Committee of the American Society of Pediatric Nephrology (ASPN) has been working with the American Board of Pediatrics to track the progress and outcomes of subspecialty trainees in order to assist and address concerns about future pediatric nephrology workforce needs. Current data suggest that approximately 3.7 percent of all pediatric subspecialists are nephrologists (approximately 650 individuals). Unfortunately, the actual efforts and practice patterns of these physicians is not known. Likewise, the number of children with renal disease in the United States is not known, making workforce predictions exceedingly complex.

Nephrology has, however, enjoyed an overall increase in the number of trainees entering training over the past several years and is currently at an all-time high of more than 50 incoming fellows yearly with 128 total fellows in training in the 2008–09 year. Nephrology is keeping pace with our sister pediatric subspecialties regarding the increase in trainees but is not gaining ground.

Compared with internal medicine, pediatric nephrology has seen an increase of approximately 100 percent in fellows in training from1998 to 2008, while internal medicine nephrology trainees have increased by 25 percent. In contrast, the number of internal medicine training programs has grown from 129 in 1998 to 139 currently, but the number of pediatric nephrology training programs has been essentially unchanged since 2001.

A significant concern to pediatric nephrology training program directors is attrition throughout and immediately following training. On the whole, only about 55 percent of first-year trainees complete the board certification process. Fellows appear to be dropping out at all phases of the process, but the reasons are largely unknown. The program directors group of the ASPN, headed by Dr. John Mahan, and pFENa (Pediatric Fellows in Nephrology Association) are working together to begin to assess this important concern.

Changing makeup of pediatric workforce

The changing distribution of American medical graduates and international medical graduates in training for pediatric nephrology and internal medicine is a trend worth watching (see article on IMG workforce, p. 13). About half of the current cohort of pediatric nephrology trainees are American medical graduates, and the other half international medical graduates. In 1998, approximately two-thirds of trainees had international medical school backgrounds. In contrast, internal medicine is currently approximately 45 percent American medical graduates, a number that has declined steadily from a recent high of 57 percent back in 2002, according to data provided by Drs. Mark Rosenberg and Donald Kohut.

As a whole, pediatric medicine has also seen a shift in its overall workforce to include significantly more female trainees over the past decade. In 1998, women made up approximately 50 percent of the pediatric subspecialty workforce. Pediatric subspecialties now average approximately 60 percent female. Pediatric nephrology is even higher, at approximately 66 percent female. Clearly, the issues of workload, cultural diversity, and work-life balance will become increasingly important to maintaining an effective workforce for the future.

Another issue of importance to the pediatric nephrology workforce is the aging of our current practitioners. The average age of pediatric nephrologists is currently more than 55 years, significantly older than the average age of all other pediatric subspecialists. Importantly, approximately 40 percent of our workforce will turn 65 within the next 10 years, and fewer than 25 percent of nephrologists are less than age 45.

Pediatric nephrology remains a competitive force in the generation of academic pediatric specialists, but we must improve our training outcomes as measured by board certification in order to significantly enhance our workforce potential. Changes in residency education, duty hour restrictions, trainee expectations, and societal pressures will all impact the outcome. The ASPN, the American Board of Pediatrics, and the ACGME will continue to work together to provide the best training in order to maximize the care of children with renal disease now and in the future.

. . . many general practice pediatricians have less time to manage children with chronic disease of any form, driving larger numbers of patients with relatively mild disease into ongoing follow-up with pediatric specialists.

ASN Kidney News *editorial board member Victoria Norwood, MD, is professor of pediatrics at the University of Virginia Children's Hospital and co-chair of the ASPN Training and Certification Committee.*

Policy Update

Kidney Policy Update: 2009 State Short Session Wrap-Up

By Caroline Jennette

Although the year is only half over, as of July, 41 states will have ended their legislative sessions for the year. Of this group, 17 states will carry over bills to the 2010 session if they have already passed both the House and the Senate. Dealing with budget shortfalls and a crumbling economy continues to take up a large chunk of political time, but policy initiatives related to kidney disease and nephrology were still introduced, and some were successful in their passage.

Figure 1 provides a snapshot of the number of bills introduced during the 2009 session related to kidney disease, dialysis, transplantation, or organ donation. Below is a summary of what passed, what failed, and what's still on the table.

General appropriations

Although budgets were tight this year, kidney disease treatment and research remained a priority for state policymakers. The Alabama legislature appropriated funds to both the National Kidney Foundation of Alabama and the Alabama Kidney Foundation (Act 2009-504) to support general operations and program activities, and also to the University of Alabama to operate a "Transplant Database" (Act 2009-550).

The University of Missouri will continue to receive funding for the "Missouri Kidney Program" if the bill is signed by the governor (HB 3). The Arkansas Organ Donation Trust Fund was given funding to increase organ donation education and awareness programs (Act 1499). Idaho showed its continued support for the Renal Disease Vocational Rehabilitation Program by keeping it afloat for another year (Session Law Chapter 328).

Chronic kidney disease

Task forces

Alabama passed legislation to continue the work of its Chronic Kidney Disease Task Force, which submitted a report in 2007 (Act 2009-467). The original task force focused on studying the impact of chronic kidney disease (CKD) on Alabama citizens and producing recommendations for a cost-effective plan for early screening and diagnosis of the disease, while the 2009 task force will study the state's role in assisting persons with CKD and state policy regarding the effective treatment and prevention of CKD. A "State CKD Plan" is due by 2013.

