

# Kidney May 2011 Vol. 3, Number 5

# Influenza Vaccine Safe and Beneficial for Transplant Recipients, Research Finds



The influenza vaccine is safe and lowers the risk of organ loss and death in kidney transplant recipients, a new study finds (Hurst FP et al., May *Clin J Am Soc Nephrol*). The findings suggest that concerns about the safety of the vaccine in transplant recipients are unwarranted and that the vaccine can provide clear benefits to these individuals.

# Safety and benefits of vaccination

While influenza infection has been linked to increased morbidity and mortality in transplant recipients, the effectiveness and safety of the influenza vaccine in these individuals have been questioned.

Some studies suggest that the vaccine may not be effective after kidney transplantation because patients may not be able to form enough protective antibodies owing to the immunosuppressant effects of the drugs they must take to prevent allograft rejection. In addition, influenza infection has been associated with allograft rejection, perhaps due to stimulation of the immune system. Because vaccination stimulates the immune system, there have been concerns that influenza vaccination could also induce an immune response that could trigger rejection.

Guidelines recommend that all transplant patients receive the influenza vaccine after transplant, but there are limited data to support its efficacy or safety in the early period after transplantation. To investigate, Frank Hurst, MD, of the Walter Reed Army Medical Center and F. Edward Hebert School of Medicine and his colleagues analyzed Medicare claims for influenza vaccination and influenza infections in 51,730 adult Medicare patients who were first transplanted from January 2000 to July 2006 and were followed through October 2006.

Among the 9678 (18.7 percent) patients who were vaccinated against the *Continued on page 3* 

# Inside

7 State of the nephrology workforce

**14 Journal View** Transplant tourism and posttransplant cancer risk

15 Japan Nuclear Accident Kidney risk from radiation exposure



**16 Policy Update** CMS drops adjuster that would have reduced ESRD payments

# 18 Industry Spotlight Concert tests kidney drug that uses

deuterium chemistry

# Donor-Specific Antibodies Accelerate Arteriosclerosis in Kidney Transplant Recipients

# By Tracy Hampton

Preformed donor-specific antibodies contribute to transplant patients' development of arteriosclerosis of the kidneys and may play a key role in organ rejection, according to research reported in the May *Journal of the American Society of Nephrology*.

The findings may change the way phy-

sicians think about the kidney rejection process and could even impact care related to cardiovascular diseases in general.

### Attack of the antibodies

The detection and treatment of donor organ rejection has historically focused on T-cell-mediated processes, but recent research by a number of institutions has revealed that antibody-mediated rejection—which can occur when a transplant recipient mounts antibodies against their new organ—is a major contributor to the declining function and ultimate loss of transplanted kidneys (Terasaki P, Mizutani K. Antibody Mediated Rejection: Update 2006. *Clin J Am Soc Nephrol* 2006; 1:400–403).

To study the effects of antibody-mediated rejection, Gary Hill, MD, of the Hôpital Européen Georges Pompidou, APHP, in Paris and his colleagues examined kidney biopsies from transplant pa-*Continued on page 4* 



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# Influenza Vaccine Safe

Continued from page 1

flu in the first year after transplantation, factors associated with vaccination included older age, diabetes, later year of transplant, and tacrolimus or mycophenolate use at discharge. Vaccinations were less frequent among men, African American recipients, and patients with high panel reactive antibody or those who received induction immunosuppression or expanded criteria donor kidneys.

"We wanted to determine whether or not it is safe to provide influenza vaccinations to recent transplant recipients based on early reports of vaccination potentially causing rejection," Hurst said. "While this can only be determined in a randomized controlled trial, we demonstrated that there was no increase in associated risk of allograft loss or death when a national sample of patients was vaccinated against influenza. There was actually a significant decrease in adverse outcomes."

Patients who were vaccinated within the first year of kidney transplantation were 23 percent less likely to experience organ loss and 18 percent less likely to die during the study period than individuals who were not vaccinated, Hurst and his team reported. A total of 310 (0.6 percent) patients got the flu, and they were no more likely to experience organ loss than patients who did not get the flu.

Influenza infection showed a trend toward increased risk of death, though. In addition, patients with claims for influenza infection in the first year were 1.58 times more likely to experience rejection in the first year after transplant.

"The observed vaccination rates are surprisingly low," said David Gilbertson, PhD, director of epidemiology and biostatistics at the U.S. Renal Data System in Minneapolis, who was not involved with the research. The low rate of vaccination may stem from either concerns for inducing an acute rejection or the possible lack of efficacy in preventing infection, the authors said. Yet "the finding of probable benefit from vaccination, combined with no evidence of increased allograft rejection episodes suggests strongly that concerns against influenza vaccination are unwarranted," Gilbertson said.

Others in the field also welcomed the findings.

"The study by Hurst *et al.* confirms the finding from previous single-center studies that influenza vaccination during the first year is safe in renal transplant recipients and is not associated with acute rejection," said Woojin James Chon, MD, a transplant nephrologist and an assistant professor at the University of Chicago's Pritzker School of Medicine.

Raymund Razonable, MD, an associate professor of medicine at the Mayo Clinic in Rochester, Minn., hopes the findings will lead to increased vaccination among transplant recipients. "As a transplant infectious disease physician, I welcome the results of this study since it reiterates our recommendation to vaccinate transplant recipients in order to reduce their risk of influenza and its associated morbidity and mortality," he said. "Indeed, one of the findings in this article is that the occurrence of influenza infection during the first year after kidney transplantation, which could have been prevented with vaccination, was associated with acute rejection."

# **Remaining questions**

Studies have generated mixed results with regard to whether kidney transplant patients can generate protective antibody titers after influenza vaccination.

Hurst and his colleagues suggest that even if vaccination does not elicit a strong enough immune response to confer protection against infection, it is possible that any response will offer some protection or at least decrease the severity of the disease.

They also noted that most studies in this area have excluded patients within six months of transplant. Yet the available evidence supports some degree of response in the period more than six months after transplant, presumably as a result of the reduction of overall levels of immunosuppression. The ideal timing of vaccination remains to be determined. Study co-authors include Jessica Lee, MD, Kevin Abbott, MD (Walter Reed Army Medical Center and F. Edward Hebert School of Medicine); Rahul Jindal, MD, PhD (Walter Reed Army Medical Center); and Lawrence Agodoa, MD (National Institutes of Health).

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# Donor-Specific Antibodies

Continued from page 1

tients who mounted antibodies directed against their transplanted kidney and patients who did not. From January 2002 to March 2007, 40 consecutive kidney transplant recipients from the investigators' transplant program of patients with preformed donor-specific anti-HLA antibodies were compared with a control group of 59 patients without preformed donor-specific antibodies.

Arteriosclerosis, in terms of Banff score, significantly progressed between three and 12 months after transplant in the antibody-positive patients. (Banff is a standardized international classification of kidney allograft biopsies.) Taken as a group, the antibody-positive group progressed from Banff cv grade 0.65 + 0.11 at three months to grade 1.12 + 0.10 at one year after transplant.

antibody-negative group The showed an increase from 0.65 + 0.11to 0.81 + 0.10, but this difference was not significant at three months. Arteriosclerosis in antibody-negative patients progressed to approximately one third the degree of that in antibody-positive patients. In addition, conversion to de novo antibody-positivity in four initially antibody-negative patients speeded the rate of acceleration of arteriosclerosis to more near the rates seen in patients who were antibody-positive from the outset. In both antibody-positive and antibody-negative groups, the rate of progression of arteriosclerosis was unaffected by the age of the donor or recipient.

In the antibody-positive patients, "we found that the degree of arteriosclerosis in the transplanted kidney is much worse than would have been expected on the basis of the donor's age, an increase calculated to be on the order of 28 years of 'aging' in the first year posttransplant," said Hill.

All patients who showed acceleration of arteriosclerosis, either at one year or on late (24 to 84 months) biopsies, had subclinical antibody-mediated rejection at three months, 12 months, or both.

The findings should lend greater importance to arteriosclerosis, which may be conspicuous in organ recipients, among transplant researchers.

"Acceleration of arteriosclerosis was a totally unexpected finding, an important one since it broadens our thinking about what constitutes transplant rejection," said Hill. "Accelerated arteriosclerosis can now be seen to form part of the rejection process, even in the absence of more overt vasculitic lesions, and it will probably be found to contribute to the ultimate decline of function in the transplanted kidney."

### Mechanisms involved

Various mechanisms could be responsible for the link between donor-specific

antibodies and arteriosclerosis. For example, the binding of anti-class I antibodies to class I molecules on the vascular endothelium and smooth muscle cells is known to induce the release of a variety of cytokines and to stimulate proliferation of myofibroblasts. Similar reactions occur with anti-class II antibodies. Antibodies other than standard class I and class II antibodies, such as MHC class I-related chain A antibodies, might play a lesser role in the progression of arteriosclerosis, which by narrowing of the arteries supplying the kidney leads to reduced blood flow and oxygen supply to renal tissues, the investigators said.

