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 patients. 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.)

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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’ non-hematologic 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 Arcajoy, MD, associate professor of medicine at the University of Minnesota. “We think that there are multiple factors at play, and we need to be very careful about how much we use.”

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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."

**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 Medicare Policy

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ESAs

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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 ef-fects and potential for decreased tumor responses.”

Typical therapeutic doses of ESAs are much higher than the body’s natural levels, said Anarotei 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 concentra-tions log orders higher than anything that the body normally sees, but that’s part of our problem,” he said during the Ameri-can 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 affect 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. Adminis-tration 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 ad-dition, Epo markedly decreased tissue ap-optosis. 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 be-sides red cell production, “the area of re-search that is most mature at this point in time is the potential neurologic [pro-tective] effect of the medication,” Arcasoy said. In a small study of stroke patients conducted by Ehrenreich and colleagues at the Max-Planck-Institute for Experi-mental Medicine of the Georg-August- University in Goettingen, Germany, re-combinant human Epo or saline placebo was administered for three days to 40 pa-tients, beginning within eight hours of an ischemic stroke.

At one month, the patients who re-ceived the active drug had greater im-provement on neurolinguistic 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 con-trol group, indicating that Epo reached the brain, suggesting a possible direct ef-fect of the drug on the brain and not just an increase in red blood cell numbers.

The dilemma is to balance the ben-eificial effects of ESAs with possible detri-mental effects. Arcasoy and Besarab said. In stroke, ESAs’ tissue protective effects could be offset by increases in red cell mass, increased blood pressure, and an in-creased 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 stimulat-ing 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 protec-tive, 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 tim-ing 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 maximally 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 Szczek and co-workers at Duke University Medical Center found that significantly more pa-tients randomized to a higher hemoglobin target group were unable to tolerate Epo to the higher target level and required high-dose Epo compared with patients randomized
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. And while higher 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), maintenance 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.

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**Medicare Policy**

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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 capitated 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.”
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. 

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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’ regulars and their friends–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’ regulars and their friends

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 Galena Limited in terms of IV iron drug market share. The report said that Venofer— from Galena 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 Lexingon, 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.

Letters

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**ASN Kidney News Tweet the Week**

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3. Send an email to [tweet@asn-online.org](mailto: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.
More Preventive Care Lowers Cardiovascular Risk in CKD Patients

Among patients with chronic 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 were included. Authors note that 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. Risk of death or non-fatal myocardial infarction was also lower among patients receiving more preventive care. When those with prevalent disease are excluded, the relative risk reductions were 36 percent for further, 50 percent for vessel revascularization, 61 percent for anticoagulation, and 88 percent for vitamin D supplementation. Overall, for every percentile increase in a composite score of preventive care, there was a 0.29 percent reduction in the cumulative incidence of an atherosclerotic heart disease outcome.

The results suggest that Medicare patients could benefit from targeted preventive care interventions. However, they advise that, although many patients could benefit from these interventions, it is most likely for patients with certain characteristics that would increase the risk of atherosclerotic heart disease outcomes. The study also highlights the importance of targeted preventive care interventions to reduce the incidence of atherosclerotic heart disease outcomes among Medicare beneficiaries with chronic kidney disease.
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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, furanaside, phenytion, metoprolol and enalapril in simulated gastric fluid. However, it is recommended that compounded solutions 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/m² 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 MRHID) 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 HGPS 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 micronuclei 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 MRHID), did not affect fertility or mating performance of male or female rats.

Pregnancy:
Category C. No adequate and well-controlled studies have been conducted in pregnant women. The effects 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 MRHID) 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 MRHID) 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 MRHID) 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>
<thead>
<tr>
<th>Adverse Event</th>
<th>FOSRENOL® % (N=180)</th>
<th>Placebo % (N=95)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Vomiting</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>Dialysis graft occlusion</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Adverse Event</th>
<th>FOSRENOL® % (N=182)</th>
<th>Placebo % (N=533)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>36</td>
<td>16</td>
</tr>
<tr>
<td>Vomiting</td>
<td>26</td>
<td>18</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>26</td>
<td>13</td>
</tr>
<tr>
<td>Headache</td>
<td>21</td>
<td>9</td>
</tr>
<tr>
<td>Diabetic graft occlusion</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>17</td>
<td>7</td>
</tr>
<tr>
<td>Constipation</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Mucositis</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Hypercalcaemia</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

OVERDOSAGE
There is no experience with FOSRENOL® overdose. 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 20000 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 overdose.

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.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [See USP controlled room temperature] Protect from moisture

Rx only
Manufactured for Shire US Inc., Wayne, PA 19087, USA 1-800-829-2088
Rev: 4/2008
251 0107 003A
FOS-00502
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 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
For years, international medical graduates (IMGs) have comprised a significant percentage of the fellows in nephrology training programs who provide care 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, 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 Rosenfeld, 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 hematologic/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 workforce 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 historically have attracted a higher proportion of IMGs.