Texas enacted legislation this year to alter its CKD task force, which released a report in January 2009. The new legislation (HB 2055) extends the task force to 2011 and asks for development of a cost-effective plan for prevention, early diagnosis, and management of CKD, as well as for surveillance and data analysis to assess the impact of CKD. With this legislation, Texas may be positioning itself to receive funding for statewide CKD demonstration projects as listed in the Medicare Patients and Providers Act of 2008 (MIPPA), although no money has been appropriated to these demo projects as of yet. Tennessee (SB 1566) and New Jersey (AB 1767) both introduced legislation to create their own state task forces on CKD, and both are still pending committee approval.

Screening and diagnosis of CKD

As a direct result of the original Texas CKD task force recommendations, a bill was introduced (HB 2330) requiring mandatory reporting of estimated glomerular filtration rates (eGFR) by laboratories for any serum creatinine test ordered for a patient 18 or older. If passed, Texas will join six other states with mandatory eGFR reporting. At press time, the bill had passed both the House and Senate and is awaiting the Governor's signature.

New York has also introduced mandatory eGFR legislation that is currently sitting in committee (AB 5158). West Virginia tried and failed to pass legislation (HB 3288) that would have included an annual screening for kidney disease for public employees as determined "medically necessary" by their physician and based on National Kidney Foundation guidelines using a combination of blood pressure, urine protein/albumin, and serum creatinine evaluations.

End stage renal disease

Access and coverage: dialysis

Florida has become the 24th state to offer Medigap coverage to end stage renal disease patients under 65. Medigap is a supplemental insurance plan administered by the federal government that helps patients pay Medicare deductibles and co-pays. The "Alonzo Mourning Access to Care Act" (HB 675) was signed by the Governor in June and coverage will start in October 2009. Illinois had a similar bill in play this session (HB 3592), but it died in committee.

Kentucky and New York worked on legislation to protect dialysis patients from unfair insurance company practices. In some cases, insurers have moved out of a preferred provider network or dropped the option to choose an out-of-network dialysis facility, creating a scenario where patients must travel long distances and pay unfair premiums for dialysis care.

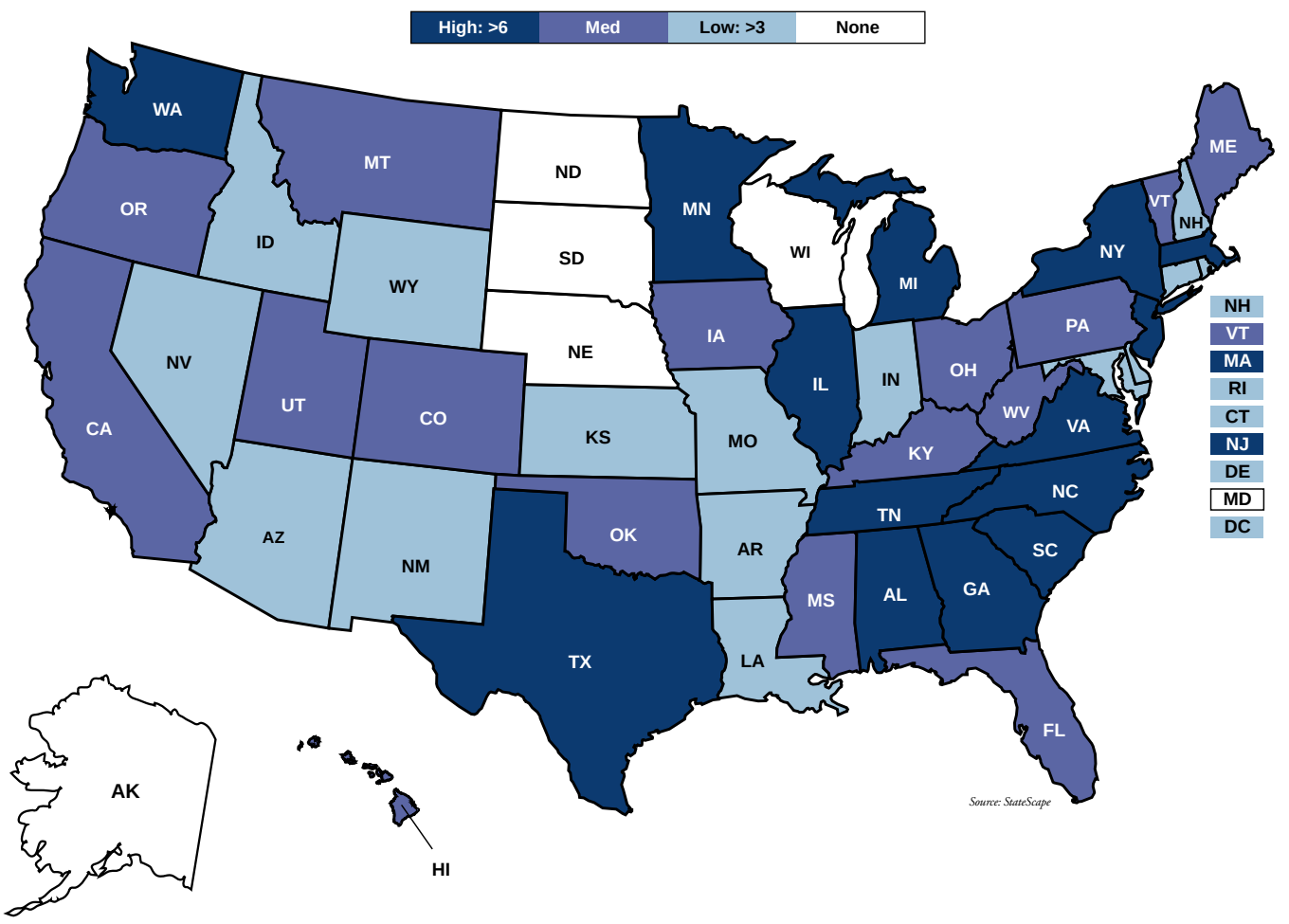
National organizations like the National Renal Alliance and the Kidney Care Council argue that dialysis patients should be provided a choice regarding whether to go out of network. If a patient chooses to go out of network, knowing that they must pay higher premiums, those premiums should still be fair and not cause an undue burden.