Previous studies have shown that the development of lesions referred to as chronic transplant arteriopathy may be a manifestation of antibody responses against transplanted kidneys and other solid organs, said Mark Haas, MD, PhD, who was not involved with the research and is a renal pathologist in the department of pathology and laboratory medicine at Cedars-Sinai Medical Center in Los Angeles. These antibody responses may contribute to intimal arteritis, which is characterized by infiltration of immune cells beneath the endothelium, Haas said.

"A key implication of the findings of Hill and workers is that the spectrum of vascular lesions associated with donorspecific antibodies may be even wider," he said. He added that important questions remain, such as whether removing donor-specific antibodies can halt or reverse these arterial effects.

"This study details a range of histologic lesions in arteries that are likely due to donor-specific antibodies and represent a form of chronic humoral rejection. Moreover, these antibody-mediated arterial lesions are progressive," said Lynn Cornell, MD, an assistant professor of laboratory medicine and pathology at the Mayo Clinic in Rochester, Minn. "This is an interesting and important study that contributes to our overall knowledge of antibodymediated damage to the allograft."

Others pointed to potential changes that might be implemented in the clinic as a result of these findings.

"This study supports the utility of both performing protocol surveillance biopsies in clinically stable high risk kidney transplant recipients (those known to have anti-HLA Donor Specific Antibody at the time of surgery) as well as prospectively monitoring anti-HLA antibody status at fixed times posttransplantation and after sensitizing events such as infections, transfusions, surgery, and pregnancy," said Erik Kraus, MD, a transplant nephrologist at Johns Hopkins Medical Center in Baltimore. "Although current interventions remain extremely limited to suppress ongoing antibody injury, pathologic staging of vascular injury combined with measurement of strength of circulating anti-HLA antibody will be useful metrics to assess the efficacy of trials of therapies in the future.'

The concept of immune-mediated arteriosclerosis fits well with recent animal data related to cardiovascular diseases, which revealed that B cell depletion reduces the development of atherosclerosis in mice. (Ait-Oufella H, et al. B Cell Depletion Reduces the Development of Atherosclerosis in Mice. *J Exp Med* 2010; 207:1579–1587).

"Our studies thus open a large area of investigation in the domain of immune-mediated arteriosclerosis beyond that of transplanted organs in the area of cardiovascular diseases in general," Hill said. He noted that the study was limited by the short, roughly three-year, follow-up, and that to fully demonstrate the effects of accelerated arteriosclerosis will require a study extending out to 10 to 15 years.

# CJASN editorial highlights workforce issues

Of interest to all kidney professionals: a *CJASN* editorial now available online (The Future Nephrology Workforce: Will There Be One?; http:// cjasn.asnjournals.org/content/early/ recent). Lead author Mark G. Parker, MD, chair of the ASN Workforce Committee, hopes this editorial will advance understanding of the issues that will impact all kidney professionals and patients. These issues include:

- The number of people with kidney disease is growing rapidly.
- Not enough nephrologists are certifying in nephrology each year to meet expected needs.
- Applications to nephrology fellowships are declining, notably among U.S. medical graduates.
- Medical school experiences in nephrology should be improved.
- Nephrology needs to attract more minorities and women.
- Nephrology must address the perception of medical students and residents that kidney professionals do not maintain appropriate work-life balance.
- More visa restrictions and increasing opportunities in other countries limit the ability of international medical graduates to train and practice in the United States.

The ASN Workforce Committee is developing strategies to address these and other workforce concerns, Parker said. Committee efforts include improving and broadening student and resident experiences in kidney care, increasing research opportunities for students, nurturing great educators, and using social media to highlight the satisfaction and appeal experienced of kidney careers.



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# **The Nephrology Workforce Crisis**

# Nephrology WorkForce Crisis: A Wake-Up Call For All of Us

By Bruce A. Molitoris, MD, FASN

s mounting evidence makes the waning interest in nephrology obvious to all of us, we must ask, "Why have we been asleep behind the wheel?" The accompanying articles in this special issue of ASN *Kidney News* detail many of the problems that have finally gotten our attention.

For instance, why were our colleagues in Australia the first to raise similar concerns about the nephrology workforce (1)? Why did the nephrology leaders in the United States not notice that the majority of medical students in this country do not take electives in nephrology? This decision means that their exposure to clinical nephrology is limited to first- and secondyear courses, which are primarily taught by basic scientists. Although they are superb educators, these faculty lack the experience in, and passion for, clinical nephrology that is needed to convey the relevance and excitement so many of us feel.



Why are internal medicine residents in the United States not required to complete a rotation in nephrology, especially if they intend to become hospitalists or intensivists? When did fluid and electrolytes, acid base, hypertension, and all forms of kidney disease cease to be recognized as an integral component of an internal medicine resident's knowledge?

Finally, I find it somewhat ironic that participants in the Kidney Research National Dialogue—sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases to identify the most critically important questions or research objectives in nephrology—identified the nephrology workforce of the future as a top concern.

To gain a better understanding of where we presently are and what is being done to help move nephrology forward, please read the excellent articles in this special issue of *ASN Kidney News*. These articles outline the problem, explain how this crisis may affect our ability to provide care to patients, and begin to provide some potential solutions for the future.

Using data from the Accreditation Council for Graduate Medical Education and surveys designed by the ASN Nephrology Training Program Directors (TPDs), ASN Policy Associate Rachel Shaffer provides evidence of a lack of interest in nephrology among graduates of medical schools in the United States. She also delineates the primary reasons for this apathy. Together with the marked reductions in J-1 visas issued—limiting talented international medical graduates from filling positions to help meet the increasing clinical needs and the lack of gender and racial diversity, the problem is real and growing.

In another article, Ms. Shaffer and TPD Executive Committee member



Mark G. Parker, MD, describe how the already rising population of patients who are best cared for by nephrologists will receive a rapid influx of additional patients as we enter a new era for health insurance coverage and accountability, as well as a change in the way we deliver care and are reimbursed for it. Attention is also given to the need for expanding other essential members of the nephrology health care team.

Always a contrarian, ASN Executive Director Tod Ibrahim contributes a controversial view of the workforce needs in nephrology. Reductions in reimbursement (especially the internal medicine component of dialysis patient care), bundled payments for care of patients with ESRD, and movement toward a more standardized approach to patient care may mandate the increased use of other providers, such as nurses and physician assistants, especially in dialysis units and accountable care organizations.

Another article, by ASN Policy Associate Daniel Kochis, predicts the results for nephrology of the 2011 Medical Specialties Matching Program. Although the fellowship match will not take place until this June, Mr. Kochis forecast this year's results using data from the Electronic Residency Application Service. Unfortunately, the near future is worse than the recent past when it comes to interest in nephrology careers.

What is the ASN doing about this deteriorating situation? I am pleased to assure you that the ASN has made this issue a top priority for the next few years. An ASN Task Force on Increasing Interest in Nephrology Careers has already completed its mission of identifying the problems and making suggestions regarding potential solutions. One suggestion, the formation of an ASN Workforce Committee to devise and implement a plan, is proceeding. ASN Grants and Development Associate Evelyn Shapiro discusses the goals and approaches of the committee in this special issue. These recommendations cover a wide range of target audiences and implementation strategies, from first-year medical students through faculty and from education reform to research stimulation.

In summary, nephrology faces a critical problem with declining interest and expanding demands. This crisis seems paradoxical because 95 percent of nephrology fellows are happy with their career choice (Figure 1.1) (2). Therefore, we must work together to find a way of designing, developing, improving, and marketing what we know to be a rewarding, stimulating, and fulfilling career.

ASN Councilor Bruce A. Molitoris, MD, FASN, is professor of medicine, director of nephrology and director of the Indiana Center for Biological Microscopy at Indiana University in Indianapolis. He chaired the ASN Task Force on Increasing Interest in Nephrology Careers.

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# The Nephrology WorkForce Crisis: By the Numbers

# By Rachel Shaffer

nterest in nephrology as a career among United States medical graduates (USMGs) is declining-and has been on the decline for the better part of a decade. From 2002 to 2009, all internal medicine subspecialties increased the number of available positions, with the exception of geriatric medicine (which shrank overall) (1, 2). Yet, in 2009, nephrology was the only internal medicine specialty to attract fewer USMGs than in 2002, the result of a steady seven-year decrease in the number of USMGs entering the renal field (Figure 2.1). During that time, the number of USMGs in nephrology fellowships dropped from 401 to 365, even though the total number of nephrology fellows increased 28.1 percent, from 711 to 911 (Figure 2.2).