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of programs</th>
<th>Fellows</th>
<th>USMGs*</th>
<th>DOs</th>
<th>IMGs</th>
<th>IMGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>149</td>
<td>240</td>
<td>146</td>
<td>4</td>
<td>1.67%</td>
<td>90</td>
</tr>
<tr>
<td>1987</td>
<td>152</td>
<td>460</td>
<td>297</td>
<td>7</td>
<td>1.52%</td>
<td>156</td>
</tr>
<tr>
<td>1988</td>
<td>153</td>
<td>486</td>
<td>307</td>
<td>7</td>
<td>1.44%</td>
<td>172</td>
</tr>
<tr>
<td>1989</td>
<td>150</td>
<td>212</td>
<td>118</td>
<td>8</td>
<td>3.77%</td>
<td>86</td>
</tr>
<tr>
<td>1990</td>
<td>146</td>
<td>417</td>
<td>249</td>
<td>12</td>
<td>2.88%</td>
<td>156</td>
</tr>
<tr>
<td>1991</td>
<td>149</td>
<td>482</td>
<td>249</td>
<td>15</td>
<td>3.11%</td>
<td>218</td>
</tr>
<tr>
<td>1992</td>
<td>143</td>
<td>544</td>
<td>252</td>
<td>19</td>
<td>3.49%</td>
<td>273</td>
</tr>
<tr>
<td>1993</td>
<td>141</td>
<td>628</td>
<td>295</td>
<td>17</td>
<td>2.71%</td>
<td>356</td>
</tr>
<tr>
<td>1994</td>
<td>142</td>
<td>637</td>
<td>265</td>
<td>15</td>
<td>2.35%</td>
<td>357</td>
</tr>
<tr>
<td>1995</td>
<td>139</td>
<td>580</td>
<td>207</td>
<td>16</td>
<td>3.76%</td>
<td>357</td>
</tr>
<tr>
<td>1996</td>
<td>137</td>
<td>609</td>
<td>231</td>
<td>20</td>
<td>3.28%</td>
<td>358</td>
</tr>
<tr>
<td>1997</td>
<td>135</td>
<td>635</td>
<td>234</td>
<td>22</td>
<td>3.46%</td>
<td>379</td>
</tr>
<tr>
<td>1998</td>
<td>129</td>
<td>638</td>
<td>242</td>
<td>19</td>
<td>2.98%</td>
<td>377</td>
</tr>
<tr>
<td>1999</td>
<td>127</td>
<td>678</td>
<td>321</td>
<td>21</td>
<td>3.10%</td>
<td>336</td>
</tr>
<tr>
<td>2000</td>
<td>127</td>
<td>626</td>
<td>286</td>
<td>22</td>
<td>3.51%</td>
<td>318</td>
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<tr>
<td>2001</td>
<td>128</td>
<td>649</td>
<td>352</td>
<td>30</td>
<td>4.62%</td>
<td>267</td>
</tr>
<tr>
<td>2002</td>
<td>128</td>
<td>711</td>
<td>407</td>
<td>33</td>
<td>4.64%</td>
<td>271</td>
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<tr>
<td>2003</td>
<td>128</td>
<td>772</td>
<td>439</td>
<td>34</td>
<td>4.40%</td>
<td>299</td>
</tr>
<tr>
<td>2004</td>
<td>130</td>
<td>772</td>
<td>423</td>
<td>38</td>
<td>4.92%</td>
<td>311</td>
</tr>
<tr>
<td>2005</td>
<td>135</td>
<td>822</td>
<td>441</td>
<td>44</td>
<td>5.35%</td>
<td>337</td>
</tr>
<tr>
<td>2006</td>
<td>136</td>
<td>802</td>
<td>401</td>
<td>55</td>
<td>6.86%</td>
<td>346</td>
</tr>
<tr>
<td>2007</td>
<td>139</td>
<td>808</td>
<td>367</td>
<td>54</td>
<td>6.68%</td>
<td>387</td>
</tr>
</tbody>
</table>

*USMGs includes graduates of Canadian medical schools
Continued from page 11

Workforce

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 6,033 in 2006. As a result, underserved rural and urban communities and current 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 nephrology fellowship program director increasingly recognizes the need for more nephrologists who can provide 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 paths, who will care for underserved populations, and for African Americans, who already have a disproportionately share of kidney disease?

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

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

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

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. Studies demonstrate that preservation of renal function is critical for long-term graft survival.

Harihara 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. 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).

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 on graft failure. Acute rejection within 1 year, however, did not reach significance.

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. This study reported that only those acute rejection episodes that impair renal function negatively affect long-term graft survival. 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). The data showed that in the presence of acute rejection episodes, renal function is the better predictor of long-term outcomes.

Figure 1. Relative hazard for graft failure according to 1-year creatinine and ∆ creatinine values.

Figure 2. Kaplan-Meier graph of overall graft survival by acute rejection/GFR grouping levels.
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. In addition, this research shows GFR at 12 months also correlates to long-term patient survival.7

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

References:
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 year’s 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 Nebraska, capturing 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 Durai-Kannan, 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 Durai-Kannan 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 Durai-Kannan, 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 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, 695 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

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 valuable 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 and recognize residents, to develop strategies to engage residents, 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 group will identify curricula needing special development and then work to create subgroups to define and develop the curriculum.

