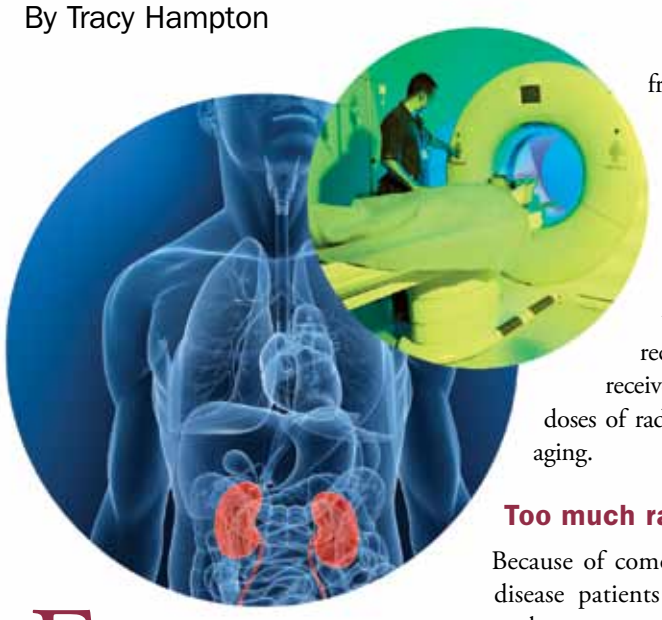
ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

KidneyNews

March 2011 | Vol. 3, Number 3

Imaging Procedures Increase Dialysis Patients' Cancer Risk

By Tracy Hampton



Efforts are needed to limit radiation exposure. New research indicates that hemodialysis patients are exposed to unnecessarily high radiation doses that put them at increased risk for the development of cancer (De Mauri A, et al. Estimated radiation exposure from medical imaging in hemodialysis patients. (*J Am Soc Nephrol*, March 2011). The results add to a growing body of literature suggesting that many patients with chronic and recurrent medical problems receive potentially dangerous doses of radiation from medical imaging.

Too much radiation

Because of comorbidities, many kidney disease patients receiving hemodialysis undergo repeated imaging procedures for both diagnostic and therapeutic purposes that result in repeated exposure to ionizing radiation. This increases their risk for the development of cancer, which is particularly troublesome because maintenance hemodialysis itself is associated with an increased incidence of cancer whose causes are unclear. Therefore, the excess risk of cancer associated with radiation exposure must be taken into careful consideration, particularly in younger patients and in those eligible for kidney transplantation.

To help quantify the extent of that excess risk, Marco Brambilla, PhD, Andreana De Mauri, MD, and their colleagues studied information from a group of 106 hemodialysis patients who were followed up for an average of three years. The investigators retrospectively calculated individual radiation exposures by collecting the number and type of radiologic procedures from hospital records. The goals were to quantify the cumulative effective dose of ionizing radiation in hemodialysis patients, to identify the subgroups that are at increased risk, and to consider the potential health consequences of this radiation exposure.

The investigators found that the mean

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Not Enough Data on Whether ESAs Improve Transplant Graft Survival, CMS Panel Says

By Rachel Shaffer and Daniel Kochis

Not enough evidence exists to say whether using erythropoiesis-stimulating agents (ESAs) for anemia management improves transplant graft survival, according to findings from a Centers for Medicare and Medicaid Services (CMS) Medicare Evidence Development and Coverage Advisory Committee (MedCAC) .

At a January meeting CMS asked MedCAC panelists to rate not only the evidence regarding the effect of ESAs on transplant survival but also the evidence regarding pretransplant donor-specific transfusions on graft survival. The meeting was titled "The Impact of ESA Use on Renal Transplant Graft Survival."

"This is just a reminder how many data there aren't," said MedCAC Panel Chair Clifford Goodman, PhD.

The ASN was one of a handful of professional societies and patient organizations selected to present testimony at the meeting. Public Policy Board member William E. Harmon, MD, a noted transplant nephrologist, spoke on the society's behalf.

In his comments, Harmon focused

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Inside

“OUR PATIENTS’ KIDNEYS ARE FAILING THEM. WE WON’T.”

— **Heather Dean and Janice MacKay**
Kidney Marchers, 2010 and 2011

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Cancer Risk

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and median annual cumulative effective doses in the patients in this study were 21.9 and 11.7 mSv per patient-year, respectively. On average, patients received the equivalent of approximately 1000 chest radiographs/year. When stratified by radiation dose, 22 patients were classified as low (<3 mSv/year), 51 as moderate (3 to <20 mSv/year), 22 as high (20 to <50 mSv/year), and 11 as very high (≥50 mSv/year). The annual cumulative effective dose was higher in younger patients and those on transplant waiting lists. This is of particular concern, given the anticipated life expectancy of these individuals and the ongoing use of immunosuppressive agents in waitlisted patients.

The mean and median total cumulative effective doses per patient during the study period were 57.7 and 27.3 mSv, respectively. Seventeen hemodialysis patients had a total cumulative effective dose >100 mSv, which is associated with a substantial increase in risk for cancer-related mortality. Computed tomography (CT) scans accounted for 76% of the total radiation dose but only 19% of the total number of radiologic procedures.

Reducing risk

This research reveals that a significant number of surviving hemodialysis patients during a three-year period receive estimated radiation doses that may put them at an increased risk for cancer. "Although the retrospective nature of this study does not allow us to draw conclusive inferences about the percentage of CT studies that could have been avoided, the significant number of examinations that resulted in non-notable findings or in negative results—about 60%—points toward the need of a more stringent process of justification of CT referral," said Brambilla.

Others in the field agreed. "We should all—radiologists, nephrologists, and other clinicians—be highly scrutinous of choosing CT or other forms of ionizing radiation in our highest-risk populations. In particular, we should be attentive to our younger hemodialysis patients, since they appear to be most at risk," said Howard Forman, MD, professor of diagnostic radiology and public health at the Yale School of Medicine in New Haven.

David Brenner, PhD, director of the center for radiological research at Columbia University Medical Center in New York City, said that the article underlines the fact that CT scans should be used only when there is a validated clinical need. But he noted that radiation exposure may be less significant for hemodialysis patients than for many other groups. "This is because the median survival time of dialysis patients is less than the median lag time between radiation exposure and radiation-induced cancer occurrence, which is more than 10 years. So the concern about imaging-related radiation exposure should be pretty low for these folks," he said.

Steps can be taken to reduce patients' cancer risk without compromising their medical care, said E. Stephen Amis, Jr., MD, professor and university chair of the department of radiology at The Albert Einstein College of Medicine and Montefiore Medical Center in the Bronx. He noted that many medical conditions, including kidney failure, can be effectively imaged with modalities that do not use ionizing radiation, such as magnetic resonance imaging or ultrasound.

Amis added that physicians who refer patients for imaging, as well as radiologists, need to be aware that total radiation exposure in patients who present again and again with chronic and recurrent conditions can rapidly exceed acceptable levels.

"Radiologists need to act as consultants and not just technicians who perform the exams ordered without question, and referring physicians need to seek and value the consultations provided by radiologists." He noted that both groups can benefit from the use of guidelines such as the American College of Radiology Appropriateness Criteria, which give a numeric ranking for various imaging examinations that could be used to evaluate a given clinical condition. Amis also recommended that institutions make historical imaging information immediately available to referring physicians when an order for imaging is placed. "Especially effective in the increasingly common electronic physician order entry systems, seeing the imaging history of the patient at that institution when an order is placed for CT will often give pause and result in a different imaging tack," he said.

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Kidney News

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ASN Kidney News is published by the American Society of Nephrology
1725 I Street NW, Suite 510, Washington, DC 20006. Phone: 202-659-0599

www.asn-online.org

Postmaster: Please send address changes to *ASN Kidney News*, c/o Customer Service, American Society of Nephrology 1725 I Street NW, Suite 510, Washington DC 20006.

Publications mail agreement No. 40624074. Return undeliverable Canadian addresses to PO Box 503, RPO West Beaver Creek, Richmond Hill ON L4B 4R6

ASN Kidney News (ISSN print 1943-8044 and online 1943-8052) is an official publication of the American Society of Nephrology, 1725 I Street NW, Suite 510, Washington DC 20006, and is published monthly. Application to mail as Periodicals Postage Pending at Washington, DC, and at additional mailing offices. Subscription rates: $12 per year. To order, please email bhenkel@asn-online.org. Subscription prices subject to change. Annual ASN membership dues include $12 for *ASN Kidney News* subscription.

Transplant Graft Survival

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National Coverage Analysis and National Coverage Decision 101

The purpose of a National Coverage Analysis (NCA) is to gather input and information from CMS staff, independent experts, and the public about a certain item or service for which Medicare provides reimbursement.

MedCAC panels are one component of the NCA evidence-gathering and analysis effort. NCAs themselves do not necessarily bring about changes to existing policy, but information collected during the course of an NCA can help bring about a National Coverage Decision (NCD), depending on the findings. An NCD is the official ruling that grants, limits, or excludes coverage.