Residency training in internal medicine, the entry point for nephrology, is increasingly unappealing to medical students in the United States. Between 2002 and 2009, the number of USMGs in internal medicine residency positions dropped from 11,807 to 10,855, even though the total number of positions increased during this time.

Of all internal medicine specialties, nephrology and geriatric medicine are now the least competitive. Correspondingly, in a recent survey of third- and fourth-year students from five medical schools, more than three in four respondents conveyed that renal pathophysiology courses were too complex, lacked relevance, or simply failed to stimulate interest (Figure 2.3).

The field of nephrology has benefitted substantially from the contributions of international medical graduates (IMGs) who enter fellowship programs in this country. Since 2002, nephrology fellowship training program directors have increasingly depended on IMGs to fill fellowship positions. In 2009, 497 nephrology fellows were IMGs, up from 271 in 2002. Because 40 percent of its physicians are IMGs, compared with an estimated 25 percent of all physicians in the United States, nephrology is more dependent on IMGs than any other specialty except geriatric medicine. So, if highly qualified IMGs are still interested in nephrology, then why is declining interest among USMGs a matter of concern?

Owing to new and more stringent legal barriers to immigration, the future of IMGs in the United States is increasingly uncertain. From 1996 to 2008, the number of IMGs obtaining J-1 visas declined from 11,471 to 6561 (3). Visa requirements and application processes for IMGs became more arduous after September 11, 2001. Meanwhile, the economy in this country increasingly necessitates a two-income household, meaning that most spouses of IMGs must also secure work visas.

As countries such as China and India create greater opportunities in medicine, more IMGs may remain in their countries of origin or return after they complete graduate medical education in this country. Perhaps as a sign of future trends, the number of

# Figure 2.1

Increase/decrease of USMGs 2002-2009)



Figure 2.2

USMGs entering nephrology vs. number of available nephrology positions



Brotherton SE, Etzel SI. JAMA 2010; 304:1255–1270 Brotherton SE, Rockney PH, Etzel SI. JAMA 2003; 290:1197–1202

# Pediatric Nephrology: Bear or Bull?

### By Rachel Shaffer

In contrast to adult nephrology, pediatric nephrology significantly increased its number of USMG fellows in recent years (1, 2). From 2002 to 2009, the number of pediatric nephrology fellows grew from 65 to 123, and the number of USMGs in pediatric nephrology fellowships jumped from 31 to 71, bringing USMGs up to 57.7 percent of the total from 47.4 percent.

During this time, more women also entered the specialty. In 2002, 34 pediatric nephrology fellows were women (53.3 percent); in 2009, 83 were women (67.5 percent). Yet pediatric nephrology may not be the bright spot it appears to represent at first glance.

"We worked very hard to increase our numbers over the last decade, and we were delighted by the fact that the increase was largely accounted for by USMGs," says H. William Schnaper, MD, president of the American Society of Pediatric Nephrology (ASPN). "However, there are a number of concerning caveats."

This growth begins from the nadir of interest in pediatric nephrology. Compared with other pediatric specialties, nephrology is experiencing greater attrition of fellows between the second and third year of the three-year fellowship training period. Furthermore, pediatric nephrology maintains, by two years, the oldest median age of any pediatric specialty. Consequently, the median age of pediatric nephrologists has not decreased during the past five years.

Most recently, early estimates of the 2011 match raise concern that the specialty observed a significant decline in the number and quality of candidates. Although official data on the most recent match will not be available until July 2011, ASPN Councilor Larry A. Greenbaum, MD, PhD, worries "that the surge in interest is beginning to wane."

Greenbaum notes that the subspecialty faces unique challenges. Besides being affected by trends in interest in general pediatrics, pediatric nephrology has a limited number of fellowship sites, lower average starting salaries than those for general pediatricians, and the additional financial disincentive of a three-year fellowship requirement. Although the pediatric nephrology community hopes to prolong the upswing in interest and ASPN continues its recruitment efforts, the specialty's future remains unclear.

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Figure 2.4 Increase/decrease of female fellows (2002–2009)



graduates of Canadian medical schools training in residency and fellowship programs in the United States dropped from 418 in 2002 to 273 in 2009.

A closer look at the USMG nephrology numbers continues to reveal a grim picture. Although the number of female nephrology fellows rose from 229 in 2002 to 333 in 2009, this growth represented the lowest proportional increase for any internal medicine specialty except geriatric medicine (Figure 2.4). During that time, all other internal medicine specialties saw, on average, a 67.8 percent increase in female fellows (ranging from 54.8 percent to 86.7 percent). Nephrology attracted significantly fewer, with just 45.4 percent more female fellows in 2009 than in 2002.

Even though the total number of geriatric medicine fellows decreased, women made up a greater percentage of geriatric medicine trainees in 2009 than in 2002. Compared with other fields of internal medicine, nephrology is not keeping pace in terms of gender diversity.

The total number of Hispanic nephrology fellows increased from 28 in 2002 to 59 in 2009, and the number of African American nephrology fellows increased from 29 to 45 during the same period. Yet, despite these increases, nephrology still trails most specialties in terms of attracting Hispanics or African Americans.

As the need for internal medicine trainees grows and the number of IMGs continues to taper, nephrology training programs will need more USMGs to compete for training positions. It is imperative to stimulate USMG interest—particularly among women and minorities—in nephrology as soon as possible.

Rachel Shaffer is an ASN policy associate.

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# How the Changing Health Care Environment Will Exacerbate the Nephrology WorkForce Crisis

By Rachel Shaffer and Mark G. Parker, MD

s is the case with many chronic diseases in the United States, chronic kidney disease (CKD) is on the rise. The recent recognition of CKD as a public health problem may be driving patients to nephrologists at earlier stages. At least 26 million Americans have some stage of CKD (Figure 3.1), and minority populations are disproportionately affected. Minorities constitute an increasingly greater portion of the United States population, and incident rates of end stage renal disease (ESRD) among African Americans and Hispanics are nearly four times and 1.5 times greater, respectively, than in whites.

The number of Americans—regardless of ethnicity—with diabetes and hypertension (the leading causes of CKD) is also growing. More than 750,000 people are expected to be alive with ESRD by 2020. These factors will boost the need for kidney care, but they are not the only pressures on the nephrology workforce. The Affordable Care Act (ACA), the aging baby boomer population, and changes to the Medicare ESRD program will each contribute to the need for more nephrologists in the coming decades.

By expanding the number of U.S. citizens with health insurance, the ACA is expected to fuel the demand for physicians, particularly primary care providers. Extending coverage to 32 million formerly uninsured Americans is also likely to increase the number of people with diagnoses of CKD, diabetes, and hypertension. Yet access to health insurance coverage will translate into access to kidney care only if an adequate workforce exists to accommodate the elevated demand.

According to a 2010 report from the Association of American Medical Colleges (AAMC), the United States will face a shortage of 91,500 physicians across all specialties by 2015 (Figure 3.2). The United States in 2002 started to expand its number of medical students, but the total number of residency and fellowship positions funded by the Medicare program has been capped since passage of the Balanced Budget Act of 1997. As the ACA places renewed emphasis on primary care rather than subspecialty care, and as medical students increasingly seek training in fields that are perceived to offer a more favorable work-life balance, nephrology training programs may face greater challenges in recruiting.

Although it is evident that the nation needs more primary care providers, data from the Department of Health and Human Services (HHS) demonstrate that Medicare beneficiaries also depend on the care of subspecialists (Figure 3.3). Encouraging students to enter internal medicine programs is an important step in meeting future health care needs—as will be attracting more of those internal medicine students to specialize in nephrology.

Besides extending insurance coverage, the ACA also encourages more coordinated, patient-centered models of health care delivery. The law specifically establishes Accountable Care

### Figure 3.1

Percent, U.S. adult population with CKD 26.3 million (13%) of US adults CKD stages 1–4 in 2006



Coresh J, et al. JAMA 2007; 298:2038-2047

# Figure 3.2

Projected supply and demand of physicians, 2008–2020



Source: HYPERLINK http://www.aamc.org/download/150612/data/md-shortage.pdf"www.aamc.org/download/150612/data/md-shortage.pdf

# Nursed Back to Health? The Nephrology WorkForce Crisis and Other Providers

## By Daniel Kochis

The workforce crisis hitting the field of nephrology extends beyond physicians to nurses, nurse practitioners, and physician assistants (PAs), who are often on the front lines in the battle against kidney disease. Nurses and nurse practitioners provide essential services to patients with kidney disease, working in hospitals, dialysis centers, and homes. They help bridge the growing gap between the number of patients with kidney disease and the availability of nephrologists.

