

March 2009 | Vol. 1, Number 2

Medicare's new Conditions for Coverage for dialysis facilities will require much from kidney specialists. Will your unit feel swamped by the data entry and other requirements? For more on dialysis, see our special section starting on p. 11.

Study Urges Early Diagnosis of CKD in Children

ncreasing efforts are being made to prevent and treat chronic kidney disease (CKD) in children, before serious complications develop during adolescence and adulthood. One recent research endeavor has focused on characterizing proteinuria in children.

Kidney

By assessing this condition, which is a hallmark of kidney dysfunction, investigators hope to not only slow the progression of CKD in children, but also to find new insights into disease progression that might be used to develop novel treatments for all kidney patients—adults and children.

Proteinuria and kidney disease

"We know that the severity of kidnev disease tends to be associated with the amount and the duration of proteinuria," said Craig Wong, MD, of the University of New Mexico, in Albuquerque. "There-

fore, persistent high grade proteinuria usually warrants a prompt evaluation for other symptoms of kidney dysfunction."

Most patients with proteinuria have no signs or symptoms, so the proteinuria is often discovered at a late stage. As a result, the distribution of proteinuria in young patients with poor kidney function is unknown.

To gain insights into the distribution of proteinuria and to identify characteristics associated with proteinuria in children, Wong and his colleagues look at a large group of children with mild to moderate kidney disease in the April Clinical Journal of the American Society of Nephrology.

The goal of their analysis of data from the Chronic Kidney Disease in Children (CKiD) study was to pinpoint potential environmental influences and to identify differences Continued on page 3

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An Official Publication of the

American Society of Nephrology

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Home Hemodialysis Industry Poised for Growth he market for home-based hemodialysis is growing and is poised to expand, nephrologists and industry representatives reported. Changes required by the Medicare Improvements for Patients and Providers Act (MIPPA),

the Centers for Medicare and Medicaid Services (CMS), and a trend toward home health care may all help shift the winds in favor of home dialysis.

Currently limiting dialysis in the home are Medicare reimbursement levels, reimbursement for training, and the ability of patients and caregivers to perform the tasks necessary for the hemodialysis. But several factors are converging to encourage more home dialysis. For example, many patients still don't know about home dialysis as an option, but MIPPA and the CMS's new Conditions for Coverage now require that patients be informed of all the modalities for treating kidney damage, including home dialysis. About one percent of dialysis patients

are now dialyzing at home, said Christopher R. Blagg, MD, professor emeritus of medicine at the University of Washington, and a pioneer and supporter of home dialysis since the 1960s.

The total number of home hemodialysis patients in the United States is about 4000 currently, compared with roughly1000 in 2005, said Joe Turk, senior vice president of commercial operations for NxStage, which manufactures the most frequently used home dialysis machine.

That number is set to change. With the number of all dialysis patients in the United States growing 2 to 3 percent per year, "by 2020, it's estimated that about 800,000 people with kidney disease will



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References: 1. Data on file, Genzyme Corp. 2. Delmez J, Block G, Robertson J, et al. A randomized, double-blind, crossover design study of sevelamer hydrochloride and sevelamer carbonate in patients on hemodialysis. *Clin Nephrol.* 2007;68:386-391. 3. Renvela [package insert]. Cambridge, MA: Genzyme Corp; 2007.



Ren/ela. sevelamer carbonate Right from the start"

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CKD in Children

Continued from page 1

in groups among children with chronic kidney disease.

Wong and his team studied data from more than 400 children one to 16 years of age who were enrolled in the CKiD study and were seen at 43 pediatric nephrology centers across North America.

"This study provides new information pertaining to the importance of proteinuria and factors associated with its development in the largest group of children with chronic kidney disease ever studied," said Wong. He added that the study has defined some of the risk factors for kidney disease progression and may help researchers design new and potentially therapeutic interventions to maintain patients' kidney function.

Identifying proteinuria in children earlier could help physicians slow or prevent kidney function loss at an early stage. For example, treatments such as angiotensin-converting enzyme inhibitors and angiotensin receptor blockers so-called renin-angiotensin system (RAS) antagonists—could be prescribed to reduce proteinuria and slow kidney disease progression.

The investigators found that the level

of proteinuria in children tended to be higher as their glomerular filtration rate decreased. Proteinuria also was associated with race. Non-Caucasian patients were more likely to have proteinuria than Caucasians, which suggests that differences in proteinuria might be related to genetic or environmental factors in some cases.

Proteinuria also was associated with glomerular causes of chronic kidney disease. Among the patients with glomerular causes of chronic kidney disease, those who took RAS antagonists tended to have lower levels of proteinuria compared with those who did not take the drugs.

"The likelihood that agents designed



to affect the RAS system will protect renal function in children with chronic kidney disease, particularly those with glomerular causes of chronic kidney disease, is strengthened by this report," said John Mahan, MD, program director of the Pediatric Residency Program and the Pediatric Nephrology Fellowship Program at Ohio State University in Columbus. "These data should encourage all pediatric nephrologists to aggressively approach treatments that affect the RAS in children with chronic kidney disease."

According to William E. Smoyer, MD, director of the Center for Clinical and Translational Research at the Research Institute at Nationwide Children's Hospital in Columbus, Ohio, "This very large pediatric study confirms the importance of proteinuria as a highly relevant marker of kidney injury in children, as well as a predictor of future loss of renal function. Given the known role of proteinuria in inducing kidney inflammation and scarring, it also highlights the important benefits of treatment of chronic glomerular proteinuria with renin-angiotensin system antagonists."

The study's results could encourage other investigators to develop novel therapies that target the RAS system, Smoyer said.

The CKiD study was established by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), in collaboration with the National Institute of Neurological Disorders and Stroke and the National Institute of Child Health and Human Development [Furth SL, Cole SR, Moxey-Mims M, et al.: *Clin J Am Soc Nephrol* 2006; 1(5):1006–1015].

Patients enrolled in the study undergo annual physical examinations that document characteristics such as height, weight, and blood pressure. Cognitive function, quality of life, nutritional, and behavioral questionnaires are also completed; glomerular filtration rates are measured; and samples of serum, plasma, urine, hair, and fingernail clippings are stored.

A number of analyses are being made with data from the CKiD study. Researchers hope to determine risk factors for progression of pediatric chronic kidney disease, to examine the impact of chronic kidney disease on neurocognitive development, to understand the impact of chronic kidney disease on risk factors for cardiovascular disease, and to learn about the impact of chronic kidney disease on growth.

"The CKiD study offers pediatric nephrologists an unprecedented opportunity to identify potentially modifiable factors that may enable them to reduce the progressive loss of kidney function in children and improve their quality of life," said Smoyer.

Conducting such analyses is important because the incidence of end stage renal disease in children in the United States is 14.4 per million people, according to the 2008 U.S. Renal Data System's Annual Data Report.

"The life expectancy of children with end stage renal disease is markedly compromised," said Wong. "Thus, any infor-*Continued on page 6*

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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

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Postmaster: Please send address changes to *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 and is published bimonthly. Periodicals Postage Pending at Washington, DC, and at additional mailing offices. Subscription rates: \$90 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.

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Willem Kolff: Honoring a pioneer of modern dialysis

illem Johan Kolff, MD, PhD, consummate inventor, doctor, researcher, and professor, died February 11 at his home in Newtown Square, Penn. Dr. Kolff saved millions of lives with his creation of the artificial kidney, which evolved into today's kidney dialysis machine. The Dutch-born doctor was 97.

"Dr. Kolff's accomplishments underscore the power of one. He identified unmet needs and thought big," said Lynda Szczech, MD, chair of the ASN Dialysis Advisory Group and associate professor of medicine at Duke University Medical Center. "His contributions were not just a piece of the pie, as so many of us strive to contribute. Dr. Kolff provided the pie plate and crust that are the vital supports for every nephrologist who follows him."

Dr. Kolff believed that technology and machines could advance medicine and treat disease. In 2002, he received the Albert Lasker Award for Clinical Medical Research for his development of kidney dialysis. Dr. Kolff was the lead designer of the first mechanical heart implanted in a human and a major contributor to the surgical pump oxygenator, now known as the heart-lung machine, which made open-heart surgery possible for the first time. He also invented the

intra-aortic balloon pump to help prevent heart failure. Other inventions such as an artificial ear and eye—were implanted in a few people, but were not successful enough to be mass produced.

Dr. Kolff began designing the artificial kidney at the University of Groningen in 1938, but moved to a small-town hospital to continue his work after Germany invaded The Netherlands during World War II. Dr. Kolff theorized that if a machine could replace the failing kidney for a few days to weeks, filtering out acid and waste materials from the blood, then the kidney tissue could regenerate and function again.

Using the restricted resources available during the war, Dr. Kolff created the first kidney machine from laundry tubs, a wooden drum, metal, a semipermeable sausage casing, and an electric motor. He filled the casing with blood, expelled the air, added the kidney waste product urea, and shook up the device in salt water. Small molecules of urea passed through the casing into the water, while the larger blood molecules stayed put.

Dr. Kolff's first several patients lived only a few days on the machine, but in 1945, the artificial kidney helped a woman live for seven more years. Dr. Kolff's improved machine worked well enough to treat acute kidney failure and end stage renal disease.

"As a pioneer in nephrology, Dr. Kolff has enabled us to save countless lives. I am grateful to Dr. Kolff for expanding the options I can offer my patients with end stage renal disease," said Mary (Tessie) Behrens, MD, chair of ASN's Practicing Nephrologists Advisory Group and a physician at Mid-Atlantic Nephrology Associates, PA, in Maryland. Today, more than 200,000 people in the United States in need of dialysis are living because of Dr. Kolff's



A patient is dialyzed using one of Kolff's first rotating drum artificial kidneys.

invention or a modification of it.

Dr. Kolff immigrated to the United States in 1950, where he worked at the Cleveland Clinic Foundation. Later, at the University of Utah, Dr. Kolff mentored Dr. Robert Jarvik, and together they created the Jarvik-7 artificial heart. Over the years, Dr. Kolff mentored many other pioneers in the artificial organ field.

Throughout his long and industrious career, Dr. Kolff held numerous distinguished titles, such as director of the Institute for Biomedical Engineering; professor emeritus of internal medicine, surgery, and bioengineering at the University of Utah; and founding member of the American Society of Artificial Internal Organs. He received more than 12 honorary doctorate degrees from universities worldwide and more than 120 international awards. He also wrote several books and published hundreds of papers and articles.

Dr. Kolff is survived by his five children, 12 grandchildren, and six greatgrandchildren.

Essay and Opinion

Amid Economic Crisis, NIH Seen as Source of Hope for Better Health and Fatter Wallets

S ince the National Institutes of Health (NIH) budget doubled between 1998 and 2003, advocates for medical research have faced an uphill battle maintaining federal support for innovative, lifesaving research. Congress failed to increase NIH funding for the past five years, leading to a 15 percent net decline in funding once inflation is considered. Success rates—the percentage of reviewed grants that receive funding in a given year—plummeted from a historic 30 percent norm to approximately 20 percent in fiscal year (FY) 2008.

As FY 2008 came to a close, NIH identified 14,000 meritorious applications that could not be funded due to insufficient budgets, according to NIH Acting Director Raynard S. Kington, MD, PhD. Although President Barack Obama promised during his campaign to "double budgets of key science agencies such as the National Institutes of Health . . . over the next 10 years," the nation's economic troubles had many advocates fearful for another difficult year arguing that additional funding for medical research is necessary if we are to find new treatments and cures for diseases affecting the American people.

As the nation's unemployment rate soared to 7.6 percent in January 2009 the highest level in 26 years—Congress publicly announced its dedication to passing legislation that stimulates the economy and encourages job creation. While Congress' economic focus could have deterred medical research advocates from making the case for a robust research enterprise, new economic data formed the backbone of a fresh lobbying approach. Advocates hammered the argument that an investment in research is an investment in new jobs, private business, and state budgets.

Families USA—a nonprofit organization dedicated to advocating for highquality, affordable health care—compiled data that support the argument that medical research not only improves the lives of the American people via better health outcomes, but by revitalizing state and local economies as well.

According to the report "In Your Own Backyard: How NIH Funding Helps Your State's Economy," NIH invested approximately \$22.8 billion in research to universities and research institutions in FY 2007. In turn, that investment spurred \$50.5 billion in new state business. In addition, NIH grants and contracts created 350,000 jobs that offered more than \$18 billion in wages. The average salary for those positions was \$52,000, almost 25 percent higher than the national average. These skilled jobs are key to addressing the economic crisis. According to Secretary-Treasurer for the Service Employees International Union Ann Burger, "We've

By Allison Haupt

got to create good jobs. Creating low-wage jobs is not going to do what we need to do for our families and our economy."

Each funded grant creates approximately seven jobs, according to NIH, but the economic value of NIH funding extends well beyond the individual research lab. "Awards help universities, medical schools, and other research institutions . . . expand their programs, to grow in reputation, and, in turn, to attract additional funding from other sources," states Families USA. According to the Association of American Medical Colleges, in 2005, its member medical schools and teaching hospitals had an economic impact of \$451 billion. In total, medical schools and teaching hospitals offered three million full-time jobs and contributed \$20 billion in state revenue. As state governments are reporting significant budget deficits-the Center on Budget and Policy Priorities reports that 41 states will face deficits in FY 2009 or 2010-academic investments may be one opportunity to support states in a way that offers long-term growth rather than a one-time, short-term fix.

NIH has also studied how research funding impacts the economy, particularly in the long term. The agency evaluated the outcomes of 31,144 grants awarded in FY 2000. These grants produced 30,477 invention disclosures, 17,341 nonprovisional patent applications, and 6909 patents, which inject additional money into local economies.

As an example of NIH's economic leverage on a smaller scale, Rutgers State University of New Jersey Professor of Biochemistry Joachim Kohn, PhD, explained to the House Energy and Commerce Subcommittee on Health in late 2008 how his \$4.5 million in direct NIH support "resulted in technology commercialization efforts in four start-up companies . . . which, over the last three years alone, have attracted almost \$120 million in private equity funding. As a consequence of these investments, these companies have created more than 100 high-salary jobs."

Partially in recognition of the economic benefits NIH research creates, the U.S. House of Representatives included \$3.5 billion for NIH research and infrastructure improvements in its economic stimulus package, initially passed January 28. Spearheaded by Sens. Arlen Specter (R-PA) and Tom Harkin (D-IA), the Senate countered the House's estimation of NIH's funding needs and dedicated \$10 billion for NIH over the next two years. According to Sen. Specter, "Including funding for the NIH in the Stimulus will provide needed economic stimulus, enable long-term economic growth, and save lives." During negotiations between the House and Senate, the research community's persistence—along with Sen. Specter and Sen. Harkin's steadfast support maintained the Senate's research allocation in the final bill, which was ultimately passed by the House and Senate February 13, and signed into law, February 17 (Table 1). Clearly, advocates of medical research were successful in making an economic argument for research funding.