Currently, no NCD exists for ESAs. However, anyone can request that the CMS initiate the NCD process, which typically involves an NCA. The CMS received a formal request for a national coverage determination for recombinant human erythropoietin for the treatment of CKD and dialysis-related anemia in March 2010.

on the well demonstrated utility of ESAs for the treatment of anemia, emphasizing their ability to prevent blood transfusions that would likely otherwise be necessary—transfusions that place patients at risk for sensitization because of exposure to foreign human antigens. Sensitization is associated with a longer time on the wait list, faster and higher rates of rejection, delayed graft function, and longer term complications. Patients who are highly sensitized often never receive an organ because no compatible graft becomes available.

Owing to the development of modern immunosuppressive therapies and tests that identify specific antigens to which a transplant recipient is sensitized, donor-specific transfusion protocols have not been used for more than 20 years. Consequently, Harmon stated, "the balance of data suggests that it is most appropriate to avoid sensitization prior to or subsequent to kidney transplantation."

Besides hearing testimony from public speakers, including Harmon, and from CMS staff, MedCAC relied heavily on a Technical Assessment prepared by a contracted team. The CMS asked the Technical Assessment team to study and present a review of the available evidence on the effect of donor-specific transfusions on renal graft outcomes, but notably did not ask the team to address the effect of ESAs on the same outcomes.

The CMS convened the MedCAC meeting as part of an ongoing National Coverage Analysis (NCA) examining evidence regarding the effects of ESAs on health outcomes for patients with chronic kidney disease, both those receiving and those not receiving dialysis (see timeline). The CMS is expected to issue a final memo on the NCA this month, which could lead to a change in existing ESA coverage policy—a so-called National Coverage Determination (NCD) (see sidebar).

MedCAC is an independent advisory committee created to help CMS weigh clinical questions related to the safety and efficacy of medications and treatments. While not binding, MedCAC's recommendations often factor heavily into the CMS's decision-making regarding NCDs.

Fourteen panelists participated in the MedCAC meeting, including an industry representative and a liaison from CMS. CMS selected 12 of these panelists from a MedCAC pool of approximately 90 individuals with expertise in a diversity of medical specialties, and invited two participants with expertise in nephrology. Consequently, the majority of panelists were not nephrologists.

Given the complexity of the questions the CMS asked the panel to consider, the MedCAC panel could have benefited from additional nephrology expertise, Harmon said. "While the panel did have the representation of one nephrologist, additional representation might have helped to frame the scope of evidence available on ESAs, putting the immediate questions regarding ESAs and graft survival in the proper context," Harmon said.

After the January meeting, CMS requested public comment on the testimony heard at the MedCAC meeting as well as on the Technical Assessment.

The ASN responded to this request and followed up Harmon's testimony

with a written letter to CMS reiterating that ESAs are a cornerstone of chronic kidney disease care—specifically for anemia management—and have been proved effective for that purpose. Because ESAs are not indicated for the purpose of improving renal transplant graft survival, the ASN urged CMS not to issue an NCD or make any other changes to existing policies based on considerations of the evidence of the effect of ESAs on renal transplant graft survival.

The ASN continues to provide evidence-based information about ESAs and kidney patients and to advocate for policies that promote the highest quality of care as the CMS progresses in its deliberations regarding the NCA on ESAs.

To read Harmon's testimony or ASN's commentary on the Technical Assessment, or to learn more about advocacy efforts related to patient care, please visit ASN Policy online at www.asn-online.org/policy_and_public_affairs.

Timeline for CMS review of ESAs in kidney care

March 2010 MedCAC reviews available evidence on the use of ESAs to manage anemia in CKD patients.

June 2010 Medicare NCA process to review evidence regarding the effects of ESAs on health outcomes in adult patients with chronic kidney disease, both before and during dialysis.

January 2011 MedCAC reviews available evidence of the impact of both donor-specific transfusions and ESAs on renal transplant graft survival.

January 2011 CMS solicits its public comment on the Technology Assessment and presentations at the January 2011 MedCAC meeting.

March 2011 CMS proposes to release a Decision Memo on the NCA on ESAs.

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Topics in Transplantation

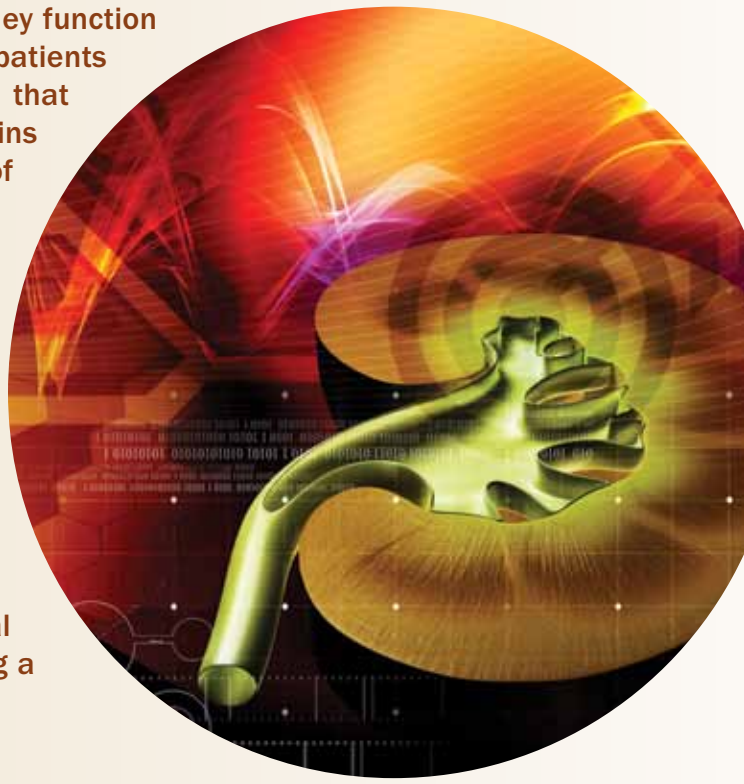
Outcomes of kidney transplants and the rate of deterioration in posttransplant kidney function in the United States have improved in recent years. This news provides optimism to patients awaiting transplants, their caregivers, and their families, as well as the assurance that they are waiting for a transplant that has a durable lifespan and function. These gains are particularly tied to advances in patient selection and medical management of the many complexities posed by renal transplantation.

Extended criteria donor kidneys (ECDs) may afford timely transplantation to patients with a high expected waitlist mortality, who could benefit from shorter wait times. But the ECD listing practices prevailing in the United States have thus far fallen short of promises. Jesse Schold outlines a general guideline for rational use of ECD organs that would benefit those most in need of short waiting times.

The ranks of patients waiting for a kidney transplant are being swelled by recipients of prior liver, heart, and lung transplant recipients with renal failure. The rate of growth of this population is much greater than the growth of the kidney-alone waitlist. The challenges posed by this emerging population, especially in the ethical domain, are addressed by David Goldfarb.

Adolescent transplant recipients transitioning to adulthood pose several medical and psychosocial challenges. Charles Kwon and Julie Corder look at this issue using a patient vignette as a backdrop.

—Titte Srinivas, MD, Kidney News *editorial board member*



Deceased Donor Kidney Allocation: *What Is the Next Step?*

By J. D. Schold

Policies governing the allocation of deceased donor organs must incorporate numerous factors, which are often very difficult to satisfy in a simultaneous manner. These policies can have a significant impact on patients' lives, but we must carefully consider objective factors such as logistical operations and efficient resource allocation along with more subjective constructs such as equity and justice.

Perhaps an even more difficult challenge is to prospectively consider possible unanticipated changes in behavior by patients and caregivers that may arise from these policies. For certain, any changes in policy should be considered deliberately and conscientiously, with the best information available and with input from many experts in the field. However, it is also clear that failure to evolve allocation policy comes at a cost. Known inequities and inefficiencies in current policies have led to suboptimal use of available scarce donor organs and to disparities in access to transplantation (1–3).

One of the perceived challenges in revising allocation policy is related to the concept of a net-zero model. From this perspective, any alteration in policy that may benefit one aspect of policy or one subgroup of the transplant candidate population will inherently come at the expense of other aspects or patient populations. In a recent article, Schold and Hall challenged this notion and described potential opportunities for enhancing kidney donor policy without deleteriously affecting equity (4). As described in this viewpoint, the authors suggested that enhanced allocation policy could be achieved through two fundamental changes.

One suggested amendment is to improve oversight and guidance of the current Expanded Criteria Donor (ECD) policy. The initial aims of this policy were to objectively define higher-risk kidneys as falling within the ECD policy and to help direct patients to consider acceptance of ECD kidneys as a tradeoff for extended waiting times for a donor organ with fewer risk factors (5). Improved implementation and oversight of this policy may lead to better matching of candidates with donor organs based on the presence of risk factors, and to transplantation at a more optimal time after patients have been placed on the waiting list. In general, failure to allocate the right donor kidney to the right patient at the right time is a significant source of inefficiencies in current allocation, leading to increased mortality on the waiting list and the need to seek additional donations after the failure of primary transplants for some patients.

Another potential enhancement to allocation may derive from more uniform implementation of the ECD policy across transplant centers. There is currently wide variability in the listing patterns for ECDs among transplant centers in the United States (6). In particular, some centers have almost their entire candidate population listed to receive ECD kidneys, whereas other centers have only a small percentage of their patients listed to receive them. This variable implementation of policy by centers leads not only to differential ramifications for listing for an ECD from one center to the next but also to suboptimal allocation of donor kidneys to patients on the basis of their risks for mortality on the waiting list or posttransplant graft loss (7).