Despite the essential role of nurses in caring for patients, the future of nursing is less than certain. In 2008, the average age for nurses reached 46, reflective of an aging trend among nurses that has accelerated over the past decade (1). Nursing retirements—especially by nurse managers—coupled with the ever-increasing demand for their expertise could compound the nephrology shortage in the near future. According to the Health Resources and Services Administration, only 64 percent of the demand for nurses will be met by 2020 (2).

On a more positive note, the number of PAs has more than doubled during the past 15 years (3). In 1997, fewer than 40,000 PAs were eligible to practice in the United States. An estimated 87,000 are in practice today, including those with a Certificate of Added Qualifications in nephrology. The National Commission on Certifi-

cation of Physicians Assistants predicts that 6277 PAs will enter practice in 2015, up from 2793 in 1997 (4).

Although the looming shortage of nephrologists remains ominous, the renal community should not lose sight of the parallel workforce shortage of other providers who care for patients with kidney disease. Only through the combined efforts of nephrologists, nurses, and PAs—as well as those who educate these caregivers—will the renal community provide essential care to patients with kidney disease in the future.

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# Figure 3.3 Medicare beneficiaries depend upon specialty care



Physicians required per 100,000 population by patient age

Source: HHS/HRSA The Physician Workforce: Projections and Research into Current Issues

Organizations (ACOs), a model intended to facilitate provider coordination, improve quality, and reduce expenditures. Integral to these coordinated care delivery systems is a sufficient number of participating subspecialists to treat patients who need specific expertise and experience, such as those with kidney disease. The nephrologist—a central provider for patients with advanced CKD, ESRD, or a kidney transplant—assumes a critical position in addressing the primary care needs of these patients, who tend to require frequent contact, and also in playing a role in their care-coordination.

Nephrologists are thus expected to

become key participants in ACOs for CKD and ESRD patients, analogous to the role suggested for specialists who treat patients with other chronic illnesses, such as asthma. Bolstering the nephrology and primary care workforce will be necessary to ensure that patients with kidney disease receive efficient, high-quality care as ACA implementation moves ahead.

"Giving an additional 32 million access to insurance is a very good start, but may be more of an illusion than a promise of health care," observes Atul Grover, MD, PhD, AAMC chief advocacy officer. "Unfortunately, the 10,000 baby boomers who will turn 65 every day for the next 19 years will gobble up much of available physicians' time leaving many Americans without access to a doctor despite whatever the card in their wallet says."

Grover adds, "Data from HHS suggest that the newly insured could quadruple their need for general internists and internal medicine specialties, like nephrology. In a way, we are a nation that is a victim of its own success in making fatal diseases chronic illnesses—there are five times as many patients living with ESRD today as there were 30 years ago."

Moreover, even before the ACA is fully in place, nephrologists will play a leading role in piloting models for national health reform. As mandated by the Medicare Improvements for Patients and Providers Act of 2008, the Medicare ESRD Program will institute bundled payments in 2011 and the first-ever true pay-for-performance system in 2012. Each of these models-bundled payments and payfor-performance-are also called to be tested in other fields of medicine, but nephrology will provide the first indication of their potential to improve outcomes while managing costs.

To ensure accessible, sustainable, and high-quality care in this novel payment environment, the United States needs an adequate supply of nephrologists. Translating this important goal into reality will require a reversal of current trends in medical students' and residents' interest in the specialty.

Rachel Shaffer is an ASN policy associate and Mark G. Parker, MD, is a member of the ASN Training Program Directors Executive Committee.

# What IF the Projections Are Wrong? A Contrarian Position on the WorkForce Crisis

# By Tod Ibrahim

rom boom to bust, the projections for the physician workforce in the United States reverse every 20 years. In the 1960s, experts projected a shortage of 40,000 physicians by 1975. During the 1980s and 1990s, some of the same experts predicted a surplus of up to 165,000 physicians by 2000. A few years ago, the country was expected to face a shortage of 55,000 physicians by 2020 (1). But with last year's passage of the Affordable Care Act (ACA), which extends coverage to the uninsured, the country is now projected to need an additional 91,500 physicians by 2020 (2).

What if this prediction is wrong and the United States actually has an oversupply of physicians—including nephrologists—by the end of the decade? What if the physician workforce projections continue their 20-year boom-tobust cycle?

No one today can predict how medical research, advances in genetic medicine, or innovations in bioengineering will affect the physician workforce during the next decade and beyond. No one today can predict how novel models of care (such as hospital medicine during the past decade) will affect the physician workforce in the future. No one today can predict how the financial realities faced by local, state, and federal government—not to mention the majority of the U.S. population—will change access to health care. No one today can predict the ultimate fate of ACA—the most controversial law in a generation—or how it will shape the delivery of care.

"I worry that the workforce numbers will be impacted by the increasing use of other providers—particularly nurse practitioners and physician assistants (PAs) in kidney care—the decreasing reimbursement for all providers, and the growing trend toward nonpayment of internal medicine care provided by nephrologists to dialysis patients," observes Sharon Adler, MD, FASN, chief of the division of nephrology and hypertension at the Harbor-UCLA Medical Center. "Together, these forces may result in less patient care provided by nephrologists."

The number of nephrology fellows increased by 28.1 percent from 2002 to 2009. To meet projected demand, the number of nephrology fellows would need to increase by at least this rate during the next seven years. Such growth would mean that currently accredited nephrology fellowship programs would need to train more fellows or that more teaching institutions would need to add accredited training programs in nephrology.

Neither of these options seems likely, however, because the number of accredited training programs has decreased (from 149 in 1986 to 141 in 2009) (4, 5), the Accreditation Council for Graduate Medical Education is unexcited about the prospect of even larger fellowship programs (the average number of nephrology fellows per accredited program has increased from 1.6 to 6.4 since 1986), and the Balanced Budget Act of 1997 capped the number of residency and fellowship positions funded by the federal government.

Because of this cap and the long educational continuum (a minimum of seven years), the number of new physicians has remained relatively flat during the past decade. At the same time, the *Continued on page 12* 



# **The Nephrology Workforce Crisis**

# Projections

Continued from page 11

number of other providers—particularly nurses and PAs—has increased more dramatically. Interestingly, nephrology is one of only a few PA specialties. The only others are cardiovascular/thoracic surgery, emergency medicine, orthopedic surgery, and psychiatry.

In a recent report, the Institute of Medicine asserts that "transforming the health care system and the practice environment will require a balance of skills and perspectives among physicians, nurses, and other health care professionals" (6). To help accomplish this goal, the Institute of Medicine recommends that "regulatory and institutional obstacles—including limits on nurses' scope of practice—should be removed so that the health system can reap the full benefit of nurses' training, skills, and knowledge in patient care."

The Medicare End-Stage Renal Disease (ESRD) Program instituted bundled payments this year and will start the first pay-for-performance system in 2012. "Bundled payments could increase financial pressures on some dialysis providers, and instituting patient care protocols is one way that facilities may seek to control costs," explains Thomas H. Hostetter, MD, who chairs the ASN Public Policy Board. "Beginning in 2012, the pay-for-performance program will penalize providers when patients' hemoglobin and urea reduction ratio values vary from a relatively narrow range."

Although Hostetter anticipates a shortage of nephrologists, he is concerned that the changes to the Medicare ESRD Program could create incentives for increasing standardization of dialysis care, potentially diminishing the need for the expertise of an autonomous nephrologist.

"As the bundled payment system and the pay-for-performance program push providers to administer more uniform care, the role of the nephrologist as an independent clinical decision-maker in the dialysis unit is arguably compromised," he says.

The actual impact of these changes on the Medicare program is unclear, but current incentives emphasize reimbursement for dialysis patients rather than prevention of kidney disease, including ESRD. "The amount of funding for medical research, including federal and corporate sources, going toward prevention and progression of kidney disease research is vastly disproportional to the health care dollars spent on kidney disease and its consequences," asserts ASN Councilor Bruce A. Molitoris, MD, FASN. "If this shift in priorities occurred, I can imagine a scenario where we may need fewer nephrologists."

Owing to the number of comorbidities, the care of patients with kidney disease involves other physicians besides nephrologists. For example, cardiologists treat heart disease and hypertension, endocrinologists care for patients with diabetes, surgeons perform organ transplants, and critical care specialists are often interventionalists.

"I worry that other specialists will care for a significant number of patients with kidney disease in the future," says Stuart L. Linas, MD, FASN, who chairs the ASN Hypertension Advisory Group.

"Even if the workforce projections are wrong," concludes Adler, "nephrology should still try to attract the best medical students, because there will always be a need for experts in kidney disease to care for patients, conduct research, and teach the next generation. I think the best opportunities for nephrologists will be in the academic sphere."

Tod Ibrahim is executive director of the American Society of Nephrology.