Yet the accumulated data cited by advocates only illustrate tangible economic benefits such as new jobs, increased wages, and business activity. Many in the medical community recognize the long-term financial benefits that improved health care can bring. Medical research can uncover forms of prevention that reduce the number of people stricken by disease, thereby limiting health-care costs. Research can also identify treatments and cures that increase life expectancy and worker productivity. According to Kevin M. Murphy, PhD, and Robert H. Topel, PhD, improved life expectancy between 1970 and 2000 added \$3.2 trillion per year to national wealth. Murphy and Topel expect a permanent 1 percent decline in mortality from cancer to provide almost \$500 billion in wealth, while a cure would be worth approximately \$50 trillion.

Given the success of research advocates' efforts to include NIH funding in the stimulus package, advocates should con

tinue to promote the broader economic merits of medical research in relation to President Obama and Congress' push for health-care reform. Sen. Specter has already argued that "NIH is part of the solution to the long-term problems of health-care costs and U.S. competitiveness in health care." Advocates should encourage greater funding for comparative effectiveness research, additional support for health services research that assesses how to improve quality of care and reduce medical errors, and dedicated attention to research related to our nation's rampant health and health-care disparities.

First and foremost, advocates lobby for increased funding for medical research so suffering patients have hope for a future where they are not bridled by the limits of their diseases. But given the current political climate where economic value is the new metric for approval, advocates would be foolhardy to not continue to pursue an economic argument for investing in NIH research. Battling 26 million people's fight with kidney disease has encouraged some research funding. Battling 300 million people's need for effective, affordable health care may encourage sustainable research support.

Allison Haupt is research policy coordinator with ASN's policy and public affairs department.

Table 1 Health programs in the stimulus package

• \$10 billion for the National Institutes of Health (NIH)

- \$8.2 billion for research—\$800 million to the Office of the Director, \$7.4 billion to be distributed to the institutes and centers
- \$1 billion for "competitive awards for the construction and renovation of extramural research facilities"
- \$500 million for intramural facility repair and construction
- ✓ \$300 million for shared instrumentation and other equipment
- \$1.1 billion for comparative effectiveness research via the Agency for Healthcare Research and Quality, NIH, and the Office of the Secretary of Health and Human Services
- \$19 billion to support and encourage the use of health information technology in doctors' offices, hospitals, and other medical facilities
- In addition to funding, the legislation includes provisions that strengthen privacy protections on behalf of patients with personally identifiable health information
- \$2.5 billion for the National Science Foundation for basic research in fundamental science and engineering
- \$500 million for the Health Resources and Services Administration to bolster the flagging health-care workforce
- \$1 billion for prevention and wellness, including \$300 million for immunizations, \$650 million for community prevention programs, and \$50 million for reducing health-care-associated infections
- \$191 million to restore Medicare capital indirect medical education payments by retroactively reversing this year's 50 percent cut to teaching hospital payments

Legislators also urged President Obama to halt progress on implementation of former President George W. Bush's proposed Medicaid graduate medical education (GME) and intergovernmental transfer rules. The rules would restrict Medicaid financing of GME and set a cap on Medicaid reimbursements to hospitals operated by state or local governments.

Journal View

Benazepril-Amlodipine Reduces Cardiovascular Risk in High-Risk Patients

For high-risk patients with hypertension, benazepril plus amlodipine offers greater protection against cardiovascular events than benazeprilhydrochlorothiazide—despite similar effects on blood pressure, according to a report in *The New England Journal* of Medicine.

The industry-funded ACCOM-PLISH trial included 11,506 patients with hypertension with a history of or risk factors for cardiovascular events. One group received the angiotensinconverting enzyme inhibitor benazepril plus the calcium-channel blocker amlodipine. The other group received benazepril plus the thiazide diuretic hydrochlorothiazide. Patients were followed up for a composite endpoint of cardiovascular death, nonfatal myocardial infarction or stroke, hospitalization for angina, resuscitation after sudden cardiac arrest, and coronary revascularization.

The study was stopped early after 36 months. There was no more than a 1 mm Hg difference in systolic blood pressure between groups. However, the primary outcome rate was 9.6 percent with benazepril-amlodipine versus 11.8 percent with benazepril-hydrochlorothiazide, with a hazard ratio of 0.80. The benazepril-amlodipine group had a similar reduction in a composite endpoint of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke.

The results add to the evidence that benazepril-amlodipine combination can protect against end-organ damage, independent of the effect on blood pressure. "[O]ur findings may increase the options for combination treatment to reduce the risk of cardiovascular events among patients with hypertension," the ACCOMPLISH investigators concluded [Jamerson K, Weber MA, Bakris GL, Dahlöf B, Pitt B, Shi V, Hester A, Gupte I, Gatlin M, and Velazquez EJ, for the ACCOMPLISH Trial Investigators: Benazepril plus amlodipine or hydrochlorothiazide for hypertension in high-risk patients. N Engl J Med 2008; 359:2417-2428].

Good Outcomes with Sirolimus Combinations in High-Risk Transplant Recipients

Sirolimus, given with either tacrolimus or cyclosporine, provides good one-year efficacy in high-risk renal allograft recipients, reports a trial in *Transplantation*.

The randomized, open-label, multicenter trial included 448 renal allograft recipients with risk factors for rejection: black race, nonprimary transplant, or high panel-reactive antibodies. They were assigned to sirolimus plus tacrolimus or sirolimus plus cyclosporine.

One-year efficacy failure rates were 22 percent with sirolimus-tacrolimus and 23 percent with sirolimus-cyclosporine. Acute rejection rates were 14 percent and 17 percent, respectively; graft survival was 90 percent in both groups. In patients receiving their assigned therapy, the glomerular filtration rate tended to be higher with sirolimus-tacrolimus.

Other one-year outcomes were similar between groups. Sirolimus-tacrolimus

was associated with higher rates of diarrhea and herpes simplex. Other adverse events were more frequent with sirolimus-cyclosporine, including hypertension, calcineurin inhibitor toxicity, and increased creatinine.

It has been difficult to perform randomized trials evaluating outcomes in high-risk renal allograft recipients. This industry-sponsored study shows "equivalent benefit or risk" with the two sirolimus combinations studied, with no clear advantage of one regimen over the other [Gaber AO, Kahan BD, Van Buren C, Schulman SL, Scarola J, and Neylan JF, for the Sirolimus High-Risk Study Group: Comparison of sirolimus plus tacrolimus versus sirolimus plus cyclosporine in high-risk renal allograft recipients: results from an open-label, randomized trial. Transplantation 2008; 86:1187–1195].

Endothelin Antagonist Reduces Albuminuria in Diabetic Nephropathy

Treatment with the endothelin Aselective antagonist avosentan can reduce urinary albumin excretion in diabetic patients with macroalbuminuria, concludes a trial in the *Journal of the American Society of Nephrology*.

The Endothelin Antagonist Evaluation in Diabetic Nephropathy Study included 286 patients with diabetic nephropathy at 58 European centers. All had macroalbuminuria, with a urinary albumin excretion rate (UAER) of 0.2 to 5.6 mg/min, and blood pressure of less than 180/110 mm Hg. In addition to standard angiotensin-converting enzyme inhibitor and/or angiotensin receptor blocker therapy, patients were randomly assigned to 12 weeks of treatment with avosentan, 5 to 50 mg, or placebo.

All avosentan dosage groups had reductions in UAER: from 16 to 30 percent, compared with a 36 percent increase in the placebo group. Median relative reductions in UAER were 29 to 45 percent with avosentan, compared

CKD Awareness Is Rising, but Remains Low

Despite efforts to increase awareness, a large majority of Americans with chronic kidney disease (CKD) are still unaware of their disease, reports a study in the *Archives of Internal Medicine*.

Led by Laura C. Plantinga, ScM, of Johns Hopkins Bloomberg School of Public Health, Baltimore, the study included 2992 adults with stage 1 to 4 CKD from the National Health and Nutrition Examination Survey, 1999– 2004. Patients were asked whether they had ever been told they had "weak or failing kidneys."

Awareness of CKD increased during the study period only in patients with stage 3 disease: from 4.7 percent in 1999–2000 to 9.2 percent in 2003–04. For patients with stage 1 or 2 CKD, the rate of awareness was about half of that for those in stage 3. Even in stage 4, less than half of respondents were aware of their CKD.

Factors associated with awareness

to a 12 percent increase with placebo. Creatinine clearance and blood pressure were unaffected. Peripheral edema occurred mainly at avosentan doses of 25 mg or higher; the rate of adverse events leading to treatment discontinuation was 7 percent.

Studies in rats suggest that endothelin antagonists can reduce inflammation, renal fibrosis, and albumin excretion. Adding avosentan to standard therapy can reduce albumin excretion in patients with advanced diabetic nephropathy, this industry-sponsored study reports. Larger confirmatory trials are needed, including data on the optimal avosentan dosage and long-term benefits of treatment [Wenzel RR, Littke T, Kuranoff S, Jürgens C, Bruck H, Ritz E, Philipp T, and Mitchell A, for the SPP301 (Avosentan) Endothelin Antagonist Evaluation in Diabetic Nephropathy Study investigators. Avosentan reduces albumin excretion in diabetics with macroalbuminuria. J Am Soc Nephrol 2009; 20:655-664].

were assessed in 1314 patients with stage 3 CKD. Those with proteinuria or hypertension were about three times more likely to be aware of their disease. Rates of awareness were twice as high for diabetics and for males. Awareness was unrelated to having a regular site for health care, educational attainment, insurance status, or obesity.

Recent guidelines have emphasized the need for early detection and prevention of CKD. The new results suggest that awareness of stage 3 CKD has nearly doubled in recent years, but remains low. The authors urge more aggressive targeting of groups with low awareness of CKD, including older patients, women, and patients without diabetes or hypertension [Plantinga LC, Boulware LE, Coresh J, Stevens LA, Miller ER III, Saran R, Messer KL, Levey AS, and Powe NR: Patient awareness of chronic kidney disease: trends and predictors. Arch Intern Med 2008; 168:2268-2275].

CKD in Children

Continued from page 3

mation that can ultimately contribute to decreasing the progressive impairment of kidney function in those with chronic kidney disease or lessen the morbidity associated with the disorder is extremely important to the health of children."

In addition to Wong's research, other investigations based on data from the CKiD study have uncovered useful information about kidney disease in children. One recent analysis found that hemoglobin declines as glomerular filtration rate decreases in these patients. These results indicate that clinicians should be mindful of the potential for hemoglobin decline and anemia even at early stages of chronic kidney disease [Fadrowski J, Pierce CB, Cole SR, et al.: *Clin J Am Soc Nephrol* 2008; 3(2):457– 462].

Another project has characterized the distribution of blood pressure and the

prevalence and risk factors for hypertension in pediatric chronic kidney disease patients. Researchers found that characteristics associated with elevated blood pressure included black race, shorter duration of chronic kidney disease, absence of antihypertensive medication use, and elevated serum potassium [Flynn JT, Mitsnefes M, Pierce C, et al.: *Hypertension* 2008; 52(4):631–637].

Such research efforts will help shape

the future of kidney disease care in the United States. "Challenges for these and other investigators in the future are to design studies that directly engage in manipulation of modifiable factors such as RAS interventions, diet, body mass index, and other therapies to promote best retention of renal function in children with chronic kidney disease," Mahan said.

Good Responses to Rituximab in Severe Lupus Nephritis

Early B-cell depletion with rituximab may improve the long-term outcomes of severe lupus nephritis, suggests a French experience reported in the *Clinical Journal of the American Society of Nephrology.* Led by Catherine Melander, MD, of

Led by Catherine Melander, MD, of Hôpital Necker, Paris, the researchers analyzed the outcomes of 20 patients with severe lupus nephritis receiving induction therapy with rituximab between 2003 and 2006. Median followup was 22 months. Fifteen patients had active class III or IV lupus nephritis, while five had class V disease. Rituximab was given for refractory lupus nephritis in 12 cases, relapsing disease in six, and as first-line therapy in two. Three patients received concomitant cyclophosphamide; 10 received additional maintenance doses of rituximab.

Twelve patients achieved complete or partial renal remission, for a response rate of 60 percent. One case of relapsed lupus nephritis responded to repeated treatment with rituximab. The occurrence of B-cell depletion within one month after rituximab treatment was strongly associated with renal response—only one of 12 patients with early B-cell depletion did not have a positive renal outcome.

Black patients and those with hypoalbuminuria were less likely to have early B-cell depletion. Patients with rapidly progressive glomerulonephritis did not respond to rituximab.

Treatment with corticosteroids plus cyclophosphamide has improved the prognosis of lupus nephritis, but patients remain at risk of resistance, relapse, or adverse effects. Rituximab is an "interesting therapeutic option" for relapsing or refractory lupus nephritis, Melander and colleagues concluded. When early B-cell depletion is obtained, the renal response rate is very high [Melander C, Sallé M, Trolliet P, Balsam EG, Candon S, Belenfant X, Daugas E, Remy P, Zarrouk V, Pillebout E, Jacquot C, Boffa J-J, Karras A, Masse V, Lesavre P, Elie C, Brocheriou I, Knebelmann B, Noel L-H, and Fakhouri F: Rituximab in severe lupus nephritis: early B-cell depletion impacts long-term renal outcome. Clin J Am Soc Nephrol 2009; 4:579-586].

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First-Morning Versus Spot Urine to Assess Microalbuminuria

A first-morning void provides a more reliable measurement of urinary albumin excretion (UAE) than does a spot urine sample, according to a paper from the *Journal of the American Society of Nephrology*. Researchers compared the findings of 24-hour urine collections, first-morning voids, and spot urine samples in 241 men and women. The UAE was measured in the 24-hour collections, while urinary albumin concentration (UAC) and albumin:creatine ratio (ACR) were measured in the morning and spot samples.

Based on UAE measurement in 24hour urine collections, the prevalence of microalbuminuria was 10 percent. This was similar to the 7.5 percent rate in firstmorning void specimens, both on UAC and ACR. In contrast, tests in spot urine samples overestimated the prevalence of microalbuminuria: 25.4 percent for UAC and 22.4 percent for ACR [Witte EC, Heerspink HJL, de Zeeuw D, Bakker SJL, de Jong PE, and Gansevoort R: First morning voids are more reliable than spot urine samples to assess microalbuminuria. *J Am Soc Nephrol* 2009; 20:436–443].



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Trends in Medical Education

Climbing the mountain to dual fellowship

ttending the American Society of Nephrology (ASN) conference in November 2005 as a second year resident inspired me to pursue nephrology training upon finishing my residency in internal medicine-pediatrics.

Many of the fellowship directors I met breathed a sigh of relief knowing that I was more than two and a half years away from finishing my residency, saying, "We will have to work fast, but we can make it happen." Perplexed by this common theme, I could not fathom why the application process for a dual fellowship in both pediatric and adult nephrology would be "rushed" in order for this prospective graduate of June 2008 to enter a fellowship program without a gap in time.