Ideally, the challenges of donor allocation would be ameliorated by improved donation programs and a reduction in risk factors leading to end stage renal disease. In reality, the chasm between available donor kidneys and the need for transplants will continue to grow, emphasizing the need to expeditiously implement allocation policies that best serve the population. More rapid evolution of the current ECD policy may be a much more palatable and expedient process than delayed formulation of new polices that must satisfy numerous stakeholders. For the sake of current and future patients requiring kidney transplantation, the time to evolve policy is now, and the transplant community should rapidly and strategically decide on the next step.

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J. D. Schold is affiliated with the Department of Quantitative Health Sciences, Cleveland Clinic, Cleveland, Ohio.

Ethical Issues in Renal Transplantation after Prior Solid Organ Transplantation

By David Goldfarb

A wide array of ethical issues comes into play regarding renal transplantation after prior solid organ transplantation. They include concerns about prevention and access. One must first understand the scope of the problem. The prevalence of chronic kidney disease (CKD) among prior non–renal organ transplant (NRTx) recipients is between 80 percent and 100 percent for those who survive three years. The more advanced stages of CKD, types IV and V, occur in 5–20 percent of patients by five years after NRTx, and they vary according to the type of transplant. CKD is lowest in heart–lung recipients and highest in intestine and liver recipients.

A recent study demonstrated that between 1995 and 2008, the NRTx representation on the national wait list increased from less than 1 percent to 3.3 percent. By way of comparison, the representation for immunoglobulin A nephropathy is 2.8 percent and for systemic lupus erythematosus is 2.9 percent. Kidney listings for patients with prior liver or lung transplantation went up by 303 percent and 635 percent, respectively, whereas listings for repeat kidney patients and those with no prior transplant went up by only 70 percent and 74 percent, respectively. Listings for NRTx significantly outpaced those for other diagnoses on the wait list.

Success with extrarenal transplantation over the past two decades has created a new etiology for CKD that has increased the burden on health care resources and amplified the disparity between transplantable organs and persons in need. The NRTx population now represents one of the most rapidly growing populations gaining access to kidney wait lists.

A variety of risk factors have been identified in NRTx that are associated with the development of CKD, most notably the use of calcineurin inhibitor drugs. If one disease begets another, it could be argued that the care of such patients requires specific attention to preservation of renal function to improve patient outcomes and control the high use of resources associated with renal replacement therapy. Is this currently being performed uniformly? One potential action item along these lines could be the development of guidelines for care that would identify certain triggers for active management of nephrology in these patients. Early intensive management of risk factors could play a role in reducing the need for renal replacement.

The second concern is that of access, which is inexorably linked to the issue of prevention. Because of the higher risk of CKD, the NRTx population should be more frequently receiving nephrologic care. This may be the case, inasmuch as NRTx recipients typically receive heightened surveillance as part of the routine care of the nonrenal organ. Do these patients have preferred access to transplantation compared with other groups as a result of their closer follow-up care?

No data are available regarding the frequency of nephrologic input in NRTx. But the manner in which these patients are listed was recently reviewed. The likelihood that NRTx patients will receive a preemptive transplant compared with candidates who had a prior kidney transplant or no prior transplant was assessed. Preemptive listing occurred for 38 percent of NRTx patients, 23 percent of prior kidney transplant patients, and 21 percent for those with no prior transplant. This greater access to early listing for NRTX candidates is striking. The reasons remain speculative but likely reflect the greater intensity of follow-up care that transplant recipients receive compared with the general CKD population. Is this preferential access unfair just because it is a highly monitored population? NRTx recipients have a higher wait list mortality than do candidates with no prior organ transplant, so early preemptive listing represents a good choice for these patients. Given this higher wait list mortality, do NRTx patients receive more Expanded Criteria Donor (ECD) kidneys? This was the rationale for the development of the ECD program: to offer patients with a higher wait list mortality a chance to get a kidney more quickly. Data suggest that NRTx patients were listed for ECD at a rate no different from those of other populations, which suggests underutilization of ECD kidneys.

This issue of higher mortality of NRTx patients on the wait list creates some independent concern regarding candidacy for a renal transplant. The fact is simple: these patients die earlier than do kidney-only candidates. Any decision to offer transplantation to NRTx patients must take into account the expected survival of the patient with the new kidney. Some factors to consider include how long the nonrenal organ has been in place, its current function, tolerance of the patient to cycling of immunosuppression, and other comorbidities. In the end, the fixed, unmodifiable comorbid conditions weigh heavily in how well NRTx will do.

Additional concerns may arise from transplant centers. In an environment under regulatory scrutiny, excessive one- or three-year graft or patient mortality may generate quality concerns at individual programs. No data are available regarding the one- and three-year outcomes in the NRTx population. We know that these patients have increased wait list mortality. The diagnosis of NRTx is not currently risk adjusted in national outcome reporting. If the outcomes are poorer and a given center has an enriched population of such patients, it could adversely affect the quality profile.

A final challenge derives from determining when it is best to transplant kidneys simultaneously with an extrarenal solid organ. This is more common in liver transplantation since the advent of the Mayo End-Stage Liver Disease score, but it may also occur in cardiac and intestinal transplantation. If a patient with established end stage renal disease is already receiving dialysis for a cause unrelated to the failure of the nonrenal organ, there is little argument against simultaneous transplantation of the nonrenal organ plus a kidney. When the failure of the kidney is precipitated by failure of the nonrenal organ, as occurs in hepatorenal syndrome, the decision may be quite complex. The use of simultaneous transplants is driven by the need to reduce early mortality from the receipt of a nonrenal organ alone in the setting of dialysis dependence or severe CKD. The renal qualifications for such decisions may be different than for kidney-only transplantation, especially when transplantation of the nonrenal organ alone may result in spontaneous posttransplant improvement in renal function, abrogating the need for a new kidney.

Suggested reading

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David Goldfarb is director of the Section of Renal Transplantation at the Glickman Urological Institute in Cleveland, Ohio.

Transitioning the Adolescent: *Are We Facilitators or Enablers?*

By Charles Kwon and Julie Corder

The call had come. A donor was identified for 18-year-old Tim. His path to transplantation was not the smoothest, but in many ways, it was perhaps quite typical. He had received a diagnosis of Alport syndrome at a young age. Throughout his adolescence, his engagement was poor. He had received immunosuppressive therapy for a few years, with fluctuant drug levels. He often sat through appointments without his hearing aids and would provide very little independent information.

When renal replacement therapy loomed near, his mother was intent on a pre-emptive transplant. Immediately, we had concerns about nonadherence and subsequent graft failure. Tim's case could easily become an unfortunate statistic, a lost transplant resulting from the defiance of youth (1, 2). His mother, affronted, cited his attendance at all appointments and the support of his parents as assurance of a successful transplant. In an almost fortunate turn of events, a history of substance abuse was revealed during Tim's transplant evaluation. His insurance company imposed a six-month period of drug testing and close follow-up before approval for transplant would be granted. Independently, but with his parents' support, Tim selected peritoneal dialysis for interim therapy.

In time, we did see behavioral changes. He would sit alone during his visits, he could recite his medication list, and he asked appropriate questions regarding his dialysis. At the end of six months, we felt confident that he was ready for transplantation.

When he was called for transplantation, his nephrologist happened to be out of town and was asked what he thought about transferring Tim's care to the adult service now, because that service was going to care for him during his postoperative course. The nephrologist's response was reflexive and immediate: "Absolutely not." Tim had had such a tumultuous road to this point. He still needed our guidance, our close follow-up, our reassurance. His nurse practitioner advocated a pause. If Tim was ready to be listed for transplant, why exactly couldn't he make the transition? It became clear to the nephrologist that his reservations about transition might have been a product of his own biases, not necessarily what was best for Tim. Reflecting on the struggles all pediatric subspecialists face in trying to take their young adult patients through the transition, we offer these thoughts.

We try to ensure the best outcomes for these patients, whom we have known for years—even decades. Yet, do we impede their progress by our desire to personally guide their care? Are we facilitators of their transition, or do we enable their delay?

Although an objective age cutoff is the policy for transition at many children's hospitals, children with chronic illness do suffer from delays in neurocognitive development and memory impairment (3). Given the significant individual variations in maturity, the use of specific chronologic criteria for transition is too rigid. There are many ongoing efforts to sort out the best time and method for transition. Approaches are quite varied from hospital to hospital and even between providers at a single institution.