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# ASN Establishes Workforce Committee to Help Address Crisis

### By Evelyn Shapiro

Responding to concerns about the future of the nephrology workforce, the ASN is currently establishing a Workforce Committee. "A key goal of the ASN Strategic Plan is to advance patient care and research in kidney disease by strengthening the pipeline of clinicians, researchers, and educators," explains ASN President Joseph V. Bonventre, MD, PhD, FASN.

The ASN Workforce Committee will help the society meet this goal by

- 1. Implementing a strategy (based on the Final Report of the ASN Task Force on Increasing Interest in Nephrology Careers) to increase interest in nephrology careers, which includes promoting diversity within the nephrology workforce.
- 2. Making recommendations to the ASN Council for using travel support to ASN educational activities for physicians and researchers training in the field of kidney disease.
- 3. Making recommendations to the ASN Council for using the ASN Grants Program to support outstanding research and fostering career development.
- 4. Identifying, prioritizing, and making recommendations or strategies to the ASN Council for increasing interest

in nephrology careers, particularly among graduates of U.S. medical schools.

Creation of the workforce committee stems from recommendations by the ASN Task Force on Increasing Interest in Nephrology Careers (Table 5.1). The task force issued its final report at the ASN Summit on the Nephrology Workforce, which took place during Renal Week 2010 in Denver. To help implement the 41 recommendations outlined in its final report, the task force urged the ASN to establish a committee. The task force added that one ASN member should be designated "to serve as a czar or czarina for increasing interest in nephrology careers." The chair of the ASN Workforce Committee would assume this important responsibility as well.

In its report, the task force addressed a variety of topics besides the need for a workforce committee. According to the task force, increasing awareness about the crisis is a central concern. The task force suggested publishing articles about the current situation, producing an annual report about the state of the nephrology fellowship, engaging policymakers about this issue, developing a public awareness campaign about kidney disease, and using social media more effectively.

The task force also recommended adapting medical student and resident rotations to highlight specific aspects of nephrology, developing new teaching tools, and supporting faculty development to increase student interest in nephrology. The ASN was encouraged by the task force to create new awards for medical schools and residency programs to recognize initiatives in increasing interest in nephrology; to focus grants and travel support on students and residents; to expand opportunities at Kidney Week for students, residents, fellows, and educators; and to update the ASN website to correspond with the new initiatives.

When finalized later this spring, the ASN Workforce Committee will begin to implement the task force's recommendations. To review the final report from the ASN Task Force on Increasing Interest in Nephrology Careers, please visit www.asn-online.org.

Eveyln Shapiro is an ASN grants and development associate.

### Table 5.1

ASN Task Force on Increasing Interest in Nephrology Careers

Errol D. Crook, MD Rochelle M. Cunningham, MD Alejandro Diez, MD Alyson Freitas Gerald A. Hladik, MD Melanie P. Hoenig, MD Donald E. Kohan, MD, PhD, FASN Phillip Kokemueller Manish R. Maski, MD Bruce A. Molitoris, MD, FASN, Chair Mark G. Parker, MD Anne Pesenson, MD Mitchell H. Rosner, MD, FASN Sharon R. Silbiger, MD Harold M. Szerlip, MD, FASN Karen M. Warburton, MD Jerry Yee, MD, FASN

# Recent Trends in the Fellowship Match Highlight Nephrology's Vulnerable State

### By Daniel Kochis

o facilitate the matching of internal medicine residents with nephrology fellowship training programs, nephrology first participated in the Electronic Residency Application Services (ERAS) in 2006 and the Medical Specialties Matching Program (MSMP) in 2007. MSMP—part of the larger National Residency Matching Program—is a service that pairs residents with available fellowship positions. Currently, 10 internal medicine specialties participate in MSMP (Table 6.1).

In 2011, continuing the downward trend that has plagued the nephrology fellowship match in recent years, the fewest number of residents applied for positions than in any year since the ASN first joined the MSMP (1). In six years, the total number of ERAS applicants to nephrology fellowships declined by 25 percent, from 712 applicants in 2006 to 539 this year (Figure 6.1).

Behind this overall decline is the reality that nephrology fellowship programs received fewer applications in 2011 from graduates of both U.S. medical schools (USMGs) and international medical schools (IMGs) than in 2010. Applications from USMGs are down 38 percent since 2006, and applications from IMGs have declined by 18 percent in the same time period.

These data confirm that even as USMGs continue to constitute a shrinking portion of the total number of applicants to nephrology, the specialty is having a harder time attracting IMGs, who have historically contributed substantially to the nephrology workforce. For nephrology, attracting IMGs is not an idle concern: 54.6 percent of the current nephrology fellows are IMGs (2).

The declining trend for IMG applicants also holds true for pediatric nephrology, which saw a precipitous decline in the number of applicants from 2010 to 2011. Conversely, pediatric nephrology saw its largest number of USMG applicants in 2011, continuing a recent uptick in the number of USMG applicants—a lone bright spot in match data that are otherwise concerning (Figure 6.2).

Although the lessening competitiveness of the match itself is troublesome, the greater concern is the implication for the future nephrology workforce. For nephrology fellowship training program directors (TPDs), the decline in applications raises alarm bells.

"Training programs are having trouble filling positions," explains Mitchell H. Rosner MD, FASN, a member of the ASN TPD Executive Committee. "Annually, nephrology falls further and further behind other specialties and the full impact of this decline will not be felt for a number of years."

Rosner and ASN Past President Sharon Anderson, MD, FASN, represent the ASN on the Alliance for Academic Internal Medicine Fellowship Match Task Force. The task force, which includes representatives from the 10 specialties that participate in MSMP, is trying to reach a consensus to move the fellowship match from

Figure 6.1 Applicants to nephrology fellowship programs



Source: Electronic Residency Application Service. *Fellowship Data: Applicants by Specialty*, January 2011.

Postgraduate Year 2 to Postgraduate Year 3. The change would allow internal medicine residents more time to experience internal medicine specialties—including nephrology—and make an informed decision about their futures.

To learn more about the ASN's efforts to alleviate a potential workforce crisis, or to see complete data on nephrology match applicants, please visit the ASN Public Policy page online at http://asn-online.org/ policy\_and\_public\_affairs/. 🔴

Daniel Kochis is an ASN policy associate.

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- Brotherton SE, Etzel SI. Graduate medical education, 2009–2010. JAMA 2010; 304:1255–1270.

### Table 6.1. Specialties participating in the MSMP

Cardiovascular Disease Infectious Disease 1. 6. 2. Endocrinology 7. Medical Oncology Nephrology 3. Gastroenterology 8. 4. 9. Pulmonology (including Hematology Interventional) Hematology/Medical 5. **10.** Rheumatology Oncology





Source: Electronic Residency Application Service. Fellowship Data: Applicants by Specialty, January 2011.

# **Journal View**

# **Transplant Tourism Linked to Increased Cancer Risk**

Patients who travel to China for kidney transplants are at a higher risk of post-transplant malignancy, reports a study in *Kidney International*.

Long-term complications were reviewed for two groups of Taiwanese patients: 215 transplant tourists who traveled to China and 321 patients who underwent kidney transplantation at a Taiwan university hospital. The transplants were performed from 1987 through 2006. The transplant tourists were older than the domestic transplant patients: 46 versus 40 years.

At 10 years' follow-up, graft survival rates were 55 percent for the transplant tourists and 60 percent for the domestic transplant group. The patient survival rates were 81.5 and 89.3 percent, respectively; the between-group differences were not significant.

However, the 10-year cumulative cancer incidence was 21.5 percent for the transplant tourists compared with 6.8 percent in the domestic group. In stepwise regression analyses that excluded time during immunosuppressive therapy—an uncontrollable factor—the incidence of cancer was significantly higher for the transplant tourists. Patients who were older at the time of transplant were at higher risk of cancer, although the risk of de novo cancer decreased with longer graft survival.

Over the objections of the transplant community, patients continue to travel to foreign countries for kidney transplants. In China, such transplant tourists can receive commercial renal transplants from executed prisoners.

This long-term retrospective study finds a higher rate of posttransplant malignancy in Taiwanese patients who travel to China for kidney transplants, compared with domestic kidney recipients. This risk appears to be greater for older recipients. Other contributing factors may include increased depleting antibody induction therapy and omission of pre-

transplant cancer screening [Tsai M-K, et al. De novo malignancy is associated with renal transplant tourism. *Kidney Int* 2011; 79:908–913].

# **Furosemide for Heart Failure: High versus Low Dose, Bolus versus Infusion**

For patients with decompensated heart failure, the outcomes of loop diuretic therapy are similar at both high and low doses and with both bolus and continuous infusion, according to a report in the *New England Journal of Medicine*.