Kentucky tried but failed to pass legislation this session that would have limited patient travel for dialysis to 30 miles from a patient's home or the nearest dialysis facility (if more than 30 miles from a patient's home) and provided protections against insurers switching plans without advance notice (SB 19/BR 331).

Although the bill died in committee, the state was successful in passing a resolution directing the Cabinet of Health and Family Services to estimate how much it costs state taxpayers when dialysis patients drop private coverage during their first 30 months on dialysis (when private insurance is primary), possibly as a means to convince policymakers that real legislation is needed to save the state money by preserving private coverage for dialysis patients. The resolution encourages private insurance companies to enhance continuity of care measures and threatens future legislative action if

Continued on page 22

Figure 1
Legislation related to kidney disease by state and number of bills introduced during 2009 short session, as of May 22, 2009



Policy Update

Continued from page 21

companies continue placing an undue burden on dialysis patients.

New York has a bill currently in session that would require all state insurers to provide at least 10 out-of-network dialysis sessions so that patients can travel. However, the bill is likely to hit a snag with its provision to allow insurers to pay out-of-network providers no more than what they pay for in-network treatments (AB 213/SB 1803).

Connecticut, Delaware, and Mississippi worked this session to make transportation less of a burden on dialysis patients. Two of these states had bills in committee at press time to continue appropriations to existing programs—Connecticut's "Dial A Ride" program (HB 5427) and Delaware's Chronic Renal Disease Program (HB 25). Mississippi was successful in passing legislation to extend funding for a program to provide transportation to elderly and/or disabled patients with incomes <135 percent of the federal poverty line and who were previously covered under Medicaid's Poverty Level and Disabled (PLAD) category, which is no longer offered in Mississippi (Session Law Chapter 415).

Increasing organ donation

Four more states—New Jersey, Oklahoma, South Carolina, and Wyoming—passed legislation this year to adopt the Uniform Anatomical Gift Act (UAGA), making the driver's license a form of legal consent for organ donation, clarifying who is allowed to make donation decisions, and encouraging an infrastructure for online organ donor registries that is easily accessible to organ procurement organizations. Florida, Illinois, Kentucky, and Vermont were unsuccessful in passing the same legislation this year. UAGA bills are still in committee in Connecticut (HB 6677), Texas (HB 2027/SB 2091), and New York (AB 6966/SB 4488).

Legislation to reimburse living organ donors through tax credits or paid leave was also popular this session, with eight states putting bills into play, four of which did not make the crossover deadline and died in committee (Hawaii, Illinois, Kentucky, and West Virginia). Bills in Kentucky (HB 36/BR 204), New York (SB 4265), New Jersey (SB 1003), and Massachusetts (SB 1333) that would offer tax deductions or tax credits of up to $10,000 to help citizens recoup costs from travel, lodging, and lost wages as a result of organ donation are still viable this year. Possibly as a result of budget issues, two states (Minnesota and Oklahoma) tried to repeal already existing tax credits, but both pieces of legislation died in committee.

Transplant

New York may be joining Illinois with the passage of a bill to allow HIV-to-HIV organ donation. The legislation (SB 4846) would allow citizens who have tested positive for HIV/AIDS to donate their organs to a person who has also tested positive for exposure to HIV/AIDS, but only in the case of immediate threat of death for the organ recipient. The bill is still in session.

Washington state enacted two bills this session to provide further protections for transplant recipients. Public Law 82 mandates that any insurance plan issued or renewed starting in 2010 must reduce the organ transplant benefit waiting period by the amount of time a covered person had prior creditable coverage (coverage equal to their current insurance plan), and Public Law 487 mandates that state insurers that offer transplant coverage increase the lifetime payment cap to $350,000.

Eight states worked this session to protect immunosuppressive drug prescription coverage for transplant recipients. Georgia (HB 523), Massachusetts (SB 589), Michigan (SB 314), and Tennessee (SB 109/HB 635) introduced legislation barring pharmacists from changing immunosuppressant medications without first getting written permission from the patient and/or the ordering physician. The Georgia bill died in committee, but legislation is still active in the other three states.

Oregon has a bill currently in Senate committee that would require the state department of human services to pay for brand name rather than generic immunosuppressive drugs prescribed in connection with organ transplants (SB 876). California continues to try to move a bill that would extend Medi-Cal coverage (state Medicaid program) for anti-rejection medication for up to three years following an organ transplant unless patients become eligible for Medicare or private insurance that will cover these expenses (AB 998).