• 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.
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 research-ers 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.
The Changing Nephrology Workforce

Creating Future Pediatric Nephrologists: Progress and Challenges Ahead

By Victoria Norwood

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, 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 Kolur.

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.


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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.
Although budgets were tight this year, 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 force

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 (MPPA), 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, urate 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.

#### Other state legislation

- **Access to care:**
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companies continue placing an undue burden on dialysis patients.

New York has a bill currently in session that would require all state insures 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 were still in committee in Connecticut (HB 6677), Texas (HB 2027/SB 2091), and New York (AB 6966/ SB 4888).

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 committees.

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.
What are the pros and cons of recerti-
MOC is a meaningful way to get feedback 
In this month’s issue, ASN Kidney News editorial board member Edgar Lerma interviewed Stuart 
of Colorado Denver School of Medicine. 
up as to how your practice is perceived by 
ules, known as PIMs, give you a heads-
year. The Practice Improvement Mod-
shot” of my knowledge and practice per-
about your practice and to make sure you 
some health plans and other qual-
ity groups acknowledge MOC and PIM 
completely in their reward and recogni-
ity groups acknowledge MOC and PIM 
licensing and MOC, and I believe there is 
You pay only an additional exam fee to 
assessments. It’s up to you. 
and helped the committee develop what 
I believe is a better exam product. 
A significant part of the recertifica-
tion 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 nepho-
rologists. So ABIM and ASN are now 
exploring some new options for practice 
 improvement tools and products that 
will fill this gap. Examples could include top-
ics such as transplant and acute kidney 
injury. 
In the meantime, nephrologists have 
several choices. Many have chosen the 
patient and peer assessment and com-
munication 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 assess-
ment. There is also a new clinical supervi-
sion PIM specifically designed for physi-
cians, including nephrologists, who work 
in academic environments. 
What would you advise those cur-
rently undergoing the recertification 
procedure? 
The best advice I can give to nephro-
logists 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 com-
pleting the medical knowledge modules. 
Later in the cycle you can focus on the 
PIM as a way to make meaningful chang-
es 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 cer-
ertificate begins when your current one ex-
pires, even if you complete the program 
before the end of your tenth year of cer-
tification. 
Is there any particular reference 
material or Board Review Course you 
would recommend for use in prepar-
ing 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 Blue-
print, 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 recerti-
fication? 
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 com-
pleted MOC, 74 percent have cited pro-
fessional value. Whether you are just en-
rolling now or in your second MOC cycle, 
I encourage you to take part. You’ll learn 
about what you know, and more impor-
tantly, you’ll identify ways to improve.

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 nephrol-
y. 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 cer-
tified since 1990 to renew their certifica-
tion every 10 years by taking an exam and 
completing a process of self-assessment. 
More than 8500 total valid certifi-
cates in nephrology have been issued by 
ABIM, and more than 80 percent of nep-
holists who certified between 1990 
and 1996 have chosen to maintain their 
certification.

What are the pros and cons of recerti-
fication 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 “snap-
shot” of my knowledge and practice per-
formance as it exists today. 
The ABIM medical knowledge mod-
ules offer a great learning tool to stay 
current on the recent advances that have 
changed our practice. In fact, ABIM in-
troduces new “update” modules every 
year. The Practice Improvement Mod-
ules, 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 in-
clude 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 certifi-
cation 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. 

Please compare the ABIM process of 
recertification versus various individu-
al states’ policies on renewing medical 
licenses. 
ABIM MOC and individual state policies 
for renewing medical licenses are separate 
initiatives. Licensing is required of all phy-
sicians to practice medicine, and, today, 
physicians must be licensed in good stand-
ing 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 Di-
rectors, I was required to complete MOC 
even though I initially certified in neph-
rology before 1990. I will admit that at 
first I had my reservations about it, but 
only 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 iden-
tify gaps in my practice operations. I also 
found that taking the MOC exam affect-
ed 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. 

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.
The Transplant Nephrology Fellowship: Current and Future Challenges

By Milagros Samaniego, David Rothstein, and Michelle Josephson

Trends in Medical Education

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 for UNOS-certified transplant physicians. The societies crafted a comprehensive academic curriculum designed for board-eligible/certified nephrologists, which included training in clinical and basic sciences. The curriculum was to be completed by fellows and posttransplant care of 35 kidney and kidney-pancreas recipients—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).

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 training.

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

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of U.S. ASN/AST-accredited transplant nephrology fellowship programs</td>
<td>50</td>
</tr>
<tr>
<td>Number of transplant nephrology graduates in 2008</td>
<td>29</td>
</tr>
<tr>
<td>Number of living kidney transplant recipients in the United States at the end of 2005†‡</td>
<td>104,388</td>
</tr>
<tr>
<td>Number of wait listed kidney transplant candidates¥</td>
<td>79,140</td>
</tr>
<tr>
<td>Number of self-reported nephrologists in the United States¶</td>
<td>74,100</td>
</tr>
</tbody>
</table>

†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

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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 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.”

Aguiar 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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References

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Adverse reactions:
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