The multicenter Diuretic Optimization Strategies Evaluation (DOSE) trial included 308 patients with acute decompensated heart failure. In a twoby-two factorial design, patients were randomly assigned to receive intravenous furosemide in bolus doses or by continuous infusion; and in a low dose (equivalent to their previous oral dose) or a high dose (2.5 times the oral dose).

Specified dose adjustments were permitted after 48 hours. Patients assigned to bolus dosing were more likely to require a dose increase than those assigned to continuous infusion: 21 percent versus 11 percent. There was no difference in the need to switch to oral diuretics.

Global symptom ratings were not significantly different between the bolus and infusion groups. There was a trend toward greater symptom improvement in the high-dose group. The mean change in creatinine level was 0.08 mg/ dL with high-dose and 0.04 mg/dL with low-dose furosemide.

Patients in the high-dose group had increased diuresis and improvement in some secondary outcomes. They also had a higher rate of transient decreases in renal function: 23 percent versus 14 percent. Serious adverse event rates were 38 and 50 percent, respectively.

The DOSE trial addresses the need for evidence to guide loop diuretic therapy for acute decompensated heart failure. The results showed similar symptoms and renal function outcomes with intravenous bolus dosing or continuous infusion and at high and low doses. The high-dose strategy may bring some additional improvement, but with more frequent worsening of renal function [Felker GM, et al. Diuretic strategies in patients with acute decompensated heart failure. *N Engl J Med* 2011; 364:797–805].

# Metformin Is More Effective Than Newer Type 2 Diabetes Drugs

The "tried and true" type 2 diabetes medication metformin offers better efficacy and safety than newer, more expensive drugs, according to a study in the *Annals of Internal Medicine*.

A systematic review was performed to identify studies of metformin, second-generation sulfonylureas, thiazolidinediones, meglitinides, dipeptidyl peptidase-4 (DPP-4) inhibitors, and glucagon-like peptide-1 receptor agonists for the treatment of type 2 diabetes in adults. A meta-analysis included data from 140 randomized controlled trials and 26 observational studies. The studies provided no strong data on long-term clinical outcomes: all-cause mortality, cardiovascular disease, nephropathy, or neuropathy.

Most drugs and two-drug combinations achieved a decrease of about 1 percent in hemoglobin  $A_{1c}$  (HbA1c). Metformin achieved greater reductions in HbA1c than DPP inhibitors and greater reductions in body weight (by about -2.5 kg) than sulfonylureas or thiazolidinediones. Metformin also led to greater reductions in low-density lipoprotein cholesterol than pioglitazone, sulfonylureas, or DDP-4 inhibitors.

The risk of hypoglycemia was higher

### with sulfonylureas than with metformin alone, and with metformin plus sulfonylureas than with metformin plus thiazolidinediones. Thiazolidinediones were associated with a higher risk of congestive heart failure than sulfonylureas and with a higher risk of fracture than metformin. Diarrhea was more common with metformin than with thiazolidinediones.

The updated review, funded by the Agency for Healthcare Research and Quality, supports the use of metformin as first-line treatment for type 2 diabetes. Although most drugs achieve similar reductions in HbA<sub>1c</sub>, sulfonylureas and meglitinides are associated with an increased risk of hypoglycemia and thiazolidinediones with increased risks of heart failure, weight gain, and fracture. "[M]etformin, both as monotherapy and in combination with other medications, has the highest benefitrisk profile in most comparisons," the investigators conclude [Bennett WL, et al. Comparative effectiveness and safety of medications for type 2 diabetes: an update including new drugs and 2-drug combinations. Ann Intern Med E-336; published ahead of print March 14, 2011].

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# Olmesartan Delays Microalbuminuria in Patients with Type 2 Diabetes

In patients with type 2 diabetes, the angiotensin-receptor blocker olmesartan delays or prevents the development of microalbuminuria, reports the *New England Journal of Medicine*.

The randomized, placebo-controlled trial included 4477 patients with type 2 diabetes and normoalbuminuria at baseline; all patients had one or more additional cardiovascular risk factors. Patients received additional antihypertensive drugs as needed (but not angiotensin-converting enzyme inhibitors or other angiotensin-receptor blockers) to keep their blood pressure below 130/80 mm Hg. The times to onset of microalbuminuria and renal and cardiovascular events were assessed after a median 3.2 years of treatment.

Patients receiving olmesartan were more likely to reach target blood pressure (approximately 80 percent versus 70 percent) and had lower blood pressure (by about 3/2 mm Hg) than the placebo group. Of 4299 evaluable patients, the microalbuminuria rate was 8.2 percent in the olmesartan group versus 9.8 percent in the placebo group. The time to onset of microalbuminuria was 23 percent longer with olmesartan.

The rate of nonfatal cardiovascular events was nonsignificantly lower in the olmesartan group: 3.6 percent versus 4.1 percent. By contrast, fatal cardiovascular events were more frequent with olmesartan: 0.7 percent versus 0.1 percent. Among patients with coronary heart disease at baseline, cardiovascular mortality was 2.0 percent in the olmesartan group versus 0.2 percent in the placebo group.

Starting olmesartan early in the course of diabetes can delay the onset of microalbuminuria, the new results suggest. This effect is greater than might be expected from the extent of blood pressure reduction achieved; patients with higher systolic blood pressure, better diabetes control, and lower renal function may be most likely to benefit. The authors voice concern about the possible increase in fatal cardiovascular events among olmesartan-treated patients with preexisting coronary heart disease [Haller H, et al. Olmesartan for the delay or prevention of microalbuminuria in type 2 diabetes. N Engl J Med 2011; 364:907-917].

CAUTION

RADIATION RISK

# Sparse Data on Mineral Levels and CKD Outcomes

In patients with chronic kidney disease (CKD), the risk of mortality is consistently linked to serum phosphorus level but not to calcium or parathyroid hormone levels, concludes a meta-analysis in the *Journal of the American Medical Association*.

In a systematic review of the literature, the researchers identified 47 cohort studies on the association of serum phosphorus, parathyroid hormone, and calcium levels with patient outcomes in CKD. The studies included 327,644 patients. A meta-analysis was performed to assess the strength of the evidence linking these mineral levels to cardiovascular disease and mortality. The analysis included adjustment for known confounders to identify those studies producing more valid estimates.

Serum phosphorus level was consistently related to the risk of death resulting from any cause: risk ratio 1.18 for each increase of 1 mg/dL in phosphorus level. However, all-cause mortality was unrelated to serum calcium or parathyroid hormone level. Only one study with adequate adjustment provided data on the association of serum phosphorus, parathyroid hormone, and calcium with risk of cardiovascular death. There were no data on nonfatal cardiovascular events; lack of adjustment for potential confounders was not a major limitation of the studies reviewed.

Current clinical practice guidelines specify serum target levels for phosphorus, parathyroid hormone, and calcium for mineral and bone disorders in patients with CKD. However, the strength of the evidence underlying these recommendations is questionable.

The new review with meta-analysis supports the association of serum phosphorus levels and all-cause mortality in patients with CKD. However, there is only weak evidence linking calcium and parathyroid levels to mortality risk. Available evidence regarding the effect of these three levels on CKD outcomes "is currently insufficient to inform clinical decision making, policy, or practice guidelines," the investigators conclude [Palmer SC, et al. Serum levels of phosphorus, parathyroid hormone, and calcium and risks of death and cardiovascular disease in individuals with chronic kidney disease: a systematic review and meta-analysis. JAMA 2011; 305:1119–1127].

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Literature review by NephrologyNow.com

# Radiation, Cancer, and Kidneys: A Look at Risk

# By Eric P. Cohen and John E. Moulder

The nuclear reactor accident in Japan has caused anxiety and uncertainty regarding radiation exposure and risk to health, both short term and long term. A recent article in the *Journal of the American Society of Nephrology* has drawn attention to the potential health risks of diagnostic radiation exposure (1). Our current assessment of both situations is that they do not pose major radiation threats. Nonetheless, patients and families may have questions for their nephrologist, which we will begin to answer.

Upon entering the fourth week after the Japanese earthquake and tsunami, the International Atomic Energy Agency (IAEA) reported that people living in some areas of Japan had received doses that may have been as high as 0.40 mSv per day, although doses in the range of 0.02–0.07 mSv per day have been more common. This should be compared to the natural background rate of about 0.001 mSv/day.

According to the IAEA, whole body doses to some workers at the Fukushima Daiichi plant have been above 100 mSv but below 250 mSv. The IAEA has also reported that a small number of workers have received partial body doses as high as 3000 mSv. Extraordinary as these doses may look, they are below the doses needed to cause acute injuries. Barring a large increase in exposures, the medical consequences, if there are any, may be an increased risk of cancer.