Conclusion

State policymakers continue to work with departments of public health, state branches of the National Kidney Foundation, local universities, and patient and family advocates to introduce and argue legislation affecting kidney patients and the nephrology community through all five stages of chronic kidney disease. For more information on state policy initiatives, visit http://www.unckidneycenter.org/healthpolicy/kidneypolicystate.html. To find contact information for state legislators, visit: www.congress.org.

ASN Kidney News *editorial board member Caroline Jennette, MSW, is legislative liaison at the University of North Carolina Kidney Center in Chapel Hill, NC.*

Practice Pointers

Maintenance of Certification For Nephrologists

In this month's issue, ASN Kidney News *editorial board member Edgar Lerma interviewed Stuart Linas, MD, about the American Board of Internal Medicine (ABIM) Maintenance of Certification program for nephrologists. Linas is the Rocky Mountain Professor of Renal Research at the University of Colorado Denver School of Medicine.*

Stuart Linas

When and how did the requirement for recertification come to be?

ABIM's Maintenance of Certification (MOC) program dates to 1990, when it introduced "time-limited" certifications for many specialties, including nephrology. The other 23 member boards of the American Board of Medical Specialties, which develops standards for evaluation and certification of physicians, also have introduced MOC programs for their diplomates. ABIM Maintenance of Certification requires nephrologists who certified since 1990 to renew their certification every 10 years by taking an exam and completing a process of self-assessment.

More than 8500 total valid certificates in nephrology have been issued by ABIM, and more than 80 percent of nephrologists who certified between 1990 and 1996 have chosen to maintain their certification.

What are the pros and cons of recertification as it applies to physicians? To patients? To HMOs?

MOC is a meaningful way to get feedback about your practice and to make sure you are up to par with today's standards of care. And it sends a signal to patients that your skills are current.

For me, MOC provided a real "snapshot" of my knowledge and practice performance as it exists today.

The ABIM medical knowledge modules offer a great learning tool to stay current on the recent advances that have changed our practice. In fact, ABIM introduces new "update" modules every year. The Practice Improvement Modules, known as PIMs, give you a heads-up as to how your practice is perceived by both peers and patients. Together, they provide a low-stakes self-assessment and also give you an opportunity to engage in quality improvement.

Some of the cons we have heard include workload and cost, but if you plan ahead, you can spread the requirements over the 10-year period for just a few hours a year.

By the way, more than two-thirds of nephrologists also maintain their certification in internal medicine, even though this is not required. The MOC program lets you do this easily because the self-assessment applies to both certifications. You pay only an additional exam fee to recertify in internal medicine.

Some health plans and other quality groups acknowledge MOC and PIM completion in their reward and recognition programs, which helps reduce redundancy in your quality improvement reporting.

Please compare the ABIM process of recertification versus various individual states' policies on renewing medical licenses.

ABIM MOC and individual state policies for renewing medical licenses are separate initiatives. Licensing is required of all physicians to practice medicine, and, today, physicians must be licensed in good standing to complete MOC. However, there is growing attention to how to better align licensing and MOC, and I believe there is a real possibility that in the future MOC will be a requirement for licensure.

Are you undergoing recertification yourself?

As a member of the ABIM Board of Directors, I was required to complete MOC even though I initially certified in nephrology before 1990. I will admit that at first I had my reservations about it, but once I enrolled and began to experience the program components, I knew that this would be a beneficial experience.

The process of completing the PIM was rewarding; it really helped me identify gaps in my practice operations. I also found that taking the MOC exam affected my related work as a member of the Nephrology subspecialty board at ABIM, where we develop questions used in the ABIM MOC Exam in Nephrology. My own experience with the exam helped me think about ways to make the exam questions more relevant to nephrologists and helped the committee develop what I believe is a better exam product.

A significant part of the recertification process is the "Self-Evaluation of Practice Performance." A number of subspecialty organizations have partnered with the ABIM to create tools that can be used to fulfill this requirement. Do you know if the ASN is involved in any of these?

One of the areas that ABIM and ASN jointly acknowledge is that we need more relevant practice performance options, including PIMs specifically for nephrologists. So ABIM and ASN are now exploring some new options for practice improvement tools and products that will fill this gap. Examples could include topics such as transplant and acute kidney injury.

In the meantime, nephrologists have several choices. Many have chosen the patient and peer assessment and communication modules. The hypertension PIM is also popular with nephrologists. Another option is the self-directed PIM. Nephrologists who are already collecting data about their practice or are already engaged in quality improvement can use this PIM to complete their quality assessment. There is also a new clinical supervision PIM specifically designed for physicians, including nephrologists, who work in academic environments.

What would you advise those currently undergoing the recertification procedure?

The best advice I can give to nephrologists is to think of MOC as a continuous process. Ideally, it is best to enroll early in the 10-year cycle. You can begin by completing the medical knowledge modules. Later in the cycle you can focus on the PIM as a way to make meaningful changes and improvements in your practice. In the latter phase, you can also prepare to take the exam.

Remember that MOC is flexible. For example, you can choose to take the exam before you complete all of your self-assessment modules. It's up to you.

And keep in mind that your new certificate begins when your current one expires, even if you complete the program before the end of your tenth year of certification.

Is there any particular reference material or Board Review Course you would recommend for use in preparing for the written examination?