Little did I know what an arduous journey lay ahead. Coordinating a dual fellowship in adult and pediatric nephrology would entail 62 applications, more than \$1000 in application fees, 15 vacation days to interview at 16 fellowship programs, a few thousand dollars of airfare, and one chief resident year buying extra time to make it logistically possible.

The journey started during my intern year when my chief resident sparked my interest in nephrology. She suggested nephrology because of my interests in procedures and in having varied experiences in outpatient clinics and critical care settings. She also knew my interests in developing long-term relationships with patients, as well as practicing in a field with intricate involvement with many other organ systems.

A pediatric nephrologist told me about the ASN meeting in Philadelphia in November 2005 and said it would be a great way to learn more about the field, network with nephrology fellowship directors, and discover cutting edge research.

In uncharted territory

Prior to attending the ASN meeting, I thought I would have to choose one fork in the road—either adult or pediatric nephrology—upon finishing residency and entering fellowship. My horizons broadened upon meeting one medicinepediatric nephrology fellow from the University of Michigan who was very encouraging about the field. Three fellowship directors from around the country were equally inspiring about making a career in medicine-pediatric nephrology work.

With adult nephrology fellowships lasting two to three years and pediatric nephrology fellowships lasting three years, I learned that a combined fellowship could be done in four years. Everything has to fall into place though. I spent an extra year (thanks to being chief resident) thinking about this extra lifetime commitment—almost like a marriage with a career field in uncharted territory.

How would I go about applying for two fellowships? There were very few people to ask for help because my residency program had only one pediatric fellow and a small number of internal medicine subspecialty fellows, none of whom were in nephrology. Of course. Fortunately, two of my chief residents in internal medicine had been accepted to nephrology programs on the East Coast. Plus, great mentors in both the pediatric and internal medicine nephrology divisions gave keen advice on where to apply.

One more feature of the 2007–2008 application cycle complicated entering a combined fellowship in July 2009. The adult nephrology fellowship programs were entering a match for the first time. Coordinating pediatric nephrology, which was not on a match, and adult nephrology, which was on a match, made this journey even more difficult.

I sought out all 31 pediatric nephrology fellowship programs that had a corresponding adult nephrology fellowship program at the same university and hoped for the best. Fortunately, they all used the Electronic Residency Application Service (ERAS), allowing me to save some time in applying by having one common application. I did have to line up eight letters of recommendation (four pediatric and four adult) and tell all authors to explain why I would be a good candidate for two fellowships. In order to be granted an interview, my personal statement had to connect with two fellowship directors in different fields. I had to explain that I was not some crazy guy who could not decide between children and adults, but rather a person who wanted to bridge the gap in care for children with chronic kidney disease as they enter adulthood.

Here was the difficult timeline: All fellowship programs could download my applications on December 1, 2007, through ERAS. The peds programs were motivated to fill their spots as soon as possible because this was being done outside the match. Due to its inaugural year as a match program, the adult programs had no idea how many people to interview to fill all of their spots in the match.

They did know, however, that time was on their side, with five months to interview candidates before a June 19, 2008, match. Having a pediatric program hold a spot for me until I could match with the adult counterpart on June 19 seemed like the impossible hurdle I would have to overcome to make this work. I soon learned that there was a much more

By Stephen Darrow

feasible approach. Foreshadowing the difficult process yet to come was the timing of interview invitations. Invites would come in from a pediatric division at one university and a medicine division at another. For the longest time, I was considering whether or not I would have to commute between two states, with a selling point if the two programs were at least in the same time zone! Then things started to work out. After endless emails, phone calls, checking of application status, and explaining what I wished to accomplish through two fellowships, the corresponding divisions offered me interviews to match the initial interview invitations. The next hurdle was scheduling interviews.

Trying to line up two consecutive interview dates—one with pediatric, the other with adults—was quite challenging. But, eventually it worked for almost all the programs I applied to. One school, which had previously accepted a combined fellow, actually was able to interview me for both fellowships on the same day—a very good sign that things could work out at this school.

Interviews Galore

Overall, I sat through 80 interviews, 80 times explaining why I was pursuing this career field. Some institutions were more receptive than others. Some became inspired by thinking outside the box. Others expressed concern that funding and logistics might not work out.

These challenges became quite apparent with the two-year adult nephrology fellowships. Who would cover all the second year of the adult fellowship? With my pursuit of only one year of adult clinical nephrology (followed by one year of pediatric clinical then two years of research), a gap in coverage year two would manifest. I realized that I would have a better shot at making this work if I pursued the threeyear adult nephrology programs (where fellows do one year of clinical and two research). The two years of research could then overlap naturally between adult and pediatric.

Most programs were very receptive to my joint fellowship idea and were courteous in allowing me to continue my personal timeline for interviews in January through early April. After that, however, it was all waiting and hoping. It was difficult getting a sense of how things were going.



During residency, I trekked to a 15,000-foot mountaintop to see the lost ruins of Machu Picchu. The trek to my fellowship was a lot longer, more costly, and with many more bumps in the road. —Stephen Darrow

With the match limiting how much feedback an adult nephrology program could give an applicant, it was like playing poker with the best players. I had decided by that point that the only way a combined fellowship might work out would be to accept a pediatric nephrology fellowship for year one then hope that the corresponding adult program would save a spot outside the match for me a year later. Fortunately, offers came that were even more promising. I was accepted into a pediatric nephrology program for the first year with the corresponding adult division agreeing in advance to hold a spot for me outside the match for year two.

During residency, I trekked to a 15,000-foot mountaintop in the Andes Mountains to see the lost ruins of Machu Picchu in Peru. The trek to my fellowship was a lot longer, more costly, and with many more bumps in the road. I heard on the interview trail that there were possibly two other medicine-pediatric grads pursuing this same goal. If you are out there, look me up at the University of Minnesota. We can all share stories about our journeys.

Stephen Darrow received his MD from Loyala University in Chicago and has completed internal medicine and pediatrics training at Creighton University and the University of Nebraska Medical Centers. He will begin his combined fellowships at University of Minnesota in July 2009.

Policy Update

Medicaid Spending in the States: Do You Know Your Specialty Code?

By Caroline Jennette

id you know that you may be listed as a urologist or an internist when you bill for Medicaid? Looking at Medicaid provider enrollment applications in 48 states (two do not have accessible applications), only 20 states have unique specialty codes for nephrology. Among these, only six have unique provider codes for pediatric nephrology.

Why is this important? According to the Center on Budget and Policy Priorities, 44 states face budget shortfalls in fiscal years 2009 and 2010 totaling more than \$350 billion. Medicaid expenditures, shared by both state and federal governments, add a significant burden to state budgets. This is especially true during periods of high unemployment, as more people lose their employersponsored health coverage and turn to state health plans for assistance (1).

Medicaid directors report that program enrollment and spending trends are already well above earlier fiscal year 2009 projections, with state cutbacks and decreases in Medicaid reimbursements to providers almost inevitable in the current economic setting (2). Containing costs requires that states be able to identify their expenses, and an important part of doing so is understanding Medicaid health-care expenditures within specialty services. Unfortunately, for many states, this is no easy task. The Centers for Medicare and Medicaid Services (CMS) does not have a standardized Medicaid code for physician specialty, leaving it to the discretion of states to apply and define codes as they choose, with many not using specialty codes at all.

Nine states specifically ask for National Provider Identifiers (NPI), the required CMS code that includes a standardized specialty taxonomy, which does include a code for nephrology and could be linked to state Medicaid claims. However, the success of using the NPI to analyze cost data is not yet known. Some early reports suggest that these codes are not ready to be used as a reliable tool for data collection and analysis. According to one source, these codes are frequently entered incorrectly or not at all, leading to coding and data entry errors that are, in turn, not well-enforced by lead agencies.

The majority of states have a "writein" column for listing physician specialties, which may or may not be assigned a specific code in the state Medicaid database. Most state applications have a spot to fill in a provider's Medicare number, which could be linked to Medicaid codes (Medicare numbers use a specialty code for nephrology). However, only three states explicitly require a Medicare provider number on applications, and it is unclear whether state departments actually use the Medicare specialty code to look at cost data.

In order for states to create cost-saving initiatives for Medicaid programs, it is important that they have data available to understand what is being billed, by whom, and for what diseases. Itemizing expenditures by specialty code would play a crucial role in figuring out ways to reduce costs by allowing investigation of expensive or highly used codes by specialty.

Although Medicaid data are already being collected through CMS's Medical Statistical Information System (MSIS) for other metrics, creating unique, standardized Medicaid provider codes for specialties would be a way for CMS and individual states to easily pull procedure and cost data by provider type. It is important that state health policy researchers, especially those looking at specific types of providers, find out how specialty care and its associated fees affect state Medicaid costs. Many states do not yet understand what those costs are, and using specialty codes would allow data system analysts to more quickly pull cost data for policy researchers.

Having the knowledge to educate state policymakers on the role of nephrologists in the Medicaid cost system will provide a gateway to understanding the impact of kidney disease on state healthcare costs. This type of knowledge can, in turn, lead to insights into how policy could help manage Medicaid costs for nephrology and, similarly, be evaluated for other specialty services.

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

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Dialysis: Change is Online

Speaking Up About a Silent Killer



this special section.

Kidney Disease Poses a Big Challenge, but Dialysis Gives Me Hope for the Future—A Patient's Perspective

Arlington, Virginia, science writer Frank Sietzen, Jr., described his experiences as a dialysis patient in this article in The Washington Post, published July 22, 2008.

By Frank Sietzen, Jr.

Three times a week, in a plain red-brick building near the Pentagon City mall in Arlington, a machine keeps me alive.

It looks much like a small filing cabinet festooned with hoses and a cranking pump that squeaks as it turns. The machine performs a cleansing of my blood called hemodialysis ("hemo" meaning "blood," "dialysis" meaning "passing through"), replacing some of the function performed by healthy kidneys that I lost to disease.

Between the time spent on dialysis and other hours devoted to related testing, I reckon I've lost about a third of my life. My focus, though, is on the 65 percent that's left.

An estimated 26 million American adults live with kidney disease, according to a recent study in the *Journal of the American Medical Association*. District residents are disproportionately affected: For example, zip code 20019 in Southeast Washington has 1,369 new cases of end stage kidney disease per 100,000 residents, 44 times the national average, according to the National Minority Quality Forum, an organization that collects data on racial and ethnic health disparities.

More than 341,000 Americans undergo regular dialysis treatments, and more than 75,000 of them are waiting for a kidney transplant, according to the National Kidney Foundation; the estimated cost to Medicare, private insurers, and patients for dialysis, transplants, and treatment is \$32 billion a year.

There's no denying dialysis is a drag, but not all of the changes brought about by my disease have been negative. Kidney disease has made me more aware of other people's problems and the need for better communication on health issues. At middle age, I was reluctant to learn a new field. But now, at age 56, I'm motivated to help people get early treatment and delay the onset of this disease.

Hoses on the machine lead to a pair of 15-gauge needles that nurses have stuck into my arm and taped into place. The needles take blood from a fistula—a surgical joining of a vein and an artery—for cleansing and then return it for distribution throughout my body.

What my kidneys used to do on their own now falls to a cylinder that contains an acidic brew to help remove waste products from my blood. A mixture of bicarbonate and pure water blends with chemicals to keep electrolytes and minerals in my blood at levels chosen by my doctors. The exact mix is unique to each patient.

The machine beeps and buzzes, R2D2-like, as it monitors the flow of blood. For me, sitting in a green reclining chair, what begins in a brief flash of pain as the nurse inserts the needles quickly becomes a battle with boredom. I'm attached to that machine for four hours at a stretch.

The dialysis process doesn't substitute for everything done by healthy kidneys. I must limit my consumption of some foods, such as potatoes and broccoli. Too much calcium from dairy products would damage my bones and heart. But not protecting my bodily stores of calcium could also be a problem. At every meal I take pills that keep my body from digesting the phosphorus in my food, which could leach calcium and weaken my bones.

My diet is now rich in foods I once ignored: fresh fruit and vegetables, fish, and rice. My last pizza was in 2006, a lifetime ago. Instead of Key lime pie, I eat a bowl of berries.

I must also control how much liquid I consume. If the machine removes too much fluid during a session, I could face extreme fatigue and muscle cramping. But leaving too much fluid could cause congestive heart failure. Without regular dialysis or a kidney transplant, I would live a few weeks at most, doctors tell me.

Diabetes, high blood pressure, heart disease, vascular disease, or a family history of kidney disease puts a person at risk for kidney problems, according to the National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK. I had three of those five factors when my kidney disease was diagnosed in 2007. My doctors initially treated me with medication and diet. But eventually, my kidneys failed; dialysis and transplant were the only options left to keep me alive.

In a sense, chronic kidney disease is a silent killer stalking large parts of the population. The Congressional Kidney Caucus estimates that 80,000 people die each year, making it the ninth-leading cause of death in the country.

Blacks are particularly at risk. Half of the country's African American population has at least one risk factor for kidney disease, according to an April 2008 report in the *American Journal of Kidney Diseases*; 30,000 reach end stage kidney disease every year, a rate four times greater than for whites. But less than 3 percent of African Americans consider kidney disease a top health concern, the study found.

The ultimate solution for failed kidneys is to get a new one. Last December I spent half a day undergoing tests to be approved for the transplant list. Nurses took a dozen samples of my blood—ouch! Once each month I must send new blood samples. More tests, including yearly stress tests, are required later to show that my heart could withstand the surgery.

The Kidney Foundation estimates that 1,177 Washington area patients are waiting for a kidney along with me; nationwide, an estimated 17,000 kidney transplants were performed in 2005.

There are days when the management of my many illnesses can seem overwhelming. The probability of survival one year after beginning dialysis, according to the

NIDDK, is 78.3 percent. After five years, that rate drops to 32.1 percent. After a decade on dialysis, the survival rate is 10 percent, according to a study of patients from 1995 to 2005.

I'm hoping to beat the Washington area's average wait—five to seven years—for a kidney transplant. I'm hoping to beat the Grim Reaper, too.

Life with kidney disease isn't easy. But it is a life well worth living. 🔴

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NKF's Kidney Early Evaluation Program Expands

By Adam Whaley-Connell



The National Kidney Foundation's (NKF) Kidney Early Evaluation Program (KEEP) provides comprehensive health risk appraisals to assess kidney function and key risk factors for chronic kidney disease (CKD), including hypertension and diabetes. Since 1997, this rapidly expanding program has screened more than 125,000 individuals. About 20,000 people were screened in 2008 alone.