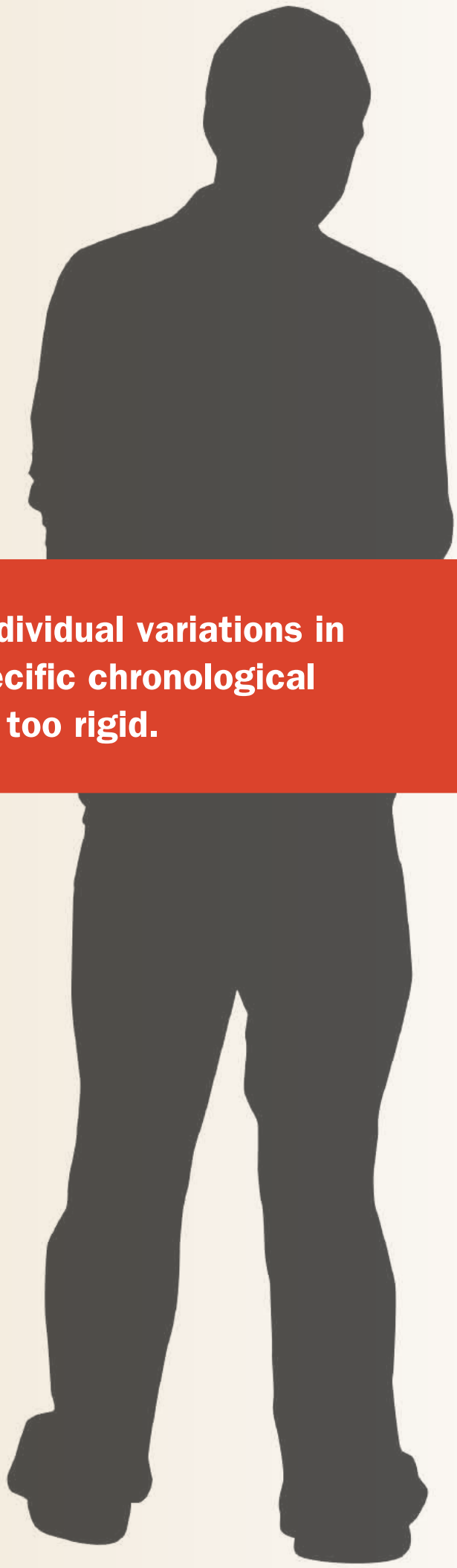
Some providers leave everything in the patient's hands. "When they are ready to leave, they will let us know." In some sense, this has merit. Indicating a desire to seek an adult provider is a strong affirmation of independence and responsibility. However, this can also lead to strange results, such as an encounter in my pediatric clinic of a patient bringing his wife to the visit and inquiring about erectile dysfunction medications.

Most pediatric subspecialists fall into a middle gray area. If we do not believe that administrative policy should dictate transition or that the decision should be left entirely to the patient, what degree of responsibility do we claim for the success of the transition and the outcome in our patient?

We are trained to loathe errors in our practice—and rightly so, given the dramatic consequences. We implement systems with multiple checkpoints, and we perform rigorous reporting and reviews of errors for prevention purposes. I wonder if a poor outcome in an adolescent who has undergone transition taps into our dread of errors. Our struggle with transition may well incorporate the challenge of identifying prevention strategies.

Most of us believe our intent is truly altruistic. We are genuinely bonded to our patients. A parental comparison is unavoidable. Some parents will cling to maintain control and protection over their young adult child's life and decisions, whereas others will sever their responsibility abruptly, accepting mistakes and failures as part of life's journey. Are we able to accept our patients' mistakes and failures? Or do we look upon them as reflections of our own shortcomings and therefore strive endlessly to prevent them?

New tools and approaches to transition continue to abound. However, even with the best evaluations, we have all seen the "perfect patient" falter and the "lost cause" succeed. We are doubtful that our personal struggle from case to case will ever cease, nor should it.



Given the significant individual variations in maturity, the use of specific chronological criteria for transition is too rigid.

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Kidney Transplant Outcomes in the United States: *Reason for Optimism*

By T. R. Srinivas

Kidney transplants are being performed in an era when higher-risk donor organs are being used. One could expect, given this scenario, that posttransplant renal function and graft survival would be adversely affected.

Refreshingly, recent studies show that kidney transplant function in the United States has improved in recent years, as has also graft survival.

In a study using Scientific Registry of Renal Transplant Recipients data from more than 90,000 recipients who underwent transplantation between 2003 and 2008, the estimated GFR 6 months after transplant averaged 54.3 mL/min/1.73 m^2 (1). The decline in GFR between 6 and 12 months after transplant averaged 0.69 mL/min/1.73 m^2 and between 6 and 24 months was 2.45 mL/min/1.73 m^2 (Figure 1). The GFR decline was significantly attenuated over the study period among both deceased and living donor transplant recipients. Factors significantly associated with steeper GFR decline were increased pretransplant dialysis time, older donor age, diabetes as a primary diagnosis, low body mass index, African American race, repeat transplants, nonprivate insurance, and elevated panel reactive antibody. Interestingly, baseline renal function or slope in renal function did not differ substantially by immunosuppressive regimen. The 1-year overall graft survival also increased over the study period from 92.3 percent to 93.9 percent.

These findings may reflect increased skill in medical management. They need further evaluation to determine whether short-term improvements translate to improved long-term survival.

In another study that also used data from the Scientific Registry of Renal Transplant Recipients, investigators demonstrated that graft half-life for deceased donor transplants was 6.6 years in 1989 and increased to 8 years in 1995 (2) (Figure 2). By 2005, graft half-life was 8.8 years. Most interestingly, greater improvements in graft survival were made in higher-risk transplants, such as in recipients of extended criteria donor transplants, wherein the half-lives increased from 3 years in 1989 to 6.4 years in 2005.

In low-risk populations such as living donor recipients, half-life did not change significantly: 11.4 years in 1989 and 11.9 years in 2005. The attrition rates of transplants in the first year showed dramatic improvements across all patient subgroups. Although attrition rates beyond the first year showed only small improvements, attrition rates among African American recipients did show modest improvement.

These results from two separate studies could reflect increased skill in selection, risk stratification, and medical management of highly complex renal transplant recipients. The period studied has also seen considerable improvements in the application of highly sensitive techniques for tissue typing, crossmatching, and assays for donor-specific antibody and refinements in the diagnosis and treatment of acute rejection episode. Such advances have minimized the incidence of hyperacute rejection in non–crossmatch positive transplants.

Over the study period and the era preceding it, the transplant community has also moved away from empirical treatment of graft dysfunction, and considerable refinements in histopathology and the standardization thereof have occurred. Entities such as antibody-mediated rejection can now be diagnosed and treated early and effectively with an ever-growing range of therapies. Over the same timeframe, universal and effective prophylaxis for cytomegalovirus infections has also been used, allowing the effective and safe use of antibody induction and intensified early immunosuppression. Furthermore, greater refinements in the management of the emerging epidemic of polyoma virus nephropathy, with effective screening and appropriate titration of the intensity of immunosuppression, may have mitigated the influence of viral nephropathy in mediating attrition of graft function. Advances in organ preservation such as pulsatile machine perfusion have also contributed to our ability to improve the early function of deceased donor kidneys.

Taken together, these two studies provide the nephrology community with some reason for cautious optimism. The stability of renal function expected of well functioning transplants and also their survival is improving over time.

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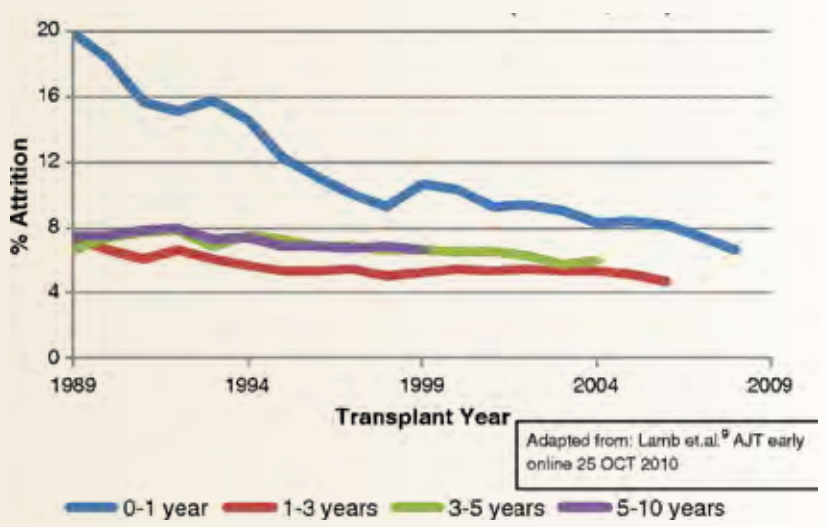
Figure 1

Average change in estimated GFR 6–12 months after kidney transplantation by year of transplant and donor type among patients with available estimated GFR at 6 months after transplantation. For patients with graft loss between 6 and 12 months, an estimated GFR of 10 mL/min/1.73 kg/m^2 was imputed (1).

Figure 2

Deceased donor kidney transplant attrition rates in the United States (N = 164,480) (Lodhi SA, et al. *Nephrol Dial Transplant* 2011: 26:15–17).



National Kidney Registry's Donor Chain Model Effective in Finding Donor Matches

By Kendall Powell

Three years ago, Garet Hil's daughter's kidneys failed, and he and his family entered a desperate race to find a living donor for her, including asking 100 family and friends to be tested and entering into every paired organ exchange program that existed in the United States. After several months of angst, they found that Hil's 23-year-old nephew was a compatible match.

"We dodged the bullet, but it showed me that the United States needs a system to get all incompatible pairs into the database," to facilitate as many matches between living donors and recipients as possible, Hil said. So he founded the National Kidney Registry, applying his business management savvy as a software executive to see if he could create a more efficient system for matching incompatible pairs through kidney donor chains.