How you did on your initial Certification Exam in Nephrology may help predict how you will do on the MOC exam.
A resource is the Nephrology Exam Blueprint, located on the ABIM web site, which provides percentages of content by topic in the exam.

Because of their mission and unique role in setting practice guidelines, societies are well positioned to provide the broadly comprehensive educational reviews of important clinical topics that certified nephrologists should be up to date on, and which will help them prepare for the MOC exam.

Is there anything you would change in the whole process of current recertification?

On the whole, the principle behind MOC is terrific, and I believe that the benefits outweigh the time and costs involved. ABIM is focusing on improving MOC to make it more meaningful and relevant to nephrologists. This is why ABIM is working closely with ASN to find ways to provide new options, particularly in the area of practice performance.

Among nephrologists who have completed MOC, 74 percent have cited professional value. Whether you are just enrolling now or in your second MOC cycle, I encourage you to take part. You'll learn about what you know, and more importantly, you'll identify ways to improve.

For more information about MOC for nephrologists, including how to enroll, visit www.abim.org. Details and links can be found in the "Get Information by Subspecialty" section. Click on the dropdown and select "Nephrology." For details, call ABIM's Contact Center at 1-800-441-ABIM.

Trends in Medical Education

The Transplant Nephrology Fellowship: Current and Future Challenges

By Milagros Samaniego, David Rothstein, and Michelle Josephson

Milagros Samaniego

For more than 20 years, the Membership and Professional Standards Committee of the Organ Procurement Transplant Network (OPTN) and the United Network for Organ Sharing (UNOS) have defined the training requirements for UNOS-certified transplant physicians.

Transplant physicians would be certified to function as medical directors of kidney transplant programs if they met the following requirements: training in the pre-, peri-, and posttransplant care of 35 kidney and kidney-pancreas recipients and in the evaluation and follow-up of living kidney donors; observation of at least three multiple organ procurements and kidney transplant procedures; and management of at least three deceased donor candidates.

During the pre-accreditation era of kidney transplant training, nephrology fellows interested in transplantation initiated their careers in transplant immunology laboratories and later developed into clinical and basic scientists. These individuals became medical directors of transplant programs through the "grandfather clause."

In 1998, the American Society of Nephrology (ASN) and the American Society of Transplantation (AST) joined efforts to standardize training in transplant nephrology to meet the OPTN/UNOS certification requirements. The societies crafted a comprehensive academic curriculum designed for board-eligible/certified nephrologists, in which the trainee would receive ample exposure to inpatient and outpatient transplant management. In addition, the AST instituted the Accreditation Committee, which, in concert with the ASN Fellowship Directors Committee, would ensure compliance with training requirements and pursue updating of the curriculum as needed.

Since 1998, 49 AST/ASN-accredited transplant nephrology fellowships—47 adult and two pediatric programs—have been established in the United States and four in Canada. These programs are not regulated or accredited by the American Board of Internal Medicine (ABIM)/Accreditation Council for Graduate Medical Education (ACGME).

Obstacles to increasing the number of transplant trainees

Funding of fellowship positions is one of the most important obstacles to increasing the number of transplant trainees. In a survey by the AST Accreditation Committee in which 60 percent of program directors participated, 70 percent of trainees were hired as fellows and 30 percent were hired as non-tenured clinical faculty.

The salary source varied from program to program, with the majority of fellows supported by hospital budgets (30 percent) and the rest by departmental, divisional, practice association, and industry-sponsored funds.

Furthermore, the need for trainees to spend a full six months in clinical service precludes most sources of research fellowship support. Not surprisingly, not all fellowship programs have been able to support fellows every year, and as many as one-third of transplant nephrology programs have lacked fellows or had only one fellow over any given period of years.

Fellows who have made the commitment to perform several years of transplant-related research have not had a direct mechanism to obtain transplant certification during their fellowship.

A shortage in the number of trainees is a concern because it will lead to limited manpower to care for the growing number of kidney transplant recipients. Such a shortage will likely have a negative impact because the future leaders of clinical transplantation are likely to emerge from this group of trainees.

Changes afoot in requirements for transplant fellowship programs

To address these issues, ASN's Transplant Advisory Group and the AST Accreditation Committee have worked together to revise the requirements of ASN/AST-accredited transplant fellowship programs. A proposal to develop an alternative fellowship pathway has recently been approved by both the ASN Council and AST Board of Directors. The proposal puts forward an alternative pathway that will allow fellows committed to two or more years of transplant-related research during their renal fellowship to attain additional clinical experience in transplantation to qualify as AST/ASN-accredited transplant nephrology fellows.

Trainees would pursue this pathway during their nephrology training, making the alternative pathway more fully integrated with existing standard nephrology fellowships than is the current single added year of transplant fellowship training.

The modified transplant nephrology fellowship does not require trainees to be board-eligible/board-certified at the initiation of the transplant fellowship if the fellow is concurrently enrolled in an ACGME-certified standard nephrology fellowship with the following expectations:

- The transplant fellowship program is an ASN/AST-accredited program.
- All clinical training that is counted toward the transplant fellowship training is done in addition to the standard renal fellowship clinical requirements. This will be documented by the training program director, who will certify that the fellow has completed all requirements for both fellowship programs.
- In order to be considered for UNOS recognition as a certified transplant nephrologist, board certification must be obtained by the end of the training.
- Research performed during this training should be relevant to the field of transplantation.