The approximately 26 million American adults with CKD comprise a population with significant co-morbidities associated with diabetes and hypertension. Unfortunately, the cumulative effects of these co-morbidities—including secondary hyperparathyroidism, anemia, and cardiovascular disease have been found to heighten awareness of CKD at later stages (stages 3–5), when it may be too late for preventive programs such as KEEP to be use-



ful. These findings will be highlighted at this month's NKF Spring Clinical Meetings in Nashville, Tenn., and will be published in the *American Journal of Kidney Diseases*.

"Most of the 26 million adults who are living with CKD in the United States are not even aware that they have it. In fact, our data show that less than 10 percent of KEEP participants with evidence of CKD were aware of the disease," said Joseph Vassalotti, MD, chief medical officer at NKF. "Earlystage CKD can be difficult to diagnose because symptoms are not usually apparent until the disease progresses to near kidney failure. Yet research shows that treating kidney disease earlier may help improve outcomes."

To gauge KEEP's effectiveness at eliciting patient action upon learning of their health status, 72,000 participants in KEEP events were mailed a follow-up questionnaire. Nearly 30 percent responded. Seventy-one percent of those who responded said they saw a physician within three months of participating in KEEP. Participants were more likely to see a physician if they were diagnosed with CKD, and the tendency to follow up with a doctor increased as kidney function declined.

Data from KEEP suggest that hypertension, diabetes, and cardiovascular disease are more prevalent in the CKD population than in the general population and that early identification is associated with improved follow-up. Individuals diagnosed with such lifethreatening conditions were more likely to pay a visit to their doctors after participating in KEEP.

Among those diagnosed with hypertension, 50 percent started monitoring their blood pressure and taking prescription medication, and nearly 17 percent adjusted their diets within three months of participating in KEEP. Among those who learned they had diabetes through their participation in KEEP, 34 percent adjusted their diets, 40 percent began taking prescription medication, and 50 percent began monitoring the levels of glucose in their blood.

"These findings show that efforts to screen people at risk for disease can boost communitywide health," said Allan J. Collins, MD, director of KEEP's data coordinating center and immediate past president of NKF. "Once people learn they are at risk or already have kidney disease, high blood pressure, or other deadly diseases, they will go to the doctor and take the medications they need to survive. Simply put, these findings show that community screening programs such as KEEP do work as a wake-up call to participants."

Peter McCullough, MD, a cardiologist and vice chair of the KEEP Program, was quoted on National Public Radio in 2007: "Most people know their cholesterol numbers but are completely unaware of their kidney function or microalbumin (kidney damage indicator) results. Furthermore, most individuals are caught by surprise when they learn that a subtle decrease in kidney function can contribute to heart disease."

In 2008, KEEP launched a longitudinal component to strengthen and broaden its programs. The new patient follow-up initiative has two primary objectives: first, to assess past participants for improvements in health outcomes, and, second, to arm community health-care providers with outcomes data based on patients' ongoing results from the KEEP follow-up.

KEEP is also expanding its activities beyond comprehensive kidney screenings to increase the program's impact on national health initiatives such as those for obesity and diabetes. This initiative will extend KEEP screenings into new geographic regions, with a focus on areas with large populations of at-risk individuals, including minorities, who have a higher incidence of the disease. Public awareness activities at individual KEEP screenings will be enhanced. "KEEP is the preeminent screening program for CKD that is helping unite the medical community, state and federal governments, and advocacy groups around addressing the increasing prevalence of CKD, particularly within minority communities where the need is greatest," said Preston Klassen, executive director of global nephrology development at Amgen.

According to U.S. Rep. Mark Kirk (R-III.), co-chair of the Congressional Kidney Caucus, "Early detection and increased awareness of chronic kidney disease and its causes are essential to helping stem the growing prevalence of the disease that we've seen in recent years. KEEP plays a key role in helping us reach that goal."

The KEEP Program stands as an excellent example of a medical society working through local affiliates to improve community health through screening and detection. KEEP builds improved awareness and knowledge about this very common form of disease.

Disclosures: Funding for KEEP is provided by Amgen, Abbott Renal Care, Genzyme, Novartis, and Genentech. Additional support is provided by Lifescan, OceanSpray, and Suplena.

Acknowledgments: Peter McCullough, MD, consultant cardiologist and chief of the division of nutrition and preventive medicine at William Beaumont Hospital in Royal Oak, Mich., and George L. Bakris, MD, FASN, of the University of Chicago Pritzer School of Medicine, contributed to this article.

Adam Whaley-Connell, DO, FASN, is assistant professor of medicine in the department of nephrology at the University of Missouri-Columbia School of Medicine and is with the Harry S. Truman VA Medical Center in Columbia, MO.

NKF Offers Free Screening, Education on World Kidney Day

In recognition of the worldwide significance of kidney disease as a public health problem, the 4th annual World Kidney Day is March 12, 2009. The National Kidney Foundation will lead U.S. activities for World Kidney Day designed to build kidney disease awareness and to educate those at risk about the importance of early detection and the critical role the kidneys play in maintaining overall health. To make early detection of chronic kidney disease as easy as possible, the foundation is offering more than 50 free kidney screenings through KEEP around the United States on World Kidney Day and throughout the month of March.

For locations and schedules, visit www.keeponline.org.

TIME FLIES WHEN THERE'S A DEADLINE

Need for Certification of Dialysis Patient Care Technicians Draws Near

By Suzann VanBuskirk



The clock started ticking for dialysis providers when the new Conditions of Medicare Coverage for ESRD facilities became effective October 14, 2008. Since the new regulations were published on April 15, 2008, dialysis pro-

viders have scrambled to put new processes in place to address changes the Conditions bring to patient safety, patient care, and administration in outpatient dialysis facilities. However, addressing the new requirements for training and certification of patient care technicians (PCTs) may have been deferred because the deadline of April 15, 2010, for certification of PCTs employed on the effective date of the new Conditions loomed far into the future relative to all other changes.

But facility leaders don't have as much time to address these changes as it seems. Nor are facility leaders the only individuals who should be concerned about the changes. Dialysis PCTs comprise a large proportion of the staff at outpatient dialysis clinics. Should a high percentage of PCTs fail to meet the training and certification requirement of the new Conditions by the target deadline, daily operations in these facilities could be curtailed and patient care may suffer. Therefore, all members of the interdisciplinary team should understand the importance of the dialysis PCT certification requirement and be actively involved in plans to ensure that each PCT is successful in achieving the requirement.

History of the dialysis patient care technician

During the 1980s, hiring of unlicensed assistive personnel grew in acute care hospitals and chronic care facilities as cost containment measures were put into place to stem the rising cost of health care. As the shortage of licensed nurses grows, use of these caregivers continues to expand—as does the variety of tasks delegated to them.

State boards of nursing and other regulatory bodies joined professional organizations and consumer groups to call for federal regulations for nursing homes and home health agencies to ensure that these unlicensed assistive personnel receive appropriate training, are supervised by the licensed nurse, obtain and maintain state-regulated credentials, and work within defined, acceptable staff mix and ratios (1).

When the original Conditions for Coverage were published in 1976, dialysis technicians were an "emerging occupation." Nurses provided much of the dialysis treatment, typically at ratios of one nurse to two patients. Today, dialysis PCTs are the primary caregivers of the dialysis treatment. It is accepted that a technician provides dialysis treatments to three or four patients at a time.

Until the new Conditions were published, there were

no federal requirements for dialysis technicians, except for reuse technicians, who are covered by American Association of Medical Instrumentation (AAMI) guidelines (2). The regulation impacts more than 30,000 PCTs, working full-time and part-time, in dialysis facilities throughout the country, based on 2006 U.S. Renal Data System Provider Characteristics (3).

Prior to the publication of the new Conditions, as many as 15 states regulated the dialysis PCT by establishing minimum qualification requirements, mandatory competency testing, registration, licensure, or certification, so some dialysis facilities and PCTs meet the new criteria. However, ambiguity exists in some regulated states as to whether the competency testing satisfies the new requirements even though the final version of the interpretive guidelines for surveyors has attempted to clarify this: "If the state has a certification and competency testing program (which includes standardized tests reflecting the content listed in the regulation, administered in a proctored environment unrelated to any dialysis facility) in place that is specific to dialysis PCTs, then State certification also satisfies this requirement. If a PCT is currently certified, as described, to practice by the State in which he or she is employed as a PCT, then he or she meets the requirements at 42 CFR 494.140(e)(4)" (4).

A word of caution

Certification of PCTs will not replace the need to comply with state-specific laws, regulations, statutes, rules, and practice standards for the nephrology specialty that regulate the practice of each licensed member of the interdisciplinary team and their delegation to others. The relationship between the licensed nurse and the PCT, as outlined in the scope of nursing practice and delegation guidelines, does not change as a result of PCT certification.

In addition, the need for the individual PCT to take responsibility for obtaining and maintaining certification, including documentation, is essential and should not be understated. Most dialysis PCTs have years of experience and are very effective at providing the dialysis treatment, but many may be concerned with one or more of the following:

- It may have been years since they have had to take a formal test.
- Their training may fall short of the required curriculum and may not even be documented as it was conducted "on the job."
- The requirement of formal continuing education as a condition of recertification may strain their financial resources and time commitments.

Your facility's plan to meet the requirement should address these areas of individual concern.

What are the changes?

The new requirements for PCT training and certification set forth in 42 CFR 494.140(e)(4) include:

- high school diploma or equivalency.
- · completion of a training course approved by the

medical director and governing body, under direction of RN, with content specifically described in the Conditions.

 certification by a state or national program: PCT employed by Oct. 14, 2008, must be certified by April 15, 2010. PCT employed after Oct. 14, 2008, must be certi-

fied within 18 months of hire (5).

Get started now

The following step-by-step guide is offered to help ensure that PCTs in your facility will be ready to meet the new requirements for dialysis PCT training and certification.

- Determine whether your state has requirements for dialysis PCT training and certification. If certification is required, is a specific examination required following training? You should consult with your state's regulatory bodies who have been working with CMS to clarify the use of certification and competency testing programs.
- 2. Evaluate your current dialysis PCT training program to ensure it includes the required subjects (Table 1) and modify accordingly. The Core Curriculum and the Kidney School materials described elsewhere in this article are excellent resources for your training program. They are available by Internet download at low cost, and could be used as standalone training manuals if these are lacking.

Table 1

Required subjects for dialysis PCT training programs

Principles of dialysis

- Care of patients with kidney failure, including interpersonal skills
- Dialysis procedures and documentation, including initiation, proper cannulation, techniques, monitoring, and termination of
- dialysis Possible complications of dialysis
- Water treatment and dialysis preparation
- Infection control

Safety

- Dialyzer reprocessing, if applicable
- Source: 42 CFR Parts 405, 410, 413 et al. Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities: Final Rule Subpart D – Administration 494.140 Condition: Personnel qualifications; (e) Standard: Patient care dialysis qualifications.

CHECH ITON



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2. KDOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. http://www.kidney.org/professionals/kdoqi/guidelines_ckd/p6_comp_g8.htm. Accessed March 12, 2008.
3. National Kidney Foundation. KDOQI clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease. *Am J Kidney Dis.* 2006;47(5 suppl 3):S11-S145.

early and often

- More than 50% of anemic CKD patients have iron deficiency¹
- KDOQI[™] guidelines recommend monitoring TSAT, ferritin, and hemoglobin as early as CKD Stage 3^{2,3}
- Regular monitoring of TSAT and ferritin along with hemoglobin is a critical part of optimal anemia management

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Certification

Continued from page 13

- 3. Review and update the dialysis PCT job description to incorporate the existing state requirements and new federal regulations. Have each dialysis PCT sign and place into the personnel record.
- 4. Review the employee records of the PCTs to:
 - determine high school graduation, GED, or four years of experience working as a PCT (if employed on Oct. 14, 2008) prior to applying for a certification exam.
 - ensure that documentation of dialysis training exists. Complete missing information. If a PCT employed for more than two years of the effective date of the regulations does not have documentation of having completed a training program, "competency may be demonstrated by successful completion of a facility's written exam(s) over the required content and a skills checklist completed by observation of the PCT's skills by a registered nurse (6)."
- 5. Identify the certification exam options best suited for the PCT in your facility. There are currently three options (see Table 3 for a summary of exam options and Table 2 for web resources). Read each option carefully and recognize that you may choose to use more than one exam for your facility, although there

Table 3

National certification exams

The three national certifying bodies have made changes to their eligibility requirements in response to the new Conditions. These organizations may make additional modifications over time, so readers are encouraged to confirm information with the cetifying agency. are obvious benefits to choosing one exam.

- 6. Assess each PCT to determine who may be at risk of failing the examination. Several certifying bodies offer sample tests for free or for a nominal fee. The 2007 Amgen Core Curriculum for Dialysis Technicians provides tests and posts test answers for the eight Learning Modules. Facility leaders could assign PCTs to study the content of specific modules in which low scores were obtained or designate volunteer facility "tutors" to review the content of modules identified by low scores.
- 7. Determine what the facility policy will be for failure of the PCT to meet the eligibility requirements to apply for and successfully pass the certification exam. Dialysis facilities operate on narrow profit margins and cannot afford to keep on the payroll dialysis PCTs who cannot fulfill their intended role.
- 8. Communicate information to facility dialysis PCTs in writing or during a special meeting. Emphasize the importance of the dialysis PCT in assuming personal accountability to ensure that certification is obtained. Address issues such as who will pay for the cost of taking the initial test or repeat exam if the individual does not pass the initial test, the ongoing cost of recertification, and the consequences of failure to meet the April 15, 2010, deadline for certification of PCTs working as of Oct. 14, 2008.
- 9. Establish the last week of August 2009 as a dead-line for the PCT to apply to sit for the certification exam. This deadline takes into consideration the fact that the "application-results cycle" could take up to 16 weeks (application deadlines are seven to 10 weeks prior to the exam dates and written results are received by the applicant within four to six weeks from the exam date). If the individual is unsuccessful in passing the initial exam, there is sufficient time for the individual to apply for a retest and to receive

the examination results before the April 15, 2010, deadline.

- 10. Collaborate with interdisciplinary dialysis team members of your facility and other facilities in your area or local chapters of professional nephrology organizations such as the American Nephrology Nurses Association (ANNA), the NKF Council of Dialysis Nurses and Technicians, the National Renal Administrators Association, and the National Association of Nephrology Technicians (NANT) to present a review course and investigate the requirements for "hosting" an exam site in your community. Investigate the availability of computer-based testing offered by two of the certifying organizations.
- 11. Obtain an "acknowledgment of understanding" and a "commitment date to register for the initial exam" completed and signed by each PCT as early as possible.
- 12. Monitor the progress of each individual and post a summary in a public area, such as a staff lounge.
- 13. Celebrate milestones and success. Consider making a contest with a nice prize for the dialysis PCT who is first to bring in evidence that he or she has completed certification.
- 14. Make new name tags for PCTs, once certified, to include the new certification credentials and make a "ceremony" of presenting the new name tags in the presence of patients and other facility staff.
- 15. Use the certification process as a springboard to encourage participation in professional associations such as NANT and the NKF Council of Dialysis Nurses and Technicians. Identify materials, resources, and local meetings that can provide continuing education and contact hours. It is never too early to begin the process of meeting requirements for recertification.