The National Kidney Registry (NKR) is a 501c3 nonprofit organization that has facilitated more than 200 transplants in a little less than three years. It works with 50 transplant centers around the country. It is on target to complete 153 transplants this year and projects completing 350 in 2011, which represents about 5 percent of the total living donor transplants performed each year.

Hil explained why the donor chain model that NKR uses is more powerful for finding matches than traditional paired exchange programs. The standard chain starts with the donation of a kidney from a "Good Samaritan" donor, who is unrelated to any of the recipients. Then, matches are made between this donor and all the incompatible pairs that can find a better match within the registry participants. The last kidney in the chain—the one from a donor whose recipient has received someone else's kidney, but whose donor kidney does not match anyone in the registry currently—then goes to someone matched from the United Network for Organ Sharing waiting list for deceased kidneys.

Gabriel Danovitch, medical director for the Kidney and Pancreas Transplant Program of the University of California, Los Angeles, has called the kidney transplant chains facilitated by the NKR "the most exciting clinical event I've seen in my recent career."

In traditional paired exchange programs, the incompatible pairs have to find another incompatible pair with whom they match exactly. In the NKR model, everyone is dumped into the pool of donors and recipients in an effort to find as many compatible matches as possible. The longer the chain, the better—to date, the NKR's longest chain involved 22 transplants—and the more quickly a chain can be ended to the waiting list, the better. So-called bridge donors, those at the end of a chain waiting to donate that "leftover" kidney, can understandably fall through, either medically or practically, if too much time passes.

In a review of 100 bridge donors, only six have resulted in broken chains. "I believe we can get this to zero eventually," said Hil, noting that the transplant centers are getting better at identifying someone who fits the profile of a bridge donor who must wait for a time, and that matching speed can be improved. He also noted that the NKR and the transplant centers are getting better at figuring out how to coordinate larger clusters, like handling 12 simultaneous transplants in one or two days across the country to ensure that chains stay together.

In 2010, the NKR's average wait time for a recipient to find a match and receive a transplant was eight months, compared with the industry average of more than six years. "That's good, but not good enough," said Hil, noting that undergoing dialysis for more than six months lowers a recipient's chances of a successful transplant.

The NKR has also begun a CHIP program to benefit patients without donors who either are children or have a panel reactive antibody score greater than 50 percent, which indicates they are at a high risk of rejection and harder to match. Participating transplant centers can nominate these patients to receive the "leftover" kidney at the end of a chain.

Hil believes that improved donor support has been a key to the NKR's success, including providing donor insurance for downstream complications for every "Good Samaritan" donor who starts a chain. In addition, he said, donors must be reimbursed for travel, lodging, and lost wages when possible and hospitals must stop accidentally billing donors—an error that causes donors major distress.

The entrance of more compatible donor pairs into the registry would be a win-win situation for everyone involved, Hil said. Say there is a husband-and-wife compatible pair, but he's 10 years older than she is, and perhaps they do not have a good HLA match. Given that HLA compatibility does matter to long-term graft survival, this woman may be better off finding an unrelated, better-matched donor based on HLA, age, and weight. Also, entering this pair into the registry pool can facilitate between one and six additional transplants.

"This could cause the whole living donor transplant industry to change," said Hil. "Currently, about 6000 living donor transplants are performed each year. By converting individual pairs into chains, we could be getting 2000–3000 more."

Living Donors on the Rise

Unrelated living donors in the United States have increased to the point where they were the most common category in 2009, most likely because of swaps and chains, said Gabriel Danovitch, medical director for the Kidney and Pancreas Transplant Program at the University of California, Los Angeles.

The total recipient pool reflects the populations undergoing dialysis; white persons form the largest category, followed by African American, Hispanic, and then Asian persons. But the donor pool reflects the demographics of the national population, meaning that African American and Hispanic individuals are overrepresented recipients and underrepresented donors. Danovitch believes that this largely follows economics: chronic kidney disease is common in the poor, and uninsured donors are unacceptable at many transplant centers.

Interestingly, there has been an increase in living altruistic, or "Good Samaritan," donors, who tend to be older, wealthier, and highly educated. In 2009, there were 141 living altruistic donors, and the numbers have been increasing each year.

Speaking of these donors and the chains they help start, Danovitch said, "I do believe this can change the whole scene of living donor transplants in this country. It has unanticipated benefits, including an impact on the deceased donor waiting list, and it replaces the medical angst of performing high-risk transplants with bureaucratic angst [of coordinating chains]—and doctors always prefer this to medical angst."

Other benefits include more income for hospitals, a positive impact on staff morale, and the publicity that chains receive, which can act as a catalyst for more living and deceased donations.

He noted that although shipping kidneys across the country still makes him nervous, the kidneys "do well and open up straight away." He pointed to the Netherlands, which invested in a national living donor exchange program a decade ago and as a result has decreased its waiting list by almost one third. Danovitch said, "I see no reason why, in principle, we cannot do the same thing with national promotion."

Garet Hil, president and founder of the National Kidney Registry, presented the talk, "Donor Swaps: A Review of the National Kidney Registry Chains," aat Renal Week 2010.

Is "Old" Ever Too Old for Transplant?

In recent years, the 60- to 80-year-old age group on the kidney transplant waiting list has increased dramatically, decreasing their chances of ever receiving a kidney. Yet studies show that even those older than 70 can decrease their chance of death and increase the length of their life with a kidney transplant.

Evaluating elderly patients for a transplant should be an "exaggeration" of evaluating younger patients, said Gabriel Danovitch, medical director for the Kidney and Pancreas Transplant Program at the University of California, Los Angeles. Physicians should rule out coronary artery disease, other cardiovascular disease, and cancer. Patients should also have good mobility, muscle strength, and nutritional status. He emphasized an assessment that looks at 'biological age' of the individual rather than chronological age.

Studies show that even those older than 70 can decrease their chance of death and increase the length of their life with a kidney transplant.

Danovitch spoke about "Transplantation in the Elderly: Is Old Ever Too Old?" at the Renal Week 2010 session, "What to Do with Medically High-Risk Kidney Transplant Candidates" in November.

Even in highly selected patients, "not surprisingly, the older you are, the more likely you are to die," Danovitch said. But graft survival does not appear to suffer with increased age of recipients. There is also a drop-off in the incidence of acute rejection in older transplant patients, presumably owing to a less aggressive or functional immune system. However, this is balanced out largely by the fact that older donor age is associated with acute rejection and older recipients tend to get older kidneys.

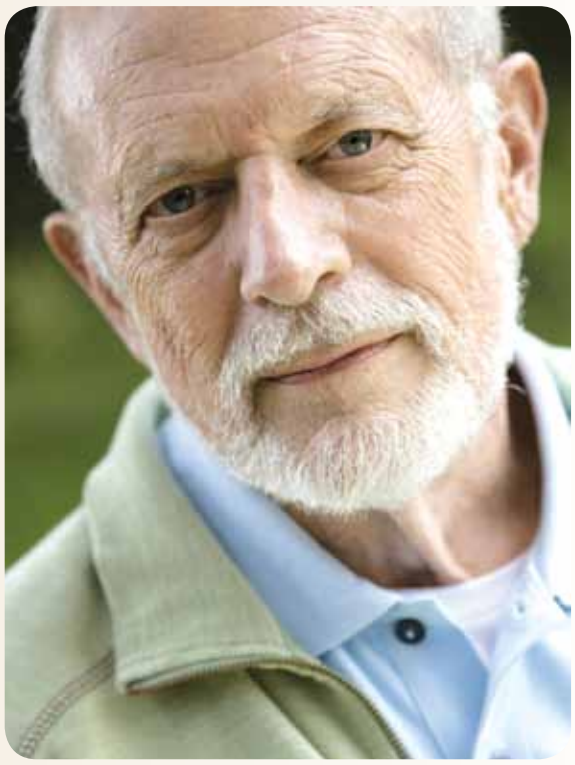
"It's important for elderly patients waiting for deceased donor kidneys to remember that they will get kidneys of lower quality," said Danovitch.

The dilemma for nephrologists, then, is whether or not to encourage living donation as a solution, when those living donors are likely to be the patient's children or even grandchildren. "We must think about, 'What are the ethical issues in transplanting younger donors into older patients who probably won't live much longer?' "

"Many elderly patients don't want to turn to their children," Danovitch said. "But they also don't want to wait eight to 10 years for a poor quality deceased donor kidney." Currently, 10 percent of living donor kidneys go to people more than 65 years old, and that percentage appears to be increasing.

Among the increased risks for elderly transplant patients are infections, surgery complications, pharmacokinetic vulnerability, and lymphomas due to immunosuppression.

Danovitch summed up the hard-learned lessons about elderly transplants from his own practice:



"Choose your patients carefully, make sure they know what they are getting into, do not take their immune systems for granted, and watch out for covert infections." He also noted that better research protocols targeted to the elderly population were needed as the numbers of these patients are likely to continue to increase.

Transplant policy session highlights continued need to create equitable, ethical, and cost-effective measures for transplant recipients and donors

By Caroline Jennette

Speakers at a "Controversies in Organ Transplant Policy" session at Renal Week 2010 described a range of issues affecting both kidney donors and recipients.