While not proposing to do away with existing "free-standing" one-year fellowships, the hope is that this approach will increase the number of highly qualified applicants interested in attaining both full training in clinical transplantation and research. In the new proposal, the clinical experience is spread out over a longer period of time than the currently required six months, yet the total clinical and academic exposure to transplantation is increased, and the OPTN/UNOS certification requirements are fulfilled.

Another advantage of the proposal is that fellows pursuing the alternative pathway would be eligible for federal, society, or foundation grant support in addition to that provided by their mentors, thereby obviating the funding difficulties that many programs have had.

ABIM and ACGME certification of fellowship programs

Certification and oversight of the Transplant Nephrology Fellowship Program by ABIM and ACGME is also complex. The main issue stems from the fact that, by rule, the ABIM seeks to certify subspecialties that train several hundreds of trainees per year. Yet in 2008, for example, only 29 trainees completed training in transplant nephrology in U.S. ASN/AST-accredited programs.

The process of ABIM/ACGME accreditation is cumbersome, as we learned through the certification of the transplant hepatology fellowships. The certification requirement may add a significant administrative burden to programs already overextended in trying to meet the requirements for nephrology certification.

Although ABIM/ACGME certification is not likely in the immediate future of transplant nephrology fellowships, curricular changes that would foster the recruitment and development of clinical and basic scientists in the field of transplantation are feasible. It is in the success of such changes where the future of transplant nephrology as a vibrant subspecialty lies.

Milagros Samaniego, MD, is associate professor of medicine and medical director of kidney and kidney-pancreas transplantation at the University of Michigan Medical School. David Rothstein, MD, is professor of surgery, medicine, and immunology at the Thomas E. Starzl Transplantation Institute at the University of Pittsburgh Medical Center. Michelle Josephson, MD, is associate professor of medicine in the department of nephrology at the University of Chicago School of Medicine.

Table 1
Transplant nephrology program statistics

Number of U.S. ASN/AST-accredited transplant nephrology fellowship programs	50
Number of transplant nephrology graduates in 2008	29
Number of living kidney transplant recipients in the United States at the end of 2005†‡	104,388
Number of wait listed kidney transplant candidates¥	79,140
Number of self-reported nephrologists in the United States¶	7410

†Includes kidney transplant alone and kidney–pancreas transplant recipients
‡Source: OPTN/SRTR data as of May 1, 2007
¥Source: OPTN data as of April 3, 2009
¶Source: The American Medical Association U.S. physicians master file as of 2006 data (includes U.S. and foreign medical graduates)

Table 2
Standard ASN/AST-accredited transplant fellowship requirements

Six months of transplant inpatient rotations
Experience in histocompatibility and immunogenetics
Experience in a nonrenal transplant service or clinical or basic research project
Primary responsibility for 30 inpatient renal transplant recipients
Primary responsibility for 30 outpatients (continuous for at least three months)
Ten transplant biopsies
Observe at least 3 kidney transplant procedures and 3 procurements
Minimum training time: 1 year

Table 3
Modified ASN/AST-accredited transplant nephrology program

Two to three months of transplant inpatient rotations per academic or calendar year†
Experience in histocompatibility and immunogenetics
Experience in a nonrenal transplant service
Primary responsibility for 30 inpatient renal transplant recipients
Primary responsibility for a minimum of 30 outpatient transplant recipients (continuous for at least 3 months) each year for a minimum of 2 training years‡
Ten transplant biopsies
Observe at least 3 kidney transplant procedures and 3 procurements
Minimum training time: 3 years

Italics represent modifications from the standard transplant nephrology fellowship
†Keeps inpatient requirements to a total of 6 months through the length of the fellowship
‡Increases outpatient exposure from 30 to 60 patients

Index to Advertisers

ASN News

ASN Extends Benefits to Fellows, the Next Generation of Members

By Susan Owens

Today's nephrology fellows represent the future of the American Society of Nephrology (ASN). These fellows will someday guide the Society, overseeing council meetings, advisory groups, and committees. They will lead ASN's educational activities and help recruit, educate, and cultivate the interests and talents of the nephrologists who come after them.

Fellows still in training have limited resources, and the Society is proud to offer free membership to all nephrology fellows. This membership lasts through December 31 of the year they complete training and includes subscriptions to the *Journal of the American Society of Nephrology*, the *Clinical Journal of the American Society of Nephrology*, *ASN Kidney News*, and Kidney Daily. Fellows also gain admittance to the "members-only" section of the web site, which includes the ASN Career Center, online Membership Directory, and online access to the journals.

Trainees are an integral part of the culture of Renal Week and Renal WeekEnds, bringing a fresh perspective and new ideas and questions to discussions. They are offered registration to these meetings at a discounted price. For the first time in 2009, ASN will provide each of 15 nephrology fellows $1000 in travel support to attend Renal Week. ASN also offers travel support to internal medicine residents who have expressed an interest in nephrology and are nominated by their program directors. In 2009, the ASN Residents Program will provide up to 150 residents with travel support as well as the opportunity to network with fellowship program directors and ASN leaders at a welcome reception and luncheon at the annual meeting.