Certification	Certifying agency	Eligibility requirements	Fees
Certified clinical hemodialysis technician (CCHT)	Nephrology Nursing Certification Commission (NNCC)	 A minimum of high school diploma or equivalent. If lacking for PCTs working as of 10/14/08, will accept 4 or more years of documented dialysis technician work experience. Successful completion of training program and supervised clinical experience. 6 months clinical experience recommended (not required); signature of preceptor or supervisor required verifying training/ clinical experience. Compliance with state requirements for practice of hemodialysis patient care technician (HPCT). 	Exam: \$150 Late fee: \$50 Recertification: \$75 Late fee:\$50
Certified hemodialysis technician/ technologist (CHT)	Board of Nephrology Examiners Nursing and Technology (BONENT)	 High school diploma. Current active participation in an ESRD facility or successful completion of an accredited dialysis course approved by the BONENT Board. 12 months of experience in nephrology patient care. 2 signed letters of reference with application. Note: applicant has 3 opportunities to pass exam within 12 months of first exam; failure to pass requires attendance/ completion and evidence of participation in a nephrology educational program. 	Paper/Pencil Test 1st Exam: \$200 Repeat: \$160 Computer-based test (CBT) 1st Exam: \$225 Repeat: \$185 Recertification: \$55 per year or \$200 for 4 years, in advance
Certification in clinical nephrology technology (CCNT)	National Nephrology Certification Organization (administered by the Professional Testing Corporation)	 Minimum of high school diploma or the equivalent. Minimum of one year full-time or the equivalent (2000 hrs) experience in nephrology technology OR completion of at least a one-year educational program in nephrology technology. Note: there is no limit to the number of times the test may be taken; exam fees apply with each attempt. 	Exam: \$245 (includes \$50 for computer- based testing) Test center is selected after applicant registers for the exam.

16. Institute a plan to incorporate all the changes above to hire the right individuals without dialysis experience to work as dialysis PCTs in your facility after October 14, 2008. Focus on the minimum educational requirement, the expectation of completion of the facility training program, and the successful completion of national certification within 18 months of the date of hire. Screening tools to assess the ability of the new hires to comprehend didactic material, to transfer this basic training into clinical practice, and to pass the certification exam should assist in the selection of the right individuals for dialysis PCT positions who will be successful and add value to your facility.

Conclusion

Although it may seem a daunting task to work through the changes brought about by the new Conditions, with a proper attitude about the rationale for the changes and a timely, well-thought-out plan, the requirement for dialysis PCT certification can be viewed as an opportunity to improve the value of a precious asset in the outpatient dialysis facility . . . the growth and development of the dialysis PCT.

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Suzann VanBuskirk, RN, has been a registered nurse for 36 years and a nephrology nurse for 31 years in all regions of the country, working as a staff nurse, educator, developer of new markets, and multisite manager of chronic, home, and acute dialysis programs. She is currently a nephrology nurse consultant and owns VanBuskirk Consulting, LLC, working to implement solutions to clinical and operational challenges in dialysis facilities.

Table 2

Web resources

- Conditions for Coverage for End Stage Renal Disease Facilities: Final Rule www.cms.hhs.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf
- End Stage Renal Disease (ESRD) Program Interpretive Guidance Version 1.1 www.cms.hhs.gov/EOG/downloads/EO%200526.pdf
- American Nephrology Nurses Association (ANNA) www.annanurse.org
- National Kidney Foundation (NKF) www.kidney.org
- Council of Nephrology Nurses and Technicians
- www.kidney.org/professionals/CNNT/
- National Association of Nephrology Technicians/Technologists (NANT)
 www.dialysistech.net
- National Renal Administrators Associations (NRAA) www.nraa.org
- Medical Education Institute (MEI) Core Curriculum for Dialysis Technicians www.meiresearch.org/CoreCurriculum/index.php
- Kidney School www.kidneyschool.org
- Nephrology Nursing Certification Commission (NNCC) www.nncc-exam.org
- Board of Nephrology Examiners Nurses and Technicians (BONENT) www.bonent.org
- National Nephrology Certification Organization (administered by the Professional Testing Corporation) (NNCO) www.ptcny.com/clients/NNCO/index/html

Recertification	Computer-based testing (CBT) available?	Other	Registration deadlines/results
 Must be CCHT. 2 years with minimum of 2000 hrs worked as HPCT. 20 contact hours of "hemodialysis-related continuing education" during recertification period. 	No	 Online 50-question practice exam for \$30. ESRD facilities and ANNA chapters can apply to "host" an exam. Exam sites posted on website. 	 Registration for an exam required 8 to 10 weeks prior to exam. Results via mail 4 to 6 weeks following exam.
 4 years. 40 hours of contact through a specified combination of 6 types of study (Groups A – F) OR Retake the examination. 	Yes; requires separate registration after application approval received.	 Online 50-question practice exam for \$50. Organizations can apply to host an exam. PPE sites and CBT locations posted on website. 	 Registration for an exam required 45 days prior to exam. Unofficial score and pass/fail at end of CBT. Official results for PPE and CBT sent via mail 3–4 weeks following exam.
 Certification recognized for 4 years, at which time candidate must: Retake and pass the current exam OR Meet alternative requirements in effect at the time in order to retain certification. 	Yes, CBT is the only available option for taking the exam at LaserGrade testing centers.	 Online tutorial and sample test available at www.lasergrade.com. 	 Application must be submitted at least one month prior to preferred testing date. Unofficial scores at completion of CBT; official results via mail 4 weeks following exam.

GoingHOME

All Patients Should Have the Opportunity for Home Dialysis . . .

By Jennifer Fillaus and Troy Plumb



Few chronic diseases require the patient commitment and lifestyle alterations that end stage renal disease does. Patients on dialysis have significant dietary restrictions and require a multitude of medications. In-center hemodialysis (HD) schedules are inflexible and require time commitments in excess of 12 hours per week. The inflexibility of in-center HD clearly affects the ability of patients to care for sick children and spouses, work, go to school, and greatly limits their ability to travel.

Chronic kidney disease requiring dialysis not only impacts patient morbidity and mortality but also overall satisfaction with care and quality of life. With this in mind, we need to more closely examine opportunities that may improve our dialysis patients' quality of life. Home dialysis is one such opportunity. Although patients without treatment partners may have physical impairments that exclude them from home dialysis, low educational level or nonadherence to in-center HD should not disqualify them as candidates for home therapies.

There is no clear difference in mortality among patients on in-center HD, peritoneal dialysis (PD), and home HD, so patient preference should dictate the modality of treatment. One of the major barriers to home dialysis is education or lack thereof—regarding home therapies. Many patients just beginning dialysis have not had prior care by a nephrologist. These patients start HD in the hospital and are not educated about the possibility of home therapies. Many of them continue incenter HD unaware

that home dialysis is a possibility. It is important to discuss home therapies with patients already receiving in-center HD. In our centers, we discuss home dialysis opportunities with patients during dialysis rounds. In addition, nurses from the home training department provide quarterly home dialysis education programs in the lobby of our dialysis units.

Education regarding opportunities for dialysis at home is crucial. Patients who are more informed about home dialysis tend to choose PD over in-center HD. PD patients report improved satisfaction with their overall care and believe that their treatment has less impact on their lives than do in-center HD patients. PD patients also report feeling better and having increased independence and flexibility in treatment schedules (1,2). One of the key factors in treatment satisfaction is patient choice. Those patients who are informed and actively involved in medical decision-making are more likely to adhere to their treatment and thus gain the full benefit of the therapy (3,4).

Home HD patients report similar improvements in quality of life, including improved depression scores and improved recovery time following HD (5). Heidenheim et al. reported that patients on home HD experienced such great improvement that they would continue the therapy even if it were proven to shorten their survival (6). In-center HD patients

often experience side effects of large volume shifts such as excessive thirst, pre-dialysis dyspnea, intradialytic hypotension, and cramping. It is not surprising that patients prefer dialysis options that limit these large volume shifts.

Our approach is to allow all patients who wish to attempt home dialysis a trial of therapy, provided they are deemed competent by the home dialysis staff and that they attend and complete training. Patients who have been "difficult" incenter HD patients often do very well as home dialysis patients provided they are motivated to "go home." In our clinic, we have seen patients who seek a second opinion regarding home dialysis because they have been denied that option elsewhere. They have been told that because their blood pressure is poorly controlled or their phosphorus is too high, they must not be adhering to their treatment and medication schedules. Or they have been told their body mass index is too high or they are too old. Likewise, we have seen patients who wish to do home HD denied that opportunity because they have a dialysis catheter and not an arteriovenous access. Patients who seek second opinions regarding their suitability for home dialysis are highly motivated and typically do very well at home.

With the continued increase in the cost of health care, providers must strive to be good stewards of the health-care dollar. Educating patients and providing them support to "go home" is one such opportunity. According to 2006 data from the U.S. Renal Data System, Medicare expenditures per patient-year were \$18,562 less for PD than HD. Annual per patient cost of PD was \$53,327 versus \$71,889 for HD (7). Although there are still relatively limited data regarding short-daily HD, it appears that the increased cost of treatments may be offset by decreases in medication and hospitalization costs (8). An in-center HD patient who misses treatments has a much greater impact on the dialysis unit than a home dialysis patient, given staffing requirements, reuse, and the possibility that someone else could be using the empty treatment chair.

Not every dialysis patient should be a home dialysis patient. Even among those patients who receive pre-dialysis education, most still choose in-center HD. The important point is that each patient be able to choose the treatment modality that is right for him or her. Even for those patients who fail a home therapy, it is important that they had the opportunity to try.

> Although we cannot change the time commitments and the lifestyle alterations required of end stage

renal disease patients, we can provide education regarding the available treatment opportunities. If we were the patient, we would expect no less than to have the opportunity to choose the type of care that best suits our needs.

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Jennifer Fillaus, DO, is a nephrology fellow, and Troy Plumb, MD, is assistant professor of medicine at the University of Nebraska Medical Center in Omaha.

... But Patient Success at Home is the Dialysis Team's Responsibility

By Allen Nissenson and Mary Showers



Patients with progressive chronic kidney disease (CKD) should receive education about all available options as kidney disease worsens, including the various forms of dialysis and renal transplantation. When dialysis is presented, both the modality and the location of care, including home treatment, should be included.

Although most patients who choose home dialysis, either hemodialysis (HD) or peritoneal dialysis (PD), will thrive and have an improved quality of life, this is not true for all. The current significant dropout rates for these modalities (1) suggest that there is an opportunity for improvement in ongoing care as well as in the initial selection of patients. It is, therefore, in the best interests of the patient, the partner, the payer, and the dialysis staff for there to be a carefully structured patient selection process as the plan of care is developed and a modality decision is made.

Although there are a few contraindications to home HD or PD, the determinants of modality selection are largely nonmedical (2). Individual patient medical and psychosocial needs should be matched with the chosen dialysis modality. As the wide diversity in the ESRD population would suggest, there is no one-sizefits-all approach to modality selection. There are some patients and partners who are better suited for in-center dialysis and others for home therapy.

Home HD requires managing a water system; drawing and sending blood and water specimens; maintaining aseptic technique during setup, tear-down, and treatment; and access care. Think of how long it takes nurses and technicians to learn these skills, and now imagine the responsibility of learning these skills as a nonmedical patient and/or partner. Some basic considerations need to be applied: patient and partner education levels, language barriers, physical demands, psychosocial needs, and the physical setup of the home, i.e., whether or not the patient has enough room for supplies, and even if the patient has a home. In considering if a patient is the right candidate for PD, the

team considers body image concerns with the catheter, caregiver support, scarring in the peritoneum, co-morbid conditions, cognitive ability, and willingness to commit to daily dialysis.

A good selection process for home therapy should be started during the pre-dialysis visits to the nephrologist and the interdisciplinary dialysis team with education about renal replacement options. The modality decision should be based on the patient's medical condition, physical abilities, support system, overall psychosocial needs, and learning capacity.

If a patient is interested in a home modality or if he or she is determined to be a candidate for a home therapy, interviews with the interdisciplinary team are scheduled and assessments completed. During this interview, the Match-D tool (3) is used to identify a good modality fit. The patient's rights and responsibilities are reviewed with the patient/partner team to make sure they understand the scope of the undertaking. For home HD, part of the interview is completed with both the patient and partner together, and then with a member of the interdisciplinary team meeting with the patient and partner separately.

We have discovered that sometimes a spouse will profess to support the patient's decision to dialyze at home when the patient is present, but will confess privately to a nurse or social worker that he or she doesn't want the responsibility or fears the situation.

A home visit follows the interview. We recommend the home visit be performed by a nurse and a social worker. We have often found that a skilled social worker can identify potential barriers to home HD that can be removed or decreased, making home dialysis possible.

We use a similar interdisciplinary approach to patient selection, interviewing, and care planning for PD, but the criteria are not so stringent given that the PD patient does not require a partner. The training is not as complex since there is no water system, patients do not need to draw their own labs, and the dialysis is less complex. The team works

with the patients to determine ways to incorporate PD into the patient's life with the existence of one or more of these issues. Studies have shown that 76 percent to 93 percent of incident patients do not have any medical contraindications for PD, yet only a third of those patients are offered the choice of PD (4–7).

We have coordinated practices among different modalities to allow for a continuum of care among in-center self-care, home therapies, and in-center staff-assisted care. Because our experience taught us that the number one reason for patient dropout was partner burnout, we encourage respite care. Respite care can be provided either in-center or in the home training area where the patient can care for himself under the purview of a nurse. We encourage the patient to take as much responsibility and involvement in his or her own care as possible. As needed, we also encourage staff-assisted home dialysis (where available), and training the patient in the home.

We agree that the key to success is patient education regarding the disease process and treatment options during the pre-dialysis period and throughout dialysis care. With good training, most patients can function quite well at home, but failing on home dialysis can lead to frustration and fear for the patient. This fear can carry over to other dialysis modalities, and because the relationship among patient, partner, and nurse is more of a case management role, if the patient fails, the nurse may also feel a sense of failure.

We believe the best scenario is for the patient to be able to move through several modalities as their situation and health status permit. By using a patient selection process, the interdisciplinary team can help guide the patient toward "the right care at right time," to set up for

the

success the patient, partner, and staff. Home HD, PD, in-center self-care, and in-center staff-assisted dialysis each has benefits and challenges. It is the interdisciplinary team's responsibility to guide the patient in making the best modality choice.

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Allen Nissenson, MD, is chief medical officer of DaVita and Mary Showers, RN, is director, outcomes and quality management at DaVita at Home.