Gabriel Danovitch, MD, director of the Kidney Transplant Program at UCLA, described the steps taken this year by the Declaration of Istanbul Custodian Group (DICG) to create a framework of "muscles and tendons" across the "skeleton" of the Declaration. The Declaration of Istanbul was created in 2008 by representatives of scientific and medical bodies from around the world to protect the poor and vulnerable from the negative effects of transplant tourism and organ trafficking.

Although the Declaration has been widely accepted and endorsed by all major transplant organizations, it is not a legal document. The DICG works to monitor, implement, and enforce the principles laid out in the Declaration and has split into six task forces covering various organ trafficking and tourism aspects. While Danovitch would like to see greater widespread acceptance, using the Declaration of Helsinki as a goal, he said tremendous progress has already been made since the Declaration was published. For more information, visit www.declarationofistanbul.org.

Roger Evans, PhD, president and CEO of the United Network for the Recruitment of Transplantation Professionals, described the ongoing struggle to pass legislation providing Medicare reimbursement for immunosuppressive medication to transplant recipients who are only Medicare-eligible due to their end stage renal disease after three years. Evans laid out an argument for lifetime coverage using data recently published in the *Clinical Journal of the American Society of Nephrology* (PMID: 20847093) describing the economic burden of "cost-related nonadherence" (CRN). In a nationwide transplant center survey done by Evans and colleagues, 70 percent of patients reported having problems paying for medication, and 68 percent reported deaths and graft losses attributable to cost-related immunosuppressive medication nonadherence.

Alan Leichtman, MD, medical director of Kidney and Pancreas Transplant Programs at the University of Michigan, discussed alternative systems for deceased donor allocation. The National Organ Transplant Act (NOTA), instituted in 1984, requires the Organ Procurement and Transplantation Network (OPTN) to determine medical criteria ensuring equitable organ allocation, which for kidneys is currently based on HLA status, wait time accrual, sensitization, and donor kidney type (standard vs. extended criteria).

The current system has been highly criticized as being a subjective process not accounting for special needs, inequities in access, and differences in outcomes across populations, in stark contrast to the original NOTA mandate. Leichtman reviewed current, proposed allocation policy changes including a new kidney allocation score (KAS) based on expected life years from transplant (LYFT score), time on dialysis, sensitization, and a donor profile index. Other alternatives to the current system include removing the allocation system all together, using a lottery-based system, or basing allocation on social and economic (versus medical) conditions. For more information on the proposed system, visit: http://optn.transplant.hrsa.gov/kars.asp.

Journal View

Cystatin C Doesn't Beat Creatinine in Estimating GFR

Estimates of glomerular filtration rate (GFR) based on cystatin C are not significantly better than estimates based on plasma creatinine, according to a study in *Kidney International*.

The iohexol clearance method was used to measure GFR in a general population sample of 1621 middle-aged adults, all free of coronary heart disease, kidney disease, stroke, or diabetes. Published equations for estimating GFR based on cystatin C or plasma creatinine measurements were compared in terms of bias and precision, calculated as the median and interquartile range of estimated minus measured GFR, respectively. Accuracy was expressed as the percentage of estimates within 30 percent of measured GFR.

The best-performing equation based on cystatin C had an accuracy of 94 percent, with bias of 3.5 and precision of 18 mL/min/1.73 m^2. By comparison, one creatinine-based equation offered accuracy of 95 percent, with bias of 2.9 and precision of 7.6 mL/min/1.73 m^2. An equation incorporating both measurements offered accuracy of 92 percent, with bias of 7.6 and precision of 15 mL/min/1.73 m^2. None of the equations based on cystatin C—alone or in combination with creatinine—provided a better estimate of GFR than the widely used Modification of Diet in Renal Disease and Chronic Kidney Disease Epidemiology Collaboration equations.

Estimates based on cystatin C are superior to creatinine in predicting cardiovascular disease. It has been suggested that cystatin C-based equations might be superior to creatinine-based equations in predicting GFR values near the range of normal.

However, this study finds that cystatin C-based equations are not superior to creatinine-based equations in predicting GFR in a healthy middle-aged population. The cardiovascular predictive value of cystatin C may involve factors other than GFR, the authors suggest [Eriksen BO, et al. Cystatin C is not a better estimator of GFR than plasma creatinine in the general population. *Kidney Int* 2010; 78: 1305–1311].

Azathioprine Beats Mycophenolate Mofetil in Preventing AAV Relapse

In patients with antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV), mycophenolate mofetil is associated with a higher risk of relapse than standard therapy with azathioprine, reports a trial in *The Journal of the American Medical Association*.

The randomized, open-label International Mycophenolate Mofetil Protocol to Reduce Outbreaks of Vasculitides (IMPROVE) trial included 156 adults with newly diagnosed AAV—100 with Wegener granulomatosis and 56 with microscopic polyangiitis—from 42 European centers. After remission induction therapy with cyclophosphamide and prednisolone, patients were randomly assigned to maintenance therapy with azathioprine or mycophenolate mofetil. Relapse-free survival was compared between groups, along with secondary outcomes.

At a median follow-up of 39 months, relapse had occurred in 42 of 76 patients in the mycophenolate mofetil group versus 30 of 80 in the azathioprine group. Mycophenolate mofetil had a lower rate of severe adverse events, 7.5 percent versus 16 percent, although the difference was not significant. Secondary outcomes were similar as well, including the Vasculitis Damage Index, estimated glomerular filtration rate, and proteinuria.

Safe and effective maintenance therapies are needed to maintain remission in patients with AAV. Studies suggest that mycophenolate mofetil is superior to azathioprine in patients with systemic lupus erythematosus or renal transplantation.

However, the IMPROVE trial finds mycophenolate mofetil inferior to azathioprine for preventing remission in patients with AAV. Mycophenolate mofetil is not recommended as initial remission maintenance therapy, although it may be useful in refractory cases [Hiemstra TF, et al. Mycophenolate mofetil vs azathioprine for remission maintenance in antineutrophil cytoplasmic antibody–associated vasculitis: a randomized controlled trial. *JAMA* 2010; 304: 2381–2388].

Industry Spotlight

Dialysis Firm Gets Infusion from Investment Bank

Renal Ventures of Denver has received $30 million from Goldman Sachs Group. The money will bolster the privately held company's ability to grow and add more treatment centers.

Shareholders of Renal Ventures Management LLC will maintain significant control of the company, which operates 25 dialysis centers in six states, according to the *Denver Post*. The centers are in Iowa, Arkansas, Texas, West Virginia, Pennsylvania, and New Jersey, which has the highest number of centers. A subsidiary of Renal Ventures Management, Infusion Center of Denver, is a clinic that collaborates with physicians to care for and treat individuals with a variety of intravenous therapies.

The management company is considering adding two clinics in Colorado, according to the *Post*. The money will also allow for building new centers and expanding into service areas related to dialysis.

Renal Ventures Management's business model is based on joint venture models, in which the company partners with local nephrologists. Starting immediately, the company will pursue new co-ventures with nephrologists nationwide, the company announced.

The company partners with physicians and offers a menu of services, including joint venture arrangements, acquiring practices on behalf of physician partners, and also training staff for the centers.

According to the *Denver Post,* company managers selected Goldman Sachs because of its foreign connections and its ability to assist the firm as well as to offer various exit strategies when the timing is right.

In addition, the Denver firm completed syndication of a senior credit facility with J.P. Morgan Chase & Co. and Vectra Bank Colorado, N.A., a Colorado-based subsidiary of Zions Bancorporation. These agents will provide additional capital for growth and operations.

Chief executive Larry Chatfield and Denver real estate developer Jerry Glick are part of the management arm that controls Renal Ventures. Earlier, they founded another dialysis provider, QualiCenters Inc., which they sold to the world's largest dialysis firm, Germany-based Fresenius.

The idea of growing the business and then selling assets is an outcome that could be repeated with Renal Ventures, said Dan May, Renal Ventures' chief financial officer, in the *Post*. At this time, revenues total about $80 million, and the company employs 600 people across the states where it has centers.

"Fresenius and DaVita own 100 percent of most of their clinics," May said. "Most of our clinics have physicians as joint-venture partners." Fresenius is the largest dialysis provider in the world, and DaVita is the second largest.

New Use for Drug May Improve Dialysis

A drug commonly used to help stroke patients immediately after their incident is proving valuable also for patients in the dialysis setting. What's the connection?

Recombinant tissue plasminogen activator (rt-PA) is a drug approved to help stroke victims by busting clots causing the stroke. A study conducted in Canada and published in the *New England Journal of Medicine* showed that using rt-PA instead of heparin in dialysis patients could help them in two ways.

The researchers found that giving patients rt-PA instead of heparin once a week, compared with using heparin three times a week, as a locking solution for central venous catheters, significantly reduced the number of both catheter malfunctions and bacterial infections in these patients.

Serious catheter-related infections are a common cause of death for people undergoing dialysis, the study authors wrote.

Over a six-month period, they found that 40 of the 115 patients assigned to heparin-only treatment (34.8 percent) and 22 of the 110 patients assigned to weekly rt-PA (20.0 percent) had catheter malfunctions.

Catheter-related bacteremia occurred in 15 patients (13.0 percent) assigned to receive heparin only, compared with 5 patients who received rt-PA weekly (4.5 percent).