Finally, ASN is committed to helping nephrology fellows prepare for their initial American Board of Internal Medicine (ABIM) certifying exam in nephrology. ASN holds its Board Review Course and Update in San Francisco in August. This year, the program will take place August 29 – September 4. New this year, ASN administered the first ASN In-Training Exam (ITE) for Nephrology Fellows. This is an Internet-based exam that was given to 693 fellows and consisted of 150 multiple-choice questions on topics that mirrored the blueprint of ABIM's exam. It will be given annually.

ASN continues to expand its services for nephrology fellows. The Society recently surveyed fellows to assess how well ASN meets the needs of this important constituency; nearly 50 percent responded. More than 91 percent of fellows said they were "very satisfied" with the services provided by ASN. One commented that "ASN membership has helped me feel professionally connected to other nephrologists and nephrology-related health-care workers at an early stage of my career in nephrology." Their thoughts regarding fellow travel support and reduced registration for Renal Week reinforced the value of providing such funding. The Society is grateful for the strong response and valuable feedback received. ASN's leaders and staff will use the survey results to help inform future directions for the Society and to improve service to all ASN members.

Susan Owens is senior policy coordinator at ASN and works to address all issues related to nephrology training programs

Expanding Nephrology Horizons: ASN-SLANH Mini-Fellowship

Through the eyes of one recipient

The American Society of Nephrology (ASN) and the Sociedad Latino-Americana de Nefrología é Hipertension (SLANH) created the ASN-SLANH Mini-Fellowship in 2003. The fellowship program provides the opportunity for 10 Latin American nephrologists to observe a North American nephrology program for three weeks and then attend Renal Week as a guest of ASN.

A new group of fellows is chosen by SLANH each year, and ASN arranges the mini-fellowships at various institutions around the country. In 2008, the fellows came from Brazil, Colombia, and Mexico, and observed programs in Alabama, California, Florida, Georgia, Massachusetts, Michigan, New York, and Pennsylvania. One such fellow was Flávio Ribeiro Dantas de Aguiar, MD.

Aguiar was born on June 14, 1978, in Natal, the capital of Rio Grande do Norte in northeastern Brazil. His mother and father are professors at the Federal University of Rio Grande do Norte. His sister is a nurse and his brother, an architect.

Aguiar recalls that as a child, he always wanted to become a doctor. When he was in kindergarten, Aguiar refused to dress as a soldier for the Independence Day parade, which celebrates Brazil's independence from Portugal on September 7 each year. Instead, he dressed in white clothes and went as a doctor.

His other inspirations for becoming the first doctor in his family included a love of biology and his family's devotion to Catholicism, both of which led him to obtain a medical degree in 2003. As he said, "I decided that my future profession had something [to do] with biology and helping people!"

He is equally enthusiastic about his motivations to become a nephrologist: "During my residency in internal medicine, I discovered how fascinating this specialty is. We work a lot, it is true. And we have a lot to do [in the way of] prevention, treatment and follow-up—it is complete! I could interact with a lot of . . . patients, from child[ren] to old people, men and women, from very sick to better ones. That is amazing!" Aguiar says he is proud of the quality of care Brazil provides to its citizens with kidney disease.

After completing his residency in Natal, Aguiar went to São José do Rio Preto Medical School in São Paulo for his nephrology fellowship. At the time, Emmanuel Burdmann, MD, was the president of SLANH and mentioned the ASN-SLANH Mini-Fellowship to Aguiar during his initial interview. Aguiar's family frequently hosted foreign medical students. In 2001, he participated in a one-month emergency medicine internship in Ferrara, Italy, promoted by the International Federation of Medical Students Association, and he enjoyed the intercultural experiences. In addition, almost all of his professors in Brazil had studied abroad. So, in 2008, during the second year of his fellowship, Aguiar applied to come to the United States through SLANH.

ASN placed Aguiar at Temple University in Philadelphia, under the guidance of program director Patricio Silva, MD. Aguiar says highlights of his time at Temple included "the acute care service [allowing me to] see continuous dialysis, waters treatment in the dialysis unit, the grand rounds…, the conferences, and the organization of the outpatient dialysis unit." While in Philadelphia, Aguiar also experienced an American pastime firsthand when the Philadelphia Phillies won the World Series and had a parade through the city.

The ASN-SLANH Mini-Fellowship has been a rewarding program for everyone involved, from the participants themselves to the host program directors to Tomas Berl, MD, and Bill Mitch, MD—ASN past presidents who have guided the program—to ASN staff who interact with the eager participants and meet people from different cultures and backgrounds. It is also a useful mechanism for facilitating connections between Latin American and North American nephrologists.

Says Aguiar: "Even though the time is short, I am convinced that such a mini-fellowship will have an impact on my career, allowing me to gain valuable experience. It will reinforce and increase my knowledge and open my mind with new advances from what I saw in the Temple nephrology center. I will be able to observe the differences in health-care systems and compare [them]. This could have applications for Brazil in the future. I gained greater capabilities as a physician, improved my English, and met new nephrology colleagues who may help me in my work, at home, by sharing medical opinions and insights."