Dialysis: Change is Online

Size Matters: Implementing Medicare's Conditions for Coverage



ASN Kidney News invited three dialysis providers to talk about the impact the new Conditions for Coverage (CfC) are having on their organizations. Ellen G. Wood, MD, is director of a four-bed pediatric hemodialysis unit within Cardinal Glennon Children's Hospital in St. Louis, MO. Karen Wiseman, RN, is director of policy and regulatory affairs for Renal Advantage Inc., a moderate-sized network of dialysis providers. Carol A. Topjian, is vice president of the regulatory affairs department for Fresenius Medical Services. Topjian was spokesperson for a team of respondents from Fresenius, one of the largest dialysis delivery companies.

Describe the process your organization used to develop strategies for meeting the requirements of the new regulations and identify key resources needed to carry out the implementation of the strategies.

Wood: Our small pediatric unit employs three RNs who are responsible for the chronic hemodialysis program, the peritoneal dialysis with home training program, and all acute dialysis and continuous renal replacement therapy for inpatients. We first divided up all the Conditions for Coverage into sections with each of our nurses working on a separate regulatory area. The groups held numerous meetings.

Summary data from our network has been helpful to be sure we are meeting all major changes. Meetings with the pharmacy, the hospital administration, infection control nursing for the hospital, and nursing administration have been needed as we are a chronic unit housed within the Children's Hospital, performing acute and chronic dialysis. We are currently piloting a new comprehensive needs assessment form. The CfC required changes to numerous policies and construction of a dedicated drug area within our unit as well.

Wiseman: We did a thorough and detailed review of each draft document that was released by CMS to determine what changes would be necessary. Renal

Advantage Inc. (RAI) is considered a medium-size dialysis company. As draft documents were received, we would task appropriate individuals in different departments with a detailed review to provide us input on significant changes that might be needed and potential difficulties in implementing the new processes.

To implement the revised regulations, we had to provide training on the changes in the actual regulations, as well as the processes specific within RAI for meeting the regulations. We selected a core CfC training group that modeled the interdisciplinary team approach. We also used this group to develop the tools and processes needed within RAI to implement the new regulations. This included center directors, dietitians, and social workers. In addition, RAI is committed to electronic medical documentation, and we had to integrate any changes into our existing systems. Without the support and input of our information systems staff, we would not have been able to provide tools and processes that readily fit into our existing system.

Topjian: The old CfC presented a retrospective look at facility operations, while the new CfC take a dynamic look at facility operations through the patient safety and outcome/quality of care lexicon. Fresenius Medical Services (FMS) established a wide scope "New Conditions Committee" comprised of subject matter expert (SME) teams, with each Condition having its own dedicated team. Each team was comprised of an SME team captain and SMEs from both the field and corporate office. Each team was charged with analyzing the new CfC, identifying gaps between what was in place and the new requirements, and implementing actions to address these gaps.

Staff training and education were undertaken. Although our gap analysis revealed that FMS was well positioned to meet the new CfC, it required an enormous workload to implement the changes within the allotted time. It was also expensive in many ways. Given the broad sweep of changes affecting industry operations, the implementation period of six months was unduly short. One-time implementation and preparation costs (conference calls, meetings, and patient and staff educational materials) were very high, especially for large dialysis organizations (LDOs), where the costs ran into hundreds of thousands of dollars. Reports from industry are that it can cost an LDO anywhere from \$1.35 to \$2 per treatment to implement the new CfC. In addition, many team members were, literally, taken away from routine functions during the long and intense implementation period.

To date, CMS has not published final Interpretive Guidelines and, thus, many related questions remain unanswered. This creates an ongoing requirement for these implementation processes and consideration for their costs.

The new regulations mandate a comprehensive needs assessment of newly admitted patients and implementation of the plan of care by an interdisciplinary team including the patient. A 30-day timeframe is designated. What challenges have been faced in putting processes in place to meet this requirement?

Topjian: A large training initiative was required to roll out policies and procedures and train all interdisciplinary team members about the new policies and procedures. The Plan of Care Condition mandates that social workers assess patients' physical and mental function using a standardized assessment tool. Although the regulations do not require a specific assessment, CMS does require, through the Clinical Performance Measures that will be reported to CROWNWeb, that facilities use the KDQOL-36. This has required us to develop an internal process to make the KDQOL-36 survey and scoring program available for use by our social workers, as well as providing education for both social workers and patients regarding this instrument.

Facilities face challenges in scheduling all team members for assessment and plan of care meetings within the timeframes mandated. Despite our educational efforts, some interdisciplinary team members are challenged by the many new requirements for comprehensive assessments and plans of care. We believe that, over time and through use, this issue will dissipate.

Wiseman: It has been difficult to ensure that key staff members are present and able to complete these tasks within the 30-day window, especially in some of our smaller centers that share key members of the team. It is very difficult to track all patients and where they are in the process of assessment and development/implementation of treatment plans, especially since our patients go in and out of the hospital and move between stable and unstable status, which completely changes the timeline for assessments and treatment plans.

RAI was particularly challenged with this because we use an electronic medical records documentation system. It takes time to program such systems, and because the final CMS regulations weren't issued until April 2008, there was little time to determine how the company would meet the regulatory requirements and complete necessary programming to develop documents and tools necessary for these processes. It was an incredible challenge to do all this and continue with normal work activity.

Wood: Our head nurse has developed a new form based directly on CfC to meet the requirement of a comprehensive needs assessment for new patients within 30 days and again in three months. We are conducting a trial of completing/signing off on the forms monthly at the end stage renal disease meetings where all members of the multidisciplinary team are usually present. The form will take a larger commitment of time for all members of the team to review and complete.

As CMS moves to a pay-for-performance model for reimbursing dialysis services, the new regulations are being used as a platform to track and evaluate quality. CMS extended the February 1, 2009, deadline for all facilities to submit clinical performance measures (CPMs) and cost data monthly using the CMS web-based system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb). But ultimately, dialysis providers will be required to do so. How will implementation of these changes impact individual facilities in your organization?

Wiseman: Before the CROWNWeb delay, our chief information officer and his staff worked very hard to develop processes and tools that would facilitate the entry of lab data into CROWNWeb and help ensure accurate data entry.

There were serious concerns about the amount of time it would take our staff to enter this volume of data into CROWNWeb.

We see the delay in implementing CROWNWeb as a benefit for both CMS and dialysis providers. For RAI it means that we will have more time to refine our internal processes with the goal of making data entry as easy as possible, minimizing the amount of time it takes and ensuring accuracy of the data entered. We believe that CMS will see the benefits of doing the smaller pilot by having the chance to identify problems and solve them on a small scale, and our hope is that when CROWNWeb is rolled out to the dialysis community at large it will be a reliable product with some assurance that data in the system is accurate (since most problems were hopefully identified and addressed during the pilot).

- **Wood:** We are very happy that there is going to be a trial period for selected units to determine problems and solutions before mandating CROWNWeb's use for all facilities. We are hopeful that a mechanism will be worked out for small units to be able to download the information needed rather than having to hand enter all data, which is so time consuming and more subject to human error.
- **Topjian:** FMS continues to prepare our facility staff with the needed training on the CROWNWeb system. As an LDO, our goal is to have all patient data electronically submitted to CMS. The expectation is that utilization of a batch system will keep the impact on the workload of individual staff members within the facilities to a minimum. As CMS continues to change the project parameters for completion, our facilities are doing their best to remain flexible with such a complex and integrated project.

In light of the new regulation requiring patient care technicians (PCTs) to pass a national certification exam within 18 months of their hire date, and in light of the national nursing shortage, do you foresee challenges with recruitment and retention of qualified and competent personnel? Are strategies in place to meet the challenges?

Wood: Our small unit does not employ dialysis technicians.

Topjian: The challenges of recruiting qualified and competent RNs continue to exist and are magnified in times of a nursing shortage. FMS views the national certification of PCTs as a wonderful opportunity to help us establish baseline knowledge for PCTs that will augment our FMS training programs, allowing nurses to feel more confident in their team's ability and commitment in caring for our patient population. It also will allow PCTs to further qualify their contribution in the nephrology setting and participate in a career pathway. We do not, to date, know which states having PCT certification programs will be exempted from the PCT certification requirement. In the meantime, we must move forward with development and implementation of PCT certification preparation classes that, for many individuals, may not be required.

Wiseman: One state we operate in recently passed a state regulation requiring certification of PCTs by a national certification body. We anticipated a loss of technicians as a result, but that was not our experience. We are hopeful that this experience will be the case as the PCT certification requirement expands to all states.

Using the model we already have in place (we used it for the state previously mentioned), we plan to provide our dialysis technicians with all the information they need to make informed decisions about the certification options best for them. Support in terms of review courses and provision of review materials has been beneficial to our PCTs who successfully took national certification exams. RAI is hopeful that national certification of PCTs will enhance not only their baseline knowledge of hemodialysis but also their sense of professionalism and their ability to function as an integral part of the caregiving team in the ever-changing, fast-paced dialysis environment.

ASN News

World Kidney Day 2009: Think Globally, Act Locally

By Jonathan Himmelfarb

Celebrated every year on the second Thursday of March in more than 100 countries on six continents, this year's World Kidney Day is March 12. The theme is "Keep the pressure down." Events and screenings will highlight the importance of high blood pressure as one of the key symptoms and causes of chronic kidney disease.

The ASN partners with the National Kidney Foundation, Dialysis Patient Citizens, and the American Society of Pediatric Nephrology to promote World Kidney Day 2009. The organizations will visit congressional and committee offices March 12 to highlight the significance of kidney disease as a serious public health problem and the need for more kidney research.

The following excerpt is from "World Kidney Day 2009: Problems and Challenges in the Emerging Epidemic of Kidney Disease," an editorial appearing in the March Journal of the American Society of Nephrology. Also watch for articles on World Kidney Day in the Clinical Journal of the American Society of Nephrology. Bakris et al. write about "The Message for World Kidney Day 2009: Hypertension and Kidney Disease: A Marriage that should be Prevented." Okusa et al. address "The Nexus of Acute Kidney Injury, Chronic Kidney Disease and World Kidney Day 2009."



educated the colleagues we interact with on a daily basis on the availability of practice guidelines and patient-centered educational materials about kidney disease?"

Access to health care, including overcoming currently existing racial and ethnic disparities, is crucial for progress to be made (3). Efforts to increase screening and early identification of kidney disease require knocking down barriers based on inability to pay or on lack of insurance. Research is needed to facilitate the optimal translation of guideline recommendations into actual health-care improvements in diverse populations.

A gap in the public's awareness of the risk of kidney disease has been well documented (4). While not surprisingly those with the most advanced disease are most likely to be aware, still less than half of patients with stage 4 CKD were aware of having reduced kidney function in the National Health and Nutrition Examination Survey. In earlier stages of CKD where interventions arguably might have an even more significant impact, awareness is reported to be as low as 3 percent to 8 percent. Prior campaigns that can be emulated include promoting awareness of cardiovascular risk factors such as "hypertension-the silent killer" and the association between good and bad cholesterol in the development of heart disease. The National Kidney Disease Education Program sponsored by the National Institutes of Health provides templates and educational materials to support this effort.

Nationally, progress toward awareness

and improvement in care is on the horizon with the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. In MIPPA, the Kidney Disease Education and Awareness Provisions authorized CMS, beginning January 2009, to conduct pilot initiatives in three states to promote awareness of chronic kidney disease, focusing on prevention. Additionally, the Agency for Healthcare Research and Quality recently hosted an open meeting to gather information and opinions on existing educational resources and programs on kidney disease. Thus momentum is being established that should lead to tangible progress over time.

There are also many examples of local successes that demonstrate the renal community recognizes the importance of more local tailored efforts and how essential it is to act now. In addition to many successful screening programs such as the Kidney Early Evaluation Program (KEEP; see story, p. 12), a number of states have recently begun grassroots campaigns on public awareness and screening. For example, North Carolina has successfully initiated the Kidney Education Outreach Program (KEOP). The objective of this program is to screen and provide education about chronic kidney disease using a mobile unit equipped with a fully functional exam room, restrooms, and a common area.

In the state of Washington, the nonprofit Northwest Kidney Center's Living Well with CKD[™] program is addressing CKD through education, health screening, and collaboration with community organizations and health-care providers, with specific outreach to the African-American community. The CDC is also pilot-testing a new kidney disease screening program in California, Florida, New York, and Minnesota in collaboration with the National Kidney Foundation and the Chronic Diseases Research Group. This effort is targeting those who are above the age of 50 or those who have diabetes or hypertension.

Clearly, efforts to recognize CKD as a public health problem are moving forward. We need to recognize that fundamental aspects of kidney disease will likely translate to unique features of a public education/screening and prevention plan. The often-asymptomatic nature of kidney disease in early stages is a major hurdle to effective disease recognition. We need to learn from what has worked in the past to get patients to doctors, doctors to screen, and insurance to cover. We need to never stop asking "why" when we uncover a barrier to improved care.

Jonathan Himmelfarb, MD, is director of the Kidney Research Institute and professor of medicine at the University of Washington in Seattle.

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orld Kidney Day is an occasion to mark growing concerns over the impact of kidney disease on global public health. Although the distribution of etiologies of kidney disease and access to dialysis and transplantation may vary among regions of the world, arguably, one point is universal. An expanding proportion of people in every nation in the world are affected by chronic kidney disease (CKD). Since the prevalence of CKD rises dramatically with age, and is also associated with obesity and diabetes mellitus, kidney disease will be a public health concern for the foreseeable future. As a global community, we need to ask ourselves if we have the strategy in place to fully address the universal health problems arising from kidney disease, given the biological and cultural heterogeneity of populations, diverse environments, and varying capabilities of health-care delivery systems around the world.

The development of guidelines for care is an essential foundation for attacking any global crisis. While standardization is a critical tool to optimize quality of care, physicians and other health-care workers must relinquish some autonomy to implement practice guidelines (1). Empirical data demonstrate that standardized care guidelines are most effective when the evidence supporting protocols and process by which guidelines are created is transparent, and when there is trust in the organization that creates standards. Other specific barriers vary significantly based on practice setting. Given this, the focus should be local and point at the needs of specific communities, taking advantage of local health-care system resources.

Physicians need to treat individual patients with chronic diseases "within the larger context of family, community and society, as well as to treat the community itself (2)." Key questions for each nephrologist to ask are: "Have we adequately disseminated information on the importance of kidney disease as a public health problem in our local area?" and "Have we

Home Hemodialysis

Continued from page 1

either undergo dialysis or have a transplant," according to Rajnish Mehrotra, MD, of the David Geffen School of Medicine at the University of California-Los Angeles and a member of the ASN Dialysis Advisory Group.

Some of these individuals will no doubt choose home dialysis. In fact, Mehrotra predicted that the home hemodialysis market will grow more quickly than other markets in the short term "as more centers open these programs and more nephrologists start to offer it."

Findings from a pair of NIH clinical trials may spur more interest in dialysis at home, though the results of the trials are delayed because of slow recruitment.