Some observers took the seemingly good news with a healthy dose of reality. According to *HealthDay*, Robert Provenzano, MD, at St. Providence Health System in Detroit said that an increased risk of bleeding is definitely a concern, as is the cost of rt-PA. Provenzano, chief of nephrology, said that other, cheaper drugs are available for catheter solutions.

Lead author Brenda Hemmelgarn at the University of Calgary also told *HealthDay* that costs for rt-PA are high. Hemmelgarn said the monthly cost of heparin for a dialysis patient is about $156 per patient, but giving a weekly dose of rt-PA would cost more than $580 per month.

She and Provenzano both noted, however, that rt-PA may end up being more cost effective if it prevents complications and the need to remove and change a dialysis patient's catheter, which can be expensive.

Hoffmann-La Roche, a manufacturer of rt-PA, funded the study.

Genentech, a member of the Roche Group, already makes a drug called Cathflo Activase (Alteplase), and this drug is used for restoring function to central venous access catheters in pediatric and adult patients to keep their catheters clear and ready for effective withdrawal of blood.

Glomerular Disease in the Elderly:
To Biopsy or Not to Biopsy

By Richard J. Glassock

The spectrum of glomerular diseases that affect the elderly is quite broad and ranges from the relatively benign minimal change disease to fulminant crescentic glomerulonephritis. Postinfectious glomerulonephritis has seen a resurgence in the elderly, whereas its occurrence in younger patients is diminishing, except in resource-poor regions of the world. Some glomerular lesions are distinctly more common in the elderly than in younger adults, such as primary (AL) amyloidosis, nonamyloid monoclonal immunoglobulin deposition diseases (e.g., light chain deposition disease), antineutrophil cytoplasmic antibody (ANCA)-associated small vessel vasculitis (SVV), and diabetic glomerulosclerosis (consequent to type 2 diabetes mellitus).

The performance of a percutaneous renal biopsy may provide crucial diagnostic and/or prognostic information in many patients suspected of having a glomerular lesion based on clinical or laboratory examinations. There is no evidence that the risk of complications from a renal biopsy procedure is any greater in the elderly than in younger adults, providing the usual precautions are taken and the procedure is conducted by an experienced practitioner. Thus, the decision to perform a renal biopsy in an elderly patient is often guided by three questions: 1) Will the information gained provide useful diagnostic value (i.e., will it reduce uncertainty of diagnosis)? 2) Will the information gained be helpful in designing a safe and effective treatment strategy, even if the diagnosis is reasonably secure? 3) Will additional prognostic information not already obtainable by noninvasive clinical and laboratory testing be forthcoming?

The decision to perform a renal biopsy will depend on how these questions are answered. It will also depend to a certain extent on the *a priori* estimates of the probability of the presence of certain disease states or entities. For example, an elderly patient with clinical features of nephrotic syndrome, impaired renal function, cardiomyopathy, carpal tunnel syndrome, orthostatic hypotension due to autonomic neuropathy, and elevated plasma-free lambda light chain concentration may not require a renal biopsy to confirm the presence of AL amyloidosis—an abdominal fat pad biopsy/aspiration may suffice. Renal tissue would not be helpful in designing a safe and effective treatment strategy, and most of the useful prognostic information is already contained in the clinical examination. On the other hand, an elderly patient presenting with the recent onset of an apparently "idiopathic" nephrotic syndrome and normal or only mildly impaired renal function would benefit greatly from the diagnostic precision afforded by a renal biopsy.

Were membranous nephropathy (MN)— one of the most common lesions seen in elderly patients with nephrotic syndrome (Table 1)—to be discovered, a sequence of additional studies would be initiated to exclude a secondary cause, most notably an underlying occult malignancy that can be present in as many as one in four or five elderly patients with MN. If a secondary cause is not found, the morphologic features of the MN lesion do not provide much aid in choosing a course of treatment or offering a more precise estimation of prognosis, over and above that enabled by clinical information (such as serum creatinine levels or urinary protein excretion rates).

One of the more common and often devastating glomerular diseases seen in the elderly is ANCA-associated crescentic glomerulonephritis (a form of SVV that is either renal-limited or multisystemic). In this circumstance, serological tools (antigen-specific [ELISA] anti-myeloperoxidase auto-antibody and anti-proteinase-3 auto-antibody and ANCA testing by indirect immunofluoresence) are readily available to render a diagnosis with high precision, even in the absence of a renal biopsy. However, the degree of crescent formation (e.g., the percentage of well-preserved [normal] glomeruli) and the extent of tubulo-interstitial fibrosis and tubular atrophy may provide information that helps generate a treatment strategy and refine the prognosis, provided that the sample size is adequate (at least 15–20 glomeruli). However, the prospect of gleaning additional information from a renal biopsy in these cases should not delay the initiation of treatment based on clinical information alone.

The utility of renal biopsy in elderly patients with type 2 diabetes mellitus and concomitant overt proteinuria with or without impaired renal function is especially difficult to determine. Most of these patients will have an underlying diabetic glomerulosclerosis (diffuse or nodular intercapillary glomerulosclerosis), and renal biopsy will not aid in diagnosis, treatment, or prognosis. However, a fraction (5–40 percent, depending on the clinical details) will have another nondiabetic glomerular lesion or one superimposed on a background of diabetic glomerulosclerosis. Recently, postinfectious glomerulonephritis with underlying immunoglobulin A–dominant glomerular deposits has been observed in elderly individuals with diabetes.

Identification of the underlying lesion can have a decided effect on treatment and/or prognosis. Clinical clues to the presence of a nonglomerular lesion in elderly patients with type 2 diabetes and overt signs of renal disease include 1) an onset of renal manifestation after only a short duration of recognized diabetes (which is often difficult to establish due to the delay in diagnosis of type 2 diabetes); 2) the presence of an "active" urinary sediment, including red cell casts and/or acanthocytes; and 3) deterioration of renal function at a pace exceeding that usually seen in type 2 diabetes with overt diabetic nephropathy. The absence of diabetic retinopathy is much less useful in enhancing suspicion of a nondiabetic glomerular disease in individuals with type 2 diabetes compared with those with type 1 diabetes. As a general rule, it is better to recommend a renal biopsy (extant contraindications) in cases of type 2 diabetes with an "atypical" presentation of overt renal disease. There are no compelling reasons to recommend a renal biopsy in patients with microalbuminuria and type 2 diabetes.

Amyloidosis, MN, ANCA-associated SVV, and diabetic nephropathy illustrate the complexities involved in determining the overall efficacy of renal biopsy in elderly individuals suspected of having an underlying glomerular disease. In some instances, it is critically important to obtain a correct diagnosis, and renal biopsy may be the only certain way of achieving this goal. In other circumstances, the diagnosis can be established with reasonable certainty via noninvasive clinical examination and well-selected laboratory testing (including imaging). Here the value of renal biopsy rests mainly in the prognostic arena in both a positive and negative sense—implementing specific treatment using evidence-based guidelines when the lesion appears to be modifiable and rendering conservative (i.e., palliative) nonspecific management when the lesion appears to be nonmodifiable. Therefore, the decision to biopsy or not to biopsy is a complicated one that can only be made on a case-by-case basis after consideration of all of the clinical information available (history, examination, laboratory, and imaging). Because renal biopsy is a reasonably safe procedure, in experienced hands, it may be better to err on the side of commission than omission when uncertainty might affect the outcome of a disease process. One should always keep in mind that glomerular lesions occur more commonly in the elderly (Table 1) when applying this principle. In this context, it is also important to be thorough in the application of an ever-enlarging array of noninvasive diagnostic and prognostic tools (e.g., serology) in this group of patients. In many cases, renal biopsy may not be an essential part of the evaluation and management of elderly patients with clinically overt glomerular disease.

Table 1. Common glomerular lesions in the elderly

- Primary and secondary amyloidosis
- Monoclonal immunoglobulin deposition diseases
- Membranous nephropathy
- ANCA-associated crescentic glomerulonephritis
- Diabetic glomerulosclerosis (type 2 diabetes mellitus) with or without superimposed nondiabetic glomerular disease
- Postinfectious glomerulonephritis

ASN Kidney News regrets that this article did not appear in the February 2011 special issue on Geriatric Kidney Care. For the full issue, go to http://onlinedigeditions.com/publication?i=61027.

Suggested reading

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States Ramp Up Efforts in 2011 to Address Health Reform Implementation

By Caroline Jennette

Although the biggest health reform changes are not slated to become effective until 2014, several provisions going into effect this year will affect state Medicaid programs. The new political climate in Washington and courtroom battles may bring about significant changes to the Affordable Care Act (ACA), but states continue to move forward in implementation.

Changes to Medicaid in 2011

States continue to buckle under budgetary restraints, spending on average 16 percent of their general fund budgets on Medicaid. Several ACA provisions that become effective this year may help state Medicaid programs implement new service delivery systems, streamlining care and reducing future health care costs.

In January, states were given the option to create so-called health homes, an expansion of the medical home model already used in many state Medicaid programs. States that take up this option or that expand already existing managed care programs will qualify for 90 percent federal matching payments for the first two years the health home model is in effect. States also have the option, this year, to apply for grants supporting the development of state programs to address chronic disease prevention.