### **Radiation and cancer risk**

The relation of radiation dose to cancer risk may or may not have a threshold, but for radiation doses of 50 mSv or less, there is no proven long-term increased risk of cancer (2). Thus, a single chest x-ray with a dose of 0.1 mSv is extremely unlikely to cause cancer, whereas a computed tomography (CT) scan of the abdomen can deliver an effective dose of 5–25 mSv (3), and 10 CT scans might put an individual at increased risk for cancer.

In evaluating the risk of diagnostic radiation exposures, it is critical to take into account the fact that radiation-induced cancers have a multidecade latency. For example, of the fatal cancers ascribed to radiation exposure that developed in atomic bomb survivors in Hiroshima and Nagasaki who were over 40 years old at the time of the bombing, 55 percent occurred more than 20 years later (2).

Because the median age of American dialysis patients is 65, and because their expected survival is less than 10 years, even 10 or 20 chest or abdominal CT scans in such patients will be unlikely to cause a detectable increase in cancer rates. However, it is possible that younger transplant-eligible individuals may be at higher than average cancer risk because of multiple diagnostic x-ray exposures.

We believe that the overall risk of radiation-induced cancer in dialysis patients has been overstated (1) because it does not take into account the typical patient's age and life expectancy, and we further note that the increased cancer risk for dialysis patients and for kidney transplant patients was well known before the era of CT scanning.

### Radiation nephropathy risk

Radiation damage to the kidneys requires doses of more than 4000 mSv for single exposures and even higher for protracted exposures (2). Thus, although a 3000-mSv exposure might cause nausea and vomiting, and perhaps some transient lymphopenia, it will not cause renal injury.

The currently known radiation exposures to the general population in Japan are causing more anxiety than they are causing actual radiation injury. Likewise, appropriate diagnostic x-ray exposures appear to yield positive benefits well in excess of their small long-term risk for causing cancer.

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Eric P. Cohen, MD, is affiliated with the Department of Medicine and John E. Moulder, MD, is affiliated with the Department of Radiation Oncology at the Medical College of Wisconsin in Milwaukee.

# **Policy Update**



# CMS Urged to Finalize Proposal to Maintain Current ESA Policy

# By Rachel Shaffer

SN recently sent a letter to the Centers for Medicare and Medicaid Services (CMS) supporting the agency's proposal not to change existing policy regarding erythropoiesis stimulating agents (ESAs) at this time. This would maintain nephrologists' flexibility in prescribing ESAs for patients with kidney disease.

If issued by CMS, a National Coverage Determination (NCD) could specify the exact indications potentially including hemoglobin ranges—for which the agency would provide reimbursement for the drug for people with kidney disease. The CMS proposal currently being considered recommends that CMS not issue an NCD at this time (See April KN for more details).

"Overall I am pleased that CMS has proposed that no NCD is appropriate at this time," said ASN Comparative Effectiveness Research Task Force and ASN Public Policy Board member Wolfgang Winkelmayer, MD, ScD, FASN. "Maintaining reasonable latitude for patients and their physicians to make individualized decisions about these medications, within FDA guidelines, is crucial. However, the vital need for comparative effectiveness research to close the evidence gap regarding the optimal role of ESAs in the treatment of relatively severe anemia remains."

CMS' proposed decision memorandum quoted ASN's previously stated positions that "current ESAs may be dangerous if used for overly aggressive treatment targets compared with practices that are compatible with current treatment guidelines. [ASN] also believes that continued access to ESAs is required to give both dialysis and non-dialysis patients with CKD a better chance at receiving and maintaining the function of a kidney transplant." In addition to ASN, patient advocacy groups emphasized to CMS the important role ESAs play in maintaining quality of life for people with kidney disease.

"I'm heartened to see that CMS incorporated these vitally important points into the proposed decision memorandum, especially since they provide support for the proposal not to issue an NCD," said ASN Public Policy Chair Thomas Hostetter, MD. "This memorandum, and CMS' proposal, speaks to the strength of ASN's advocacy ability."

CMS will announce whether or not it is finalizing the decision memorandum as proposed on June 16, 2011. For more information about ASN's advocacy work on this and other issues, please visit ASN's public policy webpage at http://www. asn-online.org/policy\_and\_public\_ affairs.

# ASN Takes Action on Proposed New Care Delivery Models

# By Rachel Shaffer

n late March, CMS released a proposed rule regarding the Accountable Care Organization (ACO) program. Mandated by H.R. 3590, the Patient Protection and Accountable Care Act of 2010 (PPACA), the ACO program is widely viewed as one of the most important components of current efforts to transform care delivery and reform the payment system. Before CMS finalizes the ACO rule, it is soliciting comments from the medical community on the appropriateness and implications of its proposals for the program, which are described in the ACO Proposed Rule.

Earlier this year, ASN formed an ACO Task Force charged with scrutinizing the proposed rule and providing comments to CMS. Given the potential influence this proposed rule could ultimately have on reimbursement and care delivery in all areas of medicine—including nephrology—the ASN Council and Public Policy Board believed it was imperative that the society provide feedback to CMS about it. This task force will ensure that CMS takes into account the perspective of nephrologists and their patients as it develops the ACO program (Table 1).

"Given the growing number of people with chronic kidney disease, and the complexity and costliness of kidney and particularly dialysis—care, greater care coordination in the context of an ACO could potentially lead to better outcomes, improve the transition of care for patients with late-stage CKD to dialysis, and generate savings," said Thomas Hostetter, MD, chair of the ASN Public Policy Board. "It's hugely important that ASN and its ACO Task Force work with CMS to make sure the unique needs of patients with kidney disease are front-and-center in CMS' mind as the agency develops the ACO Program."

Congress mandated that the ACO program begin no later than January 1, 2012. However, CMS and the Secretary of Health and Human Services have significant discretion in translating the legislation into regulation—determining the specifics of who can participate in ACOs, what an ACO model can look like, and the quality standards ACOs will have to meet. The release of the proposed rule is the first step in that process.

The law does specify, among other things, that an ACO will care for a clearly defined population of Medicare beneficiaries, who will be assigned to it based on the beneficiaries' patterns of primary care use. If an ACO meets certain quality standards (which CMS suggests in the proposed rule) and reduces the cost of that care to a level below what would otherwise have been expected, it will get to keep some of the savings it achieves.

The ASN ACO Task Force and the Public Policy Board will provide more information about the contents of the proposed rule as well as ASN's comments to CMS in the coming weeks. CMS is accepting public comments until Monday, June 6, 2011. You can access a copy of the proposed rule on ASN's patient care policy webpage http://www.asn-online.org/g/?o=patientcare.

## Table 1

## ASN Accountable Care Organization (ACO) Task Force Roster

- Lee Hamm, MD (chair) Tulane University School of Medicine
- Jeffrey Berns, MD University of Pennsylvania
- Thomas DuBose, MD, FASN Wake Forest Baptist University Medical Center
- Andrew Fenves, MD, FASN Dallas Nephrology Associates, Baylor University Medical Center
- Uptal Patel, MD Duke University
- Emily Robinson, MD Brigham and Women's Hospital
- Dan Weiner, MD Tufts Medical Center
- Amy Williams, MD Mayo Clinic
- Jonathan Himmelfarb, MD, FASN (ad hoc) University of Washington School of Medicine
- Tom Hostetter, MD, FASN (ad hoc) Albert Einstein College of Medicine
- Daniel Kochis ASN staff
- Rachel Shaffer ASN staff
- Paul Smedberg ASN staff

# CMS Changes Payment Adjuster To Reflect Reality on the Ground

The Centers for Medicare and Medicaid Services (CMS) has proposed rescinding a payment adjuster that would have reduced payments by 3.1 percent to all End Stage Renal Disease (ESRD) facilities beginning on April 1, 2011. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) mandated that CMS implement a bundled payment system for the Medicare ESRD program, a step that CMS took in January 2011.

Dialysis facilities were given two options for being paid during the transition. The first option was to opt into the new bundled payment system effective immediately. The second was to be paid under a blended payment rate during a four-year "transition period." The blended payment rate reimburses facilities based on a formula determined by CMS. For example, in the first year of the transition period, the blended payment would be based mostly on the old payment system (75 percent) and only partially on the new bundled payment system (25 percent).

In MIPAA, Congress mandated that any transition to a bundled payment system be "budget neutral," meaning that all payments made to dialysis facilities not be greater than the total amount of payments that would have been made under the old reimbursement system. In an interim final rule published in the Federal Register on April 6, 2011, CMS cites a higher than expected number of dialysis facilities opting into the bundled payment system as the reason for eliminating the payment adjuster.

In determining the payment adjuster, CMS estimated that only 43 percent of ESRD facilities would fully opt in to the new payment system with the remaining facilities receiving the blended payment rate. This would have resulted in greater payments being made to ESRD facilities than would otherwise have been made under the old payment system. As a result, to achieve the mandated budget neutrality, CMS proposed reducing payments across the board 3.1 percent to all ESRD facilities for services rendered from April 1, 2011, through December 31, 2011.