NIH studies on home dialysis

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and CMS have funded two related clinical trials, one to study the results of daily hemodialysis at centers and the other the results of night-time dialysis done at home. In both cases, these more frequent forms of dialysis will be compared with outcomes from conventional, threetimes-a-week dialysis in centers.

The endpoints of the trials will be evaluations of patients for their physical health scores on an established index (SF-36 Physical Health Composite score) and the size of the left ventricle of the heart (imaged by magnetic resonance imaging). Thinner walls of the ventricle are a desirable outcome.

Paul W. Eggers, program director for Kidney and Urology Epidemiology at NIDDK, said that the trials are enrolling more slowly than expected. "I'm afraid we've had to extend the trials due to slow recruitment," he said. Both trials are scheduled to end recruitment in 2009 and end the one-year follow-up in 2010. Results will be available in 2011.

All observational trials thus far support a benefit to patients. "I cannot think of a reason why the NIH trials would have different results," said Lynda Szczech, MD, chair of the ASN Dialysis Advisory Group and associate professor of medicine at Duke University Medical Center in Durham, N.C.

Studies tout benefits of nontraditional dialysis

A preliminary study by Bruce Culleton, MD, and colleagues at the University of Calgary, Calgary, Alberta, and other sites found that, compared with thrice-weekly hemodialysis, frequent nocturnal hemodialysis improved left ventricular mass, reduced the need for blood pressure medications, improved some measures of mineral metabolism, and improved selected measures of quality of life [J Am Med Assoc 2007; 298:1291–1299)].

"I think that the challenge will be how to implement the upcoming NIH results to a larger population of potential patients," said Szczech. "The fact that only 10 percent of available patients were interested in participating in the study by Culleton might signal that those who choose this therapy will continue to be a self-selected group."

In 2008, NxStage announced results of its FREEDOM (Following Rehabilitation, Economics and Everyday Dialysis Outcome Measurements) trial. Comparing data from 500 Medicare patients in the NxStage database with a matched group of 5000 patients from the U.S. Renal Data System database who had conventional dialysis, they found lower depression rates, higher physical and mental health composite scores, and much shorter recovery time after home dialysis—one hour versus eight hours for patients dialyzing in centers.

"The home patients can dialyze more often, which means that their toxin build-up is lower, and the fluid build-up in their system is less. Less fluid is removed at one sitting, reducing the physical strain," said Turk of NxStage.

The University of Washington's Blagg, who is executive director emeritus of Northwest Kidney Centers in Seattle, concluded with co-authors in a study published in *Kidney International* that home dialysis had lower mortality compared with in-center dialysis, even after adjusting for co-morbid conditions, age, and diabetes [*Kidney International* 1996; 49:1464–1470].

"The biggest benefit is survival," Blagg said. "There are international data showing that with short daily dialysis, five to six times per week for three to three and a half hours or so, the survival rate is about double what it is for typical patients in the U.S. Renal Data System."

Nocturnal home dialysis appears to lend some of the biggest benefits, according to Andreas Pierratos, MD, of Humber River Regional Hospital in Toronto.

"Patients don't have to drive to the hospital (or center), and nocturnal home dialysis is a much higher quality dialysis," Pierratos said. "Because the dialysis is slow and long, when dialysis is over, these people are ready to start their day. Patients can attain good blood pressure control, and many come off medications or take only one pill a day. Their diets are not restricted."

Drawbacks such as clotting of the central venous catheter (treated with lowdose warfarin) and catheter infections have largely been addressed, he said.

Reimbursement issues

Reimbursement has limited the growth of home dialysis. But in 2008, Congress and CMS worked to remove roadblocks to dialysis at home.

Medicare pays for thrice-weekly dialysis in any setting, whether at home or in a center. However, "if you are going to go to five- to six-day-a-week dialysis at home, you probably need the equivalent of reimbursement at the current rate for four and a half days," Blagg said. Home dialysis costs about 55 percent of what in-center dialysis costs, he said, because "you don't have all of the nursing tasks a center must pay for."

Under the new outpatient bundling rules in MIPPA (HR 6331), what had been separately billable drugs will become part of a new bundled payment for dialysis patients. Bundling these charges is set to begin in 2011.

Bundling drug costs into the dialysis reimbursement may encourage more home dialysis, said NxStage's Turk. "Chairman Stark specifically wrote into the Congressional Record that home dialysis should be appropriately reimbursed and encouraged."

From a nephrologist's standpoint, the payments from Medicare are the same for monthly monitoring of patients in any setting, said Edgar Lerma, MD, clinical associate professor of medicine at the University of Illinois at Chicago College of Medicine and a member of the ASN Dialysis Advisory Group. "Right now in the United States, from the CMS standpoint, any form of dialysis—peritoneal, in-center, or at-home—is still more expensive than renal transplant."

Payment for training patients and care partners for home dialysis remains poor given the costs of nursing time, just \$20 above the rate of payment for a dialysis session, Blagg and Lerma said. This figure has not changed in decades.

MIPPA would require Medicare to pay for training patients about their treatment options and for increased education funding to help patients manage other medical conditions. The law states that all patients who are on the cusp of dialysis (stage 4 chronic kidney disease patients) need to be educated about their potential options, including home hemodialysis.

The new Conditions for Coverage from CMS state that patients must receive information about home dialysis as an option for care. In addition, they must be told where they can get training if it is not offered in their facility. Caregivers need to record annually in a patient's record why a patient would not be a candidate for home dialysis.

Equipment advances keep market growing

Fresenius, with about 1700 North American dialysis centers, is now devoting more resources to the home market. The company purchased Renal Solutions, Inc. (RSI) in 2007. This is "a further promising acquisition and an important step toward expanding our technology leadership in the high-growth area of home dialysis," said Ben Lipps, CEO and chairman of the Management Board of Fresenius, based in Bad Homburg, Germany.

NxStage makes the portable NxStage System One[™], which has helped to make daily and home therapy more accessible, said Alvin Armer, area manager for Nx-Stage in Southern California. Turk said NxStage systems are used in the homes of 3000 of the 4000 patients doing home hemodialysis.

DaVia Dialysis, with more than 1400 dialysis centers in 43 states and Washington, DC, has teamed with NxStage to expand home hemodialysis opportunities. "Home (dialysis) is becoming very popular," Armer said. "It is important that we keep the home therapies going, because we've seen the benefits in patients from day to day." Fresenius and B Braun companies also make home dialysis equipment.

Dori Schatell, executive director of the Medical Education Institute, a clearinghouse of information for patients who are on dialysis at home, said her organization counts the number of programs that offer home therapy. Since 2004 there has been a 1200 percent growth in home hemodialysis, particularly in programs offering nocturnal dialysis, which had a growth of 300 percent, she said. "Peritoneal dialysis at home has grown by 20 percent."

Limitations of home hemodialysis

Although there are not many clear drawbacks to home dialysis, there are limitations. Several sources mentioned the same aphorism: "If you can drive, you can do home dialysis." Not everyone can drive, however.

Patients must have a certain level of cognitive ability to perform dialysis at home, Blagg said. Some patients have a fear of needles and do better in centers where nurses or others can do the needle management, Lerma said. Anecdotally, one patient said she chose not to dialyze at home because she did not want her home to take on the hallmarks of a treatment center. She didn't want her small children to think "Mommy is always sick," Lerma said.

Each person also should have a care partner who can attend in case of any problems. These care partners need to have the time to be trained and to participate.

Home dialysis isn't trouble free. With nocturnal dialysis, "sleep can be disturbed because of alarms," Lerma said. It's not unusual for people to be awakened once or twice during the night. "Home dialysis affects everyone in the home."

Looking ahead

Blagg said he foresees a bump from 1 percent to 5 percent of dialysis patients dialyzing at home in the next three to four years. This number, of course, will depend on the NIH outcomes, favorable reimbursement changes, and identifying and training patients and their caregivers who want the advantages of dialyzing at home.

If the NIH trials confirm that morbidity and mortality are diminished by this therapy, Szczech said, we will need to ask why more patients aren't doing this at home "and also how do we increase patient enthusiasm so that more can benefit?"

Said Lerma: "As nephrologists, we can appreciate that in-center dialysis accounts for about 12 hours per week. Normal kidneys work 24 hours per day. The big question is: 'What can we do to get kidney function as close as possible to physiological levels?'"

Practice Pointers

Home Hemodialysis



Sarah Prichard

Can you provide a little history on home hemodialysis? I understand that it was the most common form of renal replacement therapy in the early 1970s and has recently gained in popularity.

Home dialysis is widely used today, predominantly in the form of peritoneal dialysis (PD). There is a clear trend toward home dialysis therapies and increasing interest in home hemodialysis (HD), which presents an additional treatment option for patients.

As physicians began to use hemodialysis (HD) to treat chronic renal failure in the early 1960s, the number of patients being treated increased. The demand for treatment quickly exceeded the capacity of facilities to In this month's issue, ASN Kidney News editorial board member Edgar Lerma interviewed Sarah Prichard, MD, vice president of global clinical affairs for Baxter International's renal business, about the history and future potential of home hemodialysis. Kidney specialists are sometimes quick to ask, "Is home hemodialysis right for this particular patient?" Prichard points out that now may be the time for practitioners to ask, "Is it right for my practice?"

of Washington, developed a small home dialysis system after the 15year-old daughter of a friend of Babb's was turned down for dialysis at a small community dialysis center in Seattle (1). In September of the same year, Stanley Shaldon in London began using a setup similar to that of the Seattle machine. Initially patients were dialyzed at home twice a week for many hours. Shaldon was the first to dialyze patients at home thrice weekly overnight, as the daily schedule was inconvenient (2).

In the early 1960s, dialysis was unavailable in most cities in the United States and abroad. Home HD accommodated the demand for HD at an affordable price since no government funding was available to help patients pay for their beginnings of the modern dialysis industry in the United States. Dialysis providers made substantial infrastructure investments to create more facilities or to increase capacity in existing facilities, which, in turn, triggered an increase in in-center treatment for chronic renal failure.

In the 1980s, the introduction of PD offered an excellent option for patients who wanted to do home therapy. Today, the majority of patients who do home dialysis are doing PD.

As the clinical benefits of frequent HD and more flexible prescriptions emerged in the last decade, and as HD devices have been developed especially for the home, there has been an increased interest in and gradual growth in the number of between home hemodialysis and conventional in-center intermittent hemodialysis with regard to scheduler, dialysis machine, vascular access, needles, anticoagulation, and monitoring of adequacy?

Home HD can be done at night, while the patient is asleep, or during the day. It typically is done three to six times a week. The length of the dialysis varies. If done during the night, it can last as long as the patient wants to sleep-from five to eight hours. If done during the day, the treatments are usually from two to four hours. Patients on in-center HD therapy typically receive treatment at a dialysis facility three times a week for three to four hours each session. The HD machines used at home are either similar to standard in-center HD machines or are designed specifically for use in the home, such as the NxStage machine.

In the future, our hope is that patients will be able to carry out HD at home with a device that is easy to use and has been designed with "human factors"-the abilities, limitations, and potential errors of the user-in mind. The device used at home should allow the physician as much flexibility as possible in terms of the patient's prescription, including the option to dialyze daily while the patient is awake or asleep and to increase the dose of dialysis given compared to conventional in-center HD, which may improve patient outcomes.

Vascular access, needles, and anticoagulation are generally similar between home HD and in-center HD.

With respect to measuring adequacy of dialysis, the Kt/V value—the standard measurement of adequacy in in-center HD—may

If nephrologists are going to adapt to the emerging research on the benefits of nocturnal and short daily dialysis... they should consider establishing a home program within their practice.

provide it, which in turn created the need for alternative methods of treating chronic renal failure.

There is some controversy over who was first to do home HD (1). In July 1963, John Merrill began using Baxter twin coil dialyzers to treat four male patients at home. About the same time, Belding Scribner (inventor of the Scribner shunt, the first chronic dialysis blood access) and Les Babb, a professor of nuclear engineering at the University therapy. Home HD allowed the maximum number of patients to be treated with the limited resources available (3).

In 1973, the United States government passed legislation for Medicare to pay for the cost of dialysis. As a result, more patients could receive treatment because cost was no longer an issue. The number of treatment facilities and patients being served increased even more. These events are viewed as the patients doing home HD. Patients are also taking a greater interest in their treatment and health, which has contributed to the trend toward being treated in the home. In their homes, patients have more influence over how their therapy affects their work and lifestyle.

What are the types of home hemodialysis schedules, and what are the main differences among them? What are the main differences not be the best measure in home HD when daily and nocturnal prescriptions are used. Instead, phosphate levels, blood pressure, and volume status may prove to be more relevant because Kt/V values in these newer prescriptions are so much higher than in conventional prescriptions.

What are common barriers to home hemodialysis? What are the potential disadvantages of home hemodialysis?

Existing home HD technology does not always afford a physician the flexibility to prescribe the best possible treatment—which may be daily nocturnal dialysis—for the patient's condition and lifestyle preferences.

Home HD must also be easy to administer and safe for the patient. As technology becomes more user-friendly and intuitive, more patients will become eligible.

Some patients prefer the social support they experience with other patients in the in-center environment, particularly if they are otherwise living with their condition in isolation. Treatment at home is often preferred, however, by patients who do not live alone, or who have good social connections, or who want more control or involvement in their health care.

What are the benefits of home

hemodialysis? Are there any current published data comparing survival and outcomes between patients on home hemodialysis against conventional in-center intermittent hemodialysis?

Because patients on any HD therapy gain fluid weight between sessions, they may limit fluid intake and modify their diets if they are receiving dialysis only three days a week as is typical with in-center HD. When patients are able to have their therapy at home, physicians and patients can be more flexible in determining a treatment schedule that is optimal for the patient.

Observational studies suggest that home HD can offer a few key clinical advantages such as blood pressure control, improved phosphate levels, lessening of sleep apnea, return of fertility in women, and improved cardiac function. In addition to the clinical benefits of daily dialysis, patients experience significantly better quality of life, particularly if patients can dialyze at night. The time commitment required for in-center dialysis affects patients' lifestyles, including making it difficult to hold down a full-time job.

There has been only one randomized controlled trial comparing nocturnal daily home HD with a conventional thrice weekly prescription done in the home. The patients on daily nocturnal home HD had better blood pressure control and significant reduction in left ventricular mass, as well as an improved quality of life. Left ventricular mass reduction is evidence of a potential improvement in cardiac function and health-related outcomes

Published in the *Journal of the American Medical Association* in September 2007, the trial highlights the need for greater patient and physician awareness of the variety of home dialysis modalities available [*J Am Med Assoc* 2007; 298:1291–1299).

Several studies have shown that patients who are objectively informed about dialysis treatment options more often choose home dialysis than do uninformed patients. As patients become more empowered in managing their diseases, home therapies allow them to have some ownership in their treatment.