In October, an ACA provision is slated to go into effect that expands access to Medicaid home- and community-based services (HCBS) programs. The State Balancing Incentive Program will provide enhanced federal matching to states increasing non–institutionally based long-term services. States can receive matching funds until 2015, and funds must be used to expand or enhance HCBS. A new program will also be established to help states provide statewide home- and community-based attendant supports and services to low-income individuals who need assistance with daily living activities and health related tasks.

Preparing for health exchanges

Health insurance exchanges (HIEs), among the most talked-about provisions of the ACA, are scheduled to go into effect January 2014. Each state will be responsible for creating and administering a virtual "marketplace" of qualified health plans for health care consumers to "shop" for health insurance plans. Eligibility is restricted to consumers who lack access to employer- or government-sponsored insurance and to small businesses with ≤100 employees. The HIEs will also provide enrollment guidance and filter eligible individuals into appropriate public plans. Other responsibilities of state HIEs include offering standardized information to help consumers choose between plans, creating a single enrollment form for all plans in the exchange, determining eligibility for subsidies and public programs, and providing navigators to help consumers review their plan choices and enroll.

States can opt out of creating their own HIEs and can have the federal government provide one instead, but they will risk losing federal tax credits and having less control over the state insurance market. Although states have until 2013 to notify the Secretary of Health and Human Services as to whether they intend to run an HIE, grants of up to $1 million have already been awarded to 48 states and the District of Columbia to conduct research and begin planning the design of HIEs. The Department of Health and Human Services will also award Early Innovator grants this year. As many as five states could receive funding to develop information technology infrastructures necessary for operating state exchanges.

For more information on health reform implementation, see www.healthreformgps.org, http://healthreform.kff.org, and www.healthcare.gov

Policy Update

Barry Straube, Nephrologist and CMS Leader, Steps Down

By Rachel Shaffer

Barry Straube, chief medical officer and director of the Office of Clinical Standards and Quality at the Centers for Medicare and Medicaid Services (CMS), retired from the CMS on January 31, 2011. The highest-ranking nephrologist within the CMS for the past six years, Dr. Straube cochaired the End Stage Renal Disease and Clinical Laboratory Open Door Forum and was responsible for many of the significant payment and policy reforms to the Medicare end stage renal disease (ESRD) program, including the new bundled Prospective Payment System and the ESRD Quality Improvement Program. His other accomplishments include updating the Conditions for Coverage used by surveyors to qualify dialysis providers for Medicare funding, and service as a senior advisor on ESRD and transplantation issues to the agency. Besides his background in quality improvement, Dr. Straube also leaves behind a notable gap in nephrology expertise at the CMS.

"We have been immensely fortunate to have Dr. Straube's expertise and leadership at CMS for these past six years," commented ASN President Joseph Bonventre, MD, PhD, FASN. "The kidney community has benefited greatly from the nephrology perspective he brought to his roles at CMS. We wish Dr. Straube the best of luck as he embarks upon the next phase of a distinguished career."

"Dr. Straube has been a dedicated public servant and an invaluable ally at CMS in a time of tremendous change and consequence for the kidney community. His work as a champion for patients with kidney disease has been invaluable and will be missed," said ASN Councilor Jonathan Himmelfarb, MD, FASN.

Dr. Straube states that he looks forward to "exploring new opportunities and returning to the private sector after some vacation and family time."

Before assuming the roles of chief medical officer and director of the Office of Clinical Standards and Quality, Dr. Straube was the chief medical officer for CMS, Region IX. After his first year of public service in 2001, the CMS awarded him the CMS Administrator's Achievement Award, the agency's highest honor, and in 2003 he received the Secretary's Award for the U.S. Department of Health and Human Services. Before undertaking his government work, Straube's career included quality improvement roles in the private sector and service as chief of the division of nephrology at California Pacific Medical Center. He received his medical degree from the University of Michigan Medical School and completed his renal fellowship in nephrology at Tufts University School of Medicine.

ASN News

ASN Supports New *U.S. Dietary Guidelines for Americans 2010*

The American Society of Nephrology (ASN) recently announced its support of the U.S. Department of Agriculture's *U.S. Dietary Guidelines for Americans 2010*, which include advising Americans to reduce their daily salt intake. These recommendations provide direction on making healthy food choices to maintain an ideal weight and improve overall health. The recommendations are issued every five years and serve as the basis for the food pyramid.

The recommendations encourage Americans to drastically reduce their salt intake. The following groups are urged to cut their salt intake to 1500 mg of sodium daily:

1. All individuals 51 and older
2. All African Americans
3. Individuals with high blood pressure, diabetes, or chronic kidney disease (CKD)

Others are urged to cut their daily sodium intake to 2300 mg per day.

"The recommendations are important to all Americans, particularly African Americans and patients with kidney disease," said Stuart L. Linas, MD, FASN, chair, ASN's Hypertension Advisory Group. "High dietary salt worsens kidney disease in a number of ways, including causing higher blood pressure and increasing the effects of hormones, such as angiotensin, known to injure kidneys. Reducing dietary salt should reduce the number of patients requiring renal replacement therapy."

High blood pressure is the second-leading cause of kidney failure and poses a particular threat to African Americans. African Americans are six times as likely as whites to develop hypertension, and nearly 50 percent of African American adults are hypertensive.

ASN President Joseph V. Bonventre, MD, PhD, urges these high-risk groups to read the recommendations and make improvements in their eating habits.

"ASN advocates for improvements in public health, and we feel these recommendations go a long way in encouraging healthy eating habits. We hope these improvements will lead to fewer Americans developing kidney disease," Bonventre said.

Kidney-Heart Connection to be Highlight of World Kidney Day

People with kidney failure are three times as likely to have heart disease. Americans are being urged to think about protecting their kidneys and saving their hearts this March during National Kidney Month and on World Kidney Day, March 10, 2011.

"It is essential that we help the public and lawmakers recognize the importance of research in understanding the link between kidney disease and cardiovascular disease," said Joseph V. Bonventre, MD, ASN President. "World Kidney Day is a prime opportunity for the kidney community to raise awareness about improving the health of millions of kidney and heart patients."

More than 26 million Americans have chronic kidney disease and most don't know it.

According to the National Kidney Foundation, heart disease is a risk factor for kidney disease and kidney disease is a known risk factor for heart disease so it's important for those who have one of these diseases to get tested for both.

To make early detection of chronic kidney disease as easy as possible, the National Kidney Foundation offers free screenings around the country through the Kidney Early Evaluation Program (KEEP). KEEP is offered to those at risk—anyone with diabetes, high blood pressure, or a family history of kidney disease. Visit www.kidney.org to find screening sites.

Pediatric Nephrology Begins Advocacy Training Initiative

Funded by the John E. Lewy Foundation for Children's Health and initiated by the leadership of the American Society of Pediatric Nephrology (ASPN), the pediatric nephrology community recently announced a new initiative to increase the knowledge and skills of pediatric nephrologists in the areas of advocacy and governmental affairs. Designed by Lisa Satlin, MD, immediate past president of the ASPN, the Advocacy Scholars Program aims to develop a pipeline for the next generation of leaders in pediatric nephrology with specific expertise in governmental processes affecting children's health care and advocacy for pediatric nephrology. The program plans to educate future leaders in the conduct and application of advocacy by offering "mini- fellowships" for leadership and advocacy skills development.

Successful applicants will participate in a three-day legislative conference sponsored by the American Academy of Pediatrics. This conference includes visits with members of Congress and their staff and provides experience in the legislative process through hands-on work sessions and interactions with peers, politicians, and the press. At the conclusion of the conference, participants will understand the federal and state legislative process; sharpen skills and techniques to successfully impact Congress, state legislatures, and governmental regulatory agencies; and develop strategies to effectively engage the media. Following this structured learning experience, awardees will work directly with ASPN's Washington representative and senior members of the ASPN to specifically understand ASPN's advocacy and Capital Hill efforts and prepare the scholars for participation in an ongoing advocacy initiative.

The inaugural awardees are Tamar Springel, MD, and David Hains, MD. Springel is a fellow in pediatric nephrology at the Children's Hospital of Philadelphia where she is pursuing her masters of science degree in health policy research.

"Nephrologists are in a unique position in our healthcare system," Springel said. "Our ability to care for our sickest patients depends on government legislation."

Hains is assistant professor of pediatrics and director of the Integrated Research Pathway for the Pediatric Residency Program at Nationwide Children's Hospital in Columbus, Ohio. His goals are that "the knowledge and insights gained from the John Lewy Foundation Advocacy Scholars Program will help increase my effectiveness in caring for my patients, better guide fellows in research and academic careers, and make an impact as an advocate for our patients and research interests at regional and national levels."

The initiative will honor the memory of John E. Lewy, MD, who was one of pediatric nephrology's strongest advocates for children's health in the United States and around the world. Lewy had served a Robert Wood Johnson Fellowship with Sen. John Breaux of Louisiana and was intimately involved with the governmental affairs activities of the American Academy of Pediatrics and the International Pediatric Nephrology Association. He had just completed his tenure as chair of the AAP's Committee on Federal Government Affairs at the time of his unexpected death in 2007.

For more information on the John E. Lewy Foundation for Children's Health and its missions to support pediatric nephrologists and other pediatricians in activities to improve their knowledge skills and efficacy in delivering better health for children worldwide, please visit http://www.aspneph.com/JohnELewyFoundation/JELFMain.asp.

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