The interim final rule proposes to change the payment adjuster from 3.1 percent to 0 percent. In reality, 87 percent of dialysis facilities opted to be paid under the new bundled system rather than be reimbursed under the blended payment rate. CMS ultimately determined that the payment adjuster is unnecessary for budget neutrality and recognized that for some facilities, keeping the 3.1 percent adjuster in place could potentially result in compromised services for patients, while making it more difficult for facilities to recruit and train staff.

ASN continues to monitor implementation of the ESRD bundled payment system and its impact on patients with kidney disease and their caregivers. To learn more about ESRD bundled payment, please visit the ASN Public Policy webpage. (http://www.asn-online.org/policy\_and\_public\_affairs/).

# **Congress Passes FY 2011 Funding Bill**

# By Daniel Kochis

compromise budget bill passed by Congress on April 14 and signed by President Obama cuts federal spending by \$38 billion for the remainder of fiscal year (FY) 2011, including a 1 percent cut to the National Institutes of Health (NIH). The compromise bill, the result of a last minute deal between the House of Representatives and Senate, avoids the first government shutdown since 1995 and funds the federal government through September 30, 2011. By avoiding a government shutdown, the research community avoided disruption of vital ongoing research projects funded through the NIH, but must now grapple with reduced funding pools for new and existing ventures.

In the compromise FY 2011 budget bill, NIH sustained a 0.8 percent reduction in funding, from \$31 billion in FY 2010 to \$30.7 billion in FY 2011, a loss of \$260 million. Although this reduction is less than had been proposed in earlier budget discussions, any reduction in funding for NIH could have long-term effects on research and researchers. In the past few years, it has become more difficult to obtain grant funding through NIH with the consequence that many young researchers are becoming increasingly frustrated



with the field of medical research.

"We are at a decisive moment for medical research," said John Sedor, MD, chair of the ASN Research Advocacy Committee (RAC). "We need to look at the impact cuts will have on our ability to discover the next treatment or cure, our ability to secure the next generation of researchers, and ultimately the ability of a dynamic sector of our national economy to remain vibrant and competitive."

ASN continues to advocate on behalf of robust, sustained funding for NIH and other federal research agencies such as the Department of Veterans Affairs (VA) and the Agency for Healthcare Research and Quality (AHRQ).

Policy Update continued on page 18

# ASN Kidney Week Travel Support

ASN travel support opportunities are available to attend the:

- Advances in Research Conference: microRNA
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ASN AGAINST KIDNEY DISEASE

# **Policy Update**

# ASN Recommends Endorsement of New NQF Measures, With Caveats

Responding to a request for comment from the National Quality Forum (NQF), ASN recently submitted recommendations for endorsement of 11 newly proposed measures for end stage renal disease (ESRD) care.

In its "Draft National Voluntary Consensus Standards" report, NQF recommended 11 measures for endorsement as voluntary consensus standards suitable for public reporting and quality improvement (Table 1). ASN was represented on the NQF Steering Committee that developed the proposed measures by Jeffrey Berns, MD, FASN, of the University of Pennsylvania School of Medicine. Berns was joined on the steering committee by 19 other ESRD community stakeholders, including nephrologists, patient representatives, and National Institute of Diabetes, Digestive, and Kidney Disease staff.

Based on the currently available data, ASN generally supported NQF's 11 recommendations. However, ASN called attention to deficits on several measures and urged NQF to address these concerns as it finalizes the report. In particular, ASN noted that at this time, scant high-quality evidence exists to support the majority of the measures. As such, developing these new performance measures based on intermediate outcomes and retrospective observational studies will not necessarily improve care for patients with ESRD. Indeed, such measures could potentially lead to unintended adverse consequences or increased costs of care without improving meaningful, patient-centered outcomes. In the future, these measures should be replaced by new measures as scientifically validated performance targets are developed, ASN said.

ASN also noted that national voluntary consensus quality measures endorsed by NQF could potentially be used by the Centers for Medicare and Medicaid Services (CMS) as measures in the ESRD Quality Incentive Program (QIP). Although ASN generally supported the measures, the society conveyed reservations about their suitability for a financially incentivized measure owing to the insufficiency of scientifically validated evidence. ASN emphasized that any new measures CMS considers for the QIP must be subjected to rulemaking with a public comment period—even if the measures are endorsed by the NQF.

The National Quality Forum is a nonprofit organization whose mission is to improve the quality of American health care by endorsing national consensus standards that organizations can use for measuring the quality of their care and publicly reporting. While the NQF does not have any authority to make providers report or track the measures it endorses, CMS and other health care organizations often use NQF-endorsed measures when developing goals or programs for performance improvement.

ASN will continue to interact with NQF and monitor progress as the organization moves toward finalizing new consensus measures. To read ASN's comments to NQF, visit ASN's policy webpage at http://www.asn-online.org/policy\_ and\_public\_affairs/patient-care.aspx.

### Table 1

Measures recommended by NQF for endorsement as voluntary consensus standards suitable for public reporting and quality improvement for ESRD

Measure Category	Proposed Measure Number and Title	Description
Dialysis Adequacy	<b>1418:</b> Frequency of adequacy measurement for pediatric hemodialysis (HD) patients	Percentage of all pediatric (less than 18 years) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.
	<b>1421:</b> Method of adequacy measurement for pediatric hemodialysis patients	Percentage of pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.
	<b>1423:</b> Minimum spKt/V for pediatric hemodialysis patients	Percentage of all pediatric (less than 18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a pKt/V greater than or equal to 1.2.
Nutrition	<b>1425:</b> Measurement of nPCR for pediatric hemodialysis patients (time limited)	Percentage of pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis)
Anemia	<b>1424:</b> Monthly hemoglobin measurement for pediatric patients	Percentage of all pediatric (less than 18 years) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin.
	<b>1430:</b> Lower limit of hemoglobin for pediatric patients	Percentage of pediatric (less than 18 years old) hemodialysis and peritoneal dialysis patients with ESRD greater than or equal to 3 months, who have a mean hemoglobin less than 10 g/dL for a 3-month reporting period, irrespective of ESA use. The hemoglobin value reported at the end of each reporting month (end-of-month hemoglobin) is used for the calculation.
	<b>1433:</b> Use of iron therapy for pediatric patients (time-limited)	Percentage of all pediatric (less than 18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin less than 11.0 g/dL and in whom serum ferritin concentration was less than 100 ng/mL and TSAT less than 20% who received IV iron or were prescribed oral iron within the following 3 months.
Fluid management	<b>1438:</b> Periodic assessment of postdialysis weight by nephrologists (time limited)	The proportion of patients who have documentation of receiving a new postdialysis eight prescription from a nephrologist in the reporting month, irrespective of whether or not a change in postdialysis weight prescription was made.
Mineral metabolism	<b>1454:</b> Proportion of patients with hypercalcemia	Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 $\mbox{mg/dL}$
Hospitalization	<b>1463:</b> Standardized hospitalization ratio for admissions	Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.
Infection	<b>1460:</b> National Healthcare Safety Network (NHSN) bloodstream infection measure	Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.

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# Industry Spotlight

# Multimechanism Kidney Drug in Trials

Concert Pharmaceuticals, Inc., of Lexington, Massachusetts, has placed its CTP-499 drug candidate for diabetic nephropathy and other chronic kidney diseases into a phase I trial. The drug combines several properties—antiinflammatory, antioxidant, and antifibrotic properties—in what the company calls its deuterated chemical entity (DCE) platform.

President and chief executive officer Roger Tung said, "CTP-499 has the potential to be a critically needed new medical entity. Deuterium chemistry enables compounds with new mechanisms of action that can be used in many different settings." Tung said there is preclinical evidence that CTP-499 may protect kidney function and slow disease progression.

The trial of healthy volunteers will test a single ascending dose of CTP-499 for safety and tolerability. Later in 2011, the company expects to start a phase IIa efficacy trial using the drug and placebo in combination with a standarduse drug like an angiotensin inhibitor, which helps lower blood pressure to protect kidney function.

Deuterium is a naturally occurring element from sea water that is present at a level amounting to about a gram of weight in an average adult. Its size and shape are very close to those of hydrogen, so that selectively replacing hydrogen molecules with deuterium can result in new medicines that retain biochemical potency, according to the company.

Since its founding in 2006, the company has raised more than \$110 million in venture and institutional capital. In 2009, the company placed another DCE platform drug into a phase I trial with GlaxoSmithKline. The company has since started working with the Walter Reed Army Institute of Research to conduct preclinical testing on a novel compound derived from the DCE platform for seizure protection after traumatic brain injury.

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