How important is the resurgence in home hemodialysis to the overall end stage renal disease (ESRD) program?

Home dialysis therapies will be critically important to the overall ESRD program in the near future. Home HD will offer physicians an option in addition to PD for patients who prefer a home therapy. There is a clear trend toward treatment in the home—not only in the management of ESRD, but also for many other chronic diseases.

The incidence of end stage renal disease is growing, fueled largely by diseases associated with an aging population, hypertension, and increasing rates of diabetes. This growing burden is leading to more consideration of home-based therapies as a way to offer patients greater convenience and potentially increase levels of patient satisfaction and well-being, as well as to help maximize public health resources by relieving some of the burden of capital investment, staffing, and infrastructure. For example, by expanding their practices into the home, nephrologists can also alleviate the impact of the nursing shortage.

If nephrologists are going to adapt to the emerging research on the benefits of nocturnal and short daily dialysis, the changing economic environment, and the trend toward patients' involvement in their treatment, they should consider establishing a home program within their practice.

How would you compare the reimbursement of services for patients on home hemodialysis with that for conventional in-center intermittent hemodialysis and peritoneal dialysis? What potential effect will the bundling of dialysis services have on home hemodialysis in the years to come?

Currently, all dialysis is reimbursed at three times per week. Providers may also be reimbursed for separately billable drugs used in HD therapy. However, this is changing.

Bundled reimbursement requires providers to rethink how to treat their patients and manage their businesses. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) expands the bundle of covered services for ESRD to include medications that, until this point, had been excluded and were reimbursed as separately billable drugs. As providers explore ways to right-size their resources with the best possible treatment for each patient, home HD and PD offer nephrologists effective and viable levers to pull.

The new Conditions for Coverage incorporate clinical advances in dialysis therapy and emphasize quality outcomes, patient empowerment, and home as the preferred place of therapy. This, too, will impact all ESRD facilities participating in the Medicare program. The Centers for Medicare and Medicaid Services anticipates that this rule will promote "patient independence and the use of home dialysis whenever appropriate."

If a private nephrologist or group of nephrologists decides to create a home hemodialysis program, what would be the infrastructure requirements, e.g., staffing, number of patients, and payer mix?

From an infrastructure standpoint, having a competent nurse is the most critical success factor in any home program. Investing in a nurse to support your home HD program also requires investment and support of his or her training. For example, it is important for nurses to understand that home HD may require changes to patients' homes, such as their water supply and electricity.

Payers currently are reimbursing for home HD, and many of them are reimbursing at a frequency of greater than three times per week. Private payers have historically reimbursed for dialysis services at a higher rate than Medicare alone, enabling providers to offer these services to their patients. To create a sustainable and efficient home HD program, it is beneficial to aim for about 15 patients. If you are committing resources to a program, you will need to be supportive.

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Disclosures

Bruce Culleton, author of the *JAMA* clinical trial, joined Baxter as medical director in the Renal Business division last year.

Transitions

Henrich named interim president at UT Health Science Center

Former ASN President William L. Henrich, MD, FASN, has been named interim president of the University of Texas Health Science Center at San Antonio (UTHSC). Prior to assuming his new post, Henrich was Dean of the School of Medicine and Vice President for Medical Affairs for the University of Texas Health Science Center at San Antonio. Henrich will serve as interim president while a search committee looks for a long-term successor for Francisco Cigarroa, who was appointed chancellor of the UT system earlier this year.

Henrich was Chairman of Medicine at the University of Maryland School of Medicine before coming to UTHSC in 2006. Previously, he held several positions at the UT Southwestern Medical School in Dallas, including professor of internal medicine, and was associate chief of staff for research and development at the VA Medical Center in Dallas.

Among Henrich's areas of expertise are dialysis therapy and blood pressure regulation. He is the editor of a popular dialysis textbook and has authored some 280 scientific papers and other contributions. Henrich was president of ASN for the 2006–2007 term.

ASN Kidney News reports on member honors and new positions at the level of division director or higher, depending on space available. Please send announcements to kidneynews@asn-online.org.

Kidney Patients Recognize Robert W. Schrier, MD

obert W. Schrier, MD, is the 2009 recipient of the American Association of Kidney Patients (AAKP) Medal of Excellence Award. Each year, AAKP "honors a renal physician who has achieved outstanding success in caring for kidney disease patients, while also possessing extraordinary skills and devotion in the field of nephrology."

Dr. Schrier excels as a clinician, teacher, researcher, and administrator. "Dr. Schrier still sees patients in the renal clinic and the inpatient renal service, where he is a model of the devoted, caring physician, bringing to bear his extensive experience and broad-based knowledge to many patients with kidney diseases," said Tomas Berl, MD, FASN, professor of medicine in the division of renal diseases and hypertension at the University of Colorado School of Medicine.

During his career, Dr. Schrier has helped train more than 200 nephrology fellows, taught physicians in nearly 80 countries about nephrology and hypertension, and edited several textbooks and journals. Additionally, he has mentored many leaders in nephrology, internal medicine, and academic medicine.

"A consummate scholar, Dr. Schrier is the most inspiring of mentors, kind and supportive, but uncompromising in his pursuit of scientific truth," said William L. Henrich, MD, FASN, interim president of the University of Texas Health Science Center at San Antonio. "He is the best example I know of someone who moves easily from the bedside to the bench and back with great facility."

Dr. Schrier earned his undergraduate degree from DePauw University (where he was also a star basketball player) and his MD from the Indiana University Medical School. He completed residency and fellowship training at the University of Washington School of Medicine and the Peter Bent Brigham Hospital, respectively.

Published in more than 850 papers, Dr. Schrier's research combines body fluid control mechanisms, renal function, and cardiovascular function. With his hypothesis on sodium and water regulation in health and disease, Dr. Schrier sparked a global interest in medical research in these areas. "Dr. Schrier's broad and varied investigative efforts, which were always directed at understanding the mechanisms of human disease, had as their primary goal the improvement of patients' lives," Dr. Berl said.

Currently a professor of medicine at the University of Colorado's School of Medicine, Dr. Schrier chaired the institution's department of medicine for 26 years and headed the department's division of renal diseases and hypertension for 20 years. Under his leadership, the department's full-time faculty increased from approximately 75 to 500, while the department's research budget grew to \$500 million.

As further evidence of his global reputation among physicians and patients alike, Dr. Schrier is the only person to have served as President of the American Society of Nephrology (ASN), the International Society of Nephrology, and the National Kidney Foundation. In 1997, Dr. Schrier received the John P. Peters Award, which ASN bestows on "individuals who have made substantial research contributions to the discipline of nephrology and have sustained achievements in one or more domains of academic medicine, including clinical care,

education and leadership." To recognize his contribution further and establish a lasting presence during Renal Week, ASN in 2005 created the Robert W. Schrier, MD, Endowed Lectureship.

In 1969, a group of six patients established AAKP, a national organization that now reaches "one million people yearly affected by kidney disease, including patients, family members, renal professionals, and friends." The association's mission is "to improve the lives of fellow kidney patients and their families by helping them to deal with the physical, emotional, and social impact of kidney disease."

ASN is sponsoring the AAKP Medal of Excellence Award, which will be presented to Dr. Schrier during a ceremony on Sunday, March 22, 2009.

Online information available in April! ^{www.asn-online.org}

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Industry Spotlight

Regional Map for Diabetes Incidence Released

For the first time, the U.S. Centers for Disease Control and Prevention (CDC) has issued in effect a map of the regional incidence of diabetes. Although national survey data have shown that the overall incidence of diabetes has grown in the United States dramatically in the past decade or so, data now show a geographic distribution of the disease. The CDC looked at data from 1995 to1997, and from 2005 to 2007. Thirty-three states and territories had the data needed to conduct statistical analysis for the two different three-year periods. Forty states had enough data to analyze during the most recent period.

For perspective, in March 2007, the CDC reported on chronic kidney disease (CKD) between 1999 and 2004. The CDC analyzed the most recent data from the National Health and Nutrition Examination Survey (NHANES). Researchers determined that 16.8 percent of the U.S. population aged 20 or older had CKD, according to 1999–2004 data, compared with 14.5 percent from the 1988–1994 NHANES survey, an increase of 15.9 percent based on crude estimates of prevalence. People with diabetes or cardiovascular disease had a greater prevalence of CKD than those without. Thus, the diabetes study means even greater vigilance is needed to prevent or stem the increased prevalence of kidney disease.

The regional diabetes study uncovered some clear trends:

- By U.S. Census region, the average age-adjusted incidence was greatest in the South (10.5 per 1000 people), followed by the Northeast (8.6), West (8.5), and Midwest (7.4).
- By state, age-adjusted incidence ranged from 5 per 1000 population in Minnesota to 12.8 per 1000 in Puerto Rico.
- Of the 10 states with the highest diabetes incidence, nine were in the South: Alabama, Florida, Georgia, Kentucky, Louisiana, South Carolina, Tennessee, Texas, and West Virginia. The remaining state in the highest quartile was Arizona.
- Age-adjusted incidence rates were significantly higher for 2005–2007 than for 1995–1997 in 27 of the 33 states.
- Between 2005 and 2007, the states with the greatest number of annual new cases were California (approximately 208,000), Texas (156,000), and Florida (139,000).

The CDC concluded that effective population-based approaches to prevent obesity and increase physical activity might help to reduce the incidence of diabetes. In high-risk individuals, a 5 percent to 10 percent reduction in body weight coupled with 30 minutes of moderate physical activity five days a week resulted in a 58 percent reduction in diabetes over a three-year period, the CDC report noted.

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Third Largest Dialysis Firm Keeps Growing

Renal Advantage of Brentwood, Tenn., has several new dialysis centers in its national circle, thanks to the completion of an acquisition by its parent company. RA Group Holdings acquired National Renal Alliance, based in Franklin, Tenn.

The combined company, number three in the field after Fresenius and DaVita, will now operate 136 dialysis centers in 18 states, and serve about 11,000 patients.

"We are pleased to announce the completion of our acquisition of National Renal Alliance," said Michael D. Klein, chief executive officer of Renal Advantage. "We remain confident in our belief that the combination of our two companies' cultures, philosophies, and standards of excellence will serve as a basis for our success in the future, and we look forward to working with National Renal Alliance's management and employees to accomplish a smooth and seamless transition for patients and physicians."

In 2008, Renal Advantage added a freestanding dialysis center, giving it a position in Florida, on Merritt Island. At that time the company served 8100 patients in 87 centers. Renal Advantage also delivers laboratory services through RenaLab, an independent clinical laboratory located in Jackson, Mississippi.

In Bleak Year, Fresenius Revenues Up

During the first three quarters of 2008, Fresenius Medical Care, a renal services company, had a strong showing in its international markets and in the United States. Chief Executive Officer Ben Lipps gave an optimistic assessment for the company in the near future: "Despite cost pressures, an uncertain economic environment, and volatile currency developments, we are confident of achieving our midterm financial targets for 2010."

As of late 2008, Bad Homburg, Germany-based Fresenius Medical Care had treated 181,937 patients worldwide, mostly in Fresenius-owned clinics, a 6 percent increase compared with a similar period in 2007. The North American market provided dialysis treatments for 125,356 patients, an increase of 4 percent. Including 34 clinics managed by Fresenius Medical Care North America, the number of patients treated in North America was 127,172. The international segment of Fresenius served 56,581 patients, an increase of 10 percent over the prior year.

By late 2008, the company operated 2349 clinics worldwide. Of this total, 1666 clinics were in North America (1700 including the clinics that Fresenius only manages), an increase of 5 percent, and 683 clinics operated within its international division, an increase of 8 percent.

Fresenius Medical Care delivered approximately 20.7 million discrete dialysis treatments worldwide during the first nine months of 2008. This number is an increase of 5 percent over the same period in 2007. Of the total, 14.2 million treatments were delivered in North America, an increase of 4 percent. The international segment delivered 6.4 million treatments, an increase of 9 percent over last year.

The company expected to close 2008 with revenue of more than \$10.4 billion, an increase of more than 7 percent over revenue in 2007.

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- · NO mortality benefits with sevelamer when compared to calcium-based phosphate binders in DCOR (Genzyme-sponsored) study.
- NO mortality, morbidity, or hospitalization benefits with sevelamer over calcium-based binders as stated in DCOR secondary analysis.4

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with end-stage renul failure may develop hypercalcentia when given calcium with meals. No other calcium supplements should be given concurrently with Prost. Progressive hypercalcentia due to overdosa of Phost.o may be severe as to require emergency measures. Chronic hypercalcentia may lead to vascular calcification.

and other soft-tissue calcification The servini calcium level should be monitored

twice weekly during the early dose adjustment period. The serum calcium times phosphate (Ca x P) product should not be allowed to exceed 66. Radiographic eval-uation of suspect anatomical region may be helpful in early detection of soft-base

BRIEF SUMMARY OF PRESCRIBING INFORMATION

REFERENCES: 1. Guide WC Prosters PL, MCD world L, et al. Themenet di Ingenet esplanaria en interstava palantia. The calcum a other menor localizes (CAPE States) waters are participation of provide a Maratini, M. Maene LL, et al. A L year rectorized build calcum podate with a security or provide of carcing aniwy section on the models and patients offic despitation of provide a security of menants of CAPE (2) many Am / Acting (16: 2005) 1952/965 (2) State Wile Scoresh IT, Caroliano L, et al. PRECAUTIONS: Excessive dosage induces hypercalcentia; therefore, early in the treatment during docage adjustment serum calcium should be determined twice weekly. Should hypercalcemia develop, the docage should be reduced or the treatment discontinued immediately depending on the severity of hyperculcentia. Do not give to patients on digitalis, because hyperculcentia may precipitate cardiac a. Effects of excellence and calculated plenging landers an instability in terrocalogical parents. Active 38: Aug 29, 1007 4, 31 Febre WL, Liu J. Waveseld E, Figs Q. A comparison of assumes and accumulation programs hindows on moments. Exceptionalizes and montality is humania and accumulation. antivitimize Always start Phosico at luw dose and do not increase without careful monitoring of serum calcium. An estimate of daity calcium intake shocid be larris data. Art. / William Da made initially and the intake adjusted as needed. Serum phosphorus should also 200051 445-454 S. Pressor prescripting neurophys. Reserve Medical Gate, Walthers MA. Strawy 2007 B. Marents P. Naple, JJ Watters M. Herdele, activate in neurostarce sample potentic chronic remnanticity. X-May MC 200064 page 509-513-525 be determined periodically

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Pregnancy: Teratogonic Effects: Calegory C Animal reproduction studies have not been conducted, it is not known whether Phosto can cause fetal hann when administered to a pregnant woman or can affect reproduction capacity. One to a pregnant woman only II clearly reacted.

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younger subjects, and other reported clinical expensions has not identified officiences In responses between the elderly and younger patients, but greater sensitivity of some other individuals cannot be ruled out.

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