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Proven results

- **PhosLo® (calcium acetate) achieved K/DOQI target levels** for mean serum phosphorus and Ca x P product within 3 weeks in 8-week CARE study.[1]
- **NO significant difference in the progression of coronary artery calcification** following equivalent lipid control in the PhosLo and sevelamer treated groups in CARE-2 study.[2]
- **NO mortality benefits with sevelamer** when compared to calcium-based phosphate binders in DCOR (Genzyme-sponsored) study.[3]
- **NO mortality, morbidity, or hospitalization benefits with sevelamer** over calcium-based binders as stated in DCOR secondary analysis.[4]

Proven consistency

- Well tolerated with limited GI side effects[5]
- Not associated with metabolic acidosis[6]
- Nearly two decades of proven results

PhosLo is indicated for control of hyperphosphatemia in end-stage renal failure. Patients with higher-than-normal serum calcium levels should be closely monitored and their dose adjusted or terminated to bring levels to normal. PhosLo is contraindicated in patients with hypercalcemia. No other calcium supplements should be given concurrently with PhosLo. Nausea, hypercalcemia and pruritus have been reported during PhosLo therapy.

Please see brief summary of prescribing information and references below.
For more information on PhosLo, please contact Fresenius Medical Care at 800-323-5188 or visit phoslo.com.

PhosLo® GelCaps (CalciumAcetate) 667 mg

Dispense as written

REFERENCES: 1. Qunibi WY, Hootkins RE, McDowell LL, et al. Treatment of hyperphosphatemia in hemodialysis patients: the calcium acetate renagel evaluation (CARE Study). Kidney Int. 2004;65:1914-1926. **2.** Qunibi W, Moustafa M, Muenz LR, et al. A 1-year randomized trial of calcium acetate versus sevelamer on progression of coronary artery calcification in hemodialysis patients with comparable lipid control: the calcium acetate renagel evaluation-2 (CARE-2) study. Am J Kidney Dis. 2008;51:952-965. **3.** Suki WN, Zabaneh R, Cangiano JL, et al. Effects of sevelamer and calcium-based phosphate binders on mortality in hemodialysis patients. Kidney Int. Aug 29, 2007. **4.** St. Peter WL, Liu J, Weinhandl E, Fan Q. A comparison of sevelamer and calcium-based phosphate binders on mortality, hospitalization, and morbidity in hemodialysis: a secondary analysis of the dialysis clinical outcomes revisited (DCOR) randomized trial using claims data. Am J Kidney Dis. 2008;51:445-454. **5.** PhosLo® [prescribing information]. Fresenius Medical Care; Waltham, MA. January 2007. **6.** Mehrotra R, Kopple JD,Wolfson M. Metabolic acidosis in maintenance dialysis patients: clinical considerations. Kidney Int. 2003;64(suppl 88):S17-S25.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

CONTRAINDICATIONS: Patients with hypercalcemia. INDICATIONS AND USAGE: For the control of hyperphosphatemia in end-stage renal failure. **WARNINGS:** Patients with end-stage renal failure may develop hypercalcemia when given calcium with meals. No other calcium supplements should be given concurrently with PhosLo. Progressive hypercalcemia due to overdose of PhosLo may be severe as to require emergency measures. Chronic hypercalcemia may lead to vascular calcification, and other soft-tissue calcification. The serum calcium level should be monitored twice weekly during the early dose adjustment period. The serum calcium times phosphate (Ca x P) product should not be allowed to exceed 66. Radiographic evaluation of suspect anatomical region may be helpful in early detection of soft-tissue calcification.

PRECAUTIONS: Excessive dosage induces hypercalcemia; therefore, early in the treatment during dosage adjustment serum calcium should be determined twice weekly. Should hypercalcemia develop, the dosage should be reduced or the treatment discontinued immediately depending on the severity of hypercalcemia. Do not give to patients on digitalis, because hypercalcemia may precipitate cardiac arrhythmias. Always start PhosLo at low dose and do not increase without careful monitoring of serum calcium. An estimate of daily calcium intake should be made initially and the intake adjusted as needed. Serum phosphorus should also be determined periodically.

Information for the Patient: Inform the patient about: 1) compliance with dosage, 2) adherence to diet instructions and avoidance of nonprescription antacids, and 3) symptoms of hypercalcemia. Drug Interactions: PhosLo may decrease the bioavailability of tetracyclines. Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed.

Pregnancy: Teratogenic Effects: Category C. Animal reproduction studies have not been conducted. It is not known whether PhosLo can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Give to a pregnant woman only if clearly needed.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Of the total number of subjects in clinical studies of PhosLo (n = 91), 25 percent were 65 and over, while 7 percent were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS: In clinical studies, patients have occasionally experienced nausea during PhosLo therapy. Hypercalcemia may occur during treatment with PhosLo. Mild hypercalcemia (Ca>10.5 mg/dl) may be asymptomatic or manifest itself as constipation, anorexia, nausea and vomiting. More severe hypercalcemia (Ca>12 mg/dl) is associated with confusion, delirium, stupor and coma. Mild hypercalcemia is easily controlled by reducing the PhosLo dose or temporarily discontinuing therapy. Severe hypercalcemia can be treated by acute hemodialysis and discontinuing PhosLo therapy. Decreasing dialysate calcium concentration could reduce the incidence and severity of PhosLo induced hypercalcemia. The long-term effect of PhosLo on the progression of vascular or soft-tissue calcification has not been determined. Isolated cases of pruritus have been reported which may represent allergic reactions.

OVERDOSAGE: Administration of PhosLo in excess of appropriate daily dosage can cause severe hypercalcemia (see **ADVERSE REACTIONS**).

For more information on PhosLo, please contact Fresenius Medical Care at (800 323-5188.
Manufactured for and distributed by: Fresenius Medical Care North America,Waltham, MA 02451

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