ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

KidneyNews

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The New Health Care Legislation: A Look Ahead

By Rachel Shaffer

Congress and the Obama administration took a historic step toward expanding access and improving health care for all Americans in passing health reform legislation last month. The most comprehensive health reform in decades, "The Patient Protection and Affordable Care Act (HR 3590)," was built upon through subsequent legislation "The Reconciliation Act of 2010 (HR 4872)," also passed by Congress and signed into law by President Obama last month.

Strong interdisciplinary teams form the backbone of care for chronic kidney disease
See our special section, beginning on p. 7

The health reform legislation focuses primarily on expanding insurance coverage and increasing its affordability, reducing health care costs, and transforming care delivery. Eventually, the legislation aims to ensure coverage for 32 million people—meaning more than 94 percent of all legal U.S. residents will be covered. However, reforms laid out in the bills will not be implemented immediately, and some of the most important provisions will not go into effect for years. Significant responsibility for carrying out health reform goes to the Department of Health and Human Services (HHS); H.R. 4872 appropriates $1 billion to HHS for enactment. Table 1 shows when provisions of the health care legislation become effective and highlights components pertinent to the kidney care community, and can also be downloaded as a pdf from ASN's *Kidney News* website at http://asn-online.org/publications/kidneynews/.

Many aspects of these broad reforms—greater access to coverage, emphasis on prevention, closure of the donut hole, expansion of comparative effectiveness research—will almost certainly influence patients at every level in the coming years, including those with kidney disease. Health reform does not address kidney disease at length, but there are a number of key sections of interest for the nephrology community in the 2400-plus pages of legislation.

Models of care delivery

Transforming the delivery system is a primary focus in the health care bill. The legislation paves the way for a host of pilot programs and enables physicians to begin sharing in savings derived from improved care delivery as early as 2010.

The Patient Protection and Afford-

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President Obama Outlines Budget Priorities

Although the First Step in a Long Process, Budget Proposes Increases for NIH, NIDDK, VA, AHRQ, FDA, and NSF

By Rachel Shaffer

With the U.S. economy struggling, the budget deficit expanding, and his health reform effort facing an uphill battle, President Obama released his proposed $3.8 trillion budget for fiscal year 2011 (FY 2011), which will start October 1, 2010. Despite a spending freeze on all discretionary funds, except those dedicated to defense or national security, medical care and research remain clear priorities for the Obama administration. Nearly every health-related research agency—except the Centers for Disease Control and Prevention (CDC)—received an increase in the president's budget.

Each February, the president submits a budget to Congress proposing funding for federal departments and agencies, including justifications for spending reductions or increases. The House and Senate Budget Committees then draft budget resolutions, nonbinding legislation that sets overall discretionary spending and divides spending totals into categories. The budget is organized into "functions" of related spending categories. For instance, function 550 includes all health programs, such as the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ).

The budget regulates two types of spending: mandatory spending for "entitlement" programs that the law requires the federal government fund annually, such as

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Inside

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Please see Brief Summary of Prescribing Information on adjacent page.

Reference: 1. Renvela [package insert]. Cambridge, MA: Genzyme Corp; 2009.

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Health care reform

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able Care Act establishes a "shared savings program" through which groups of providers coordinate care for Medicare beneficiaries in accountable care organizations (ACOs). ACOs—which are groups of providers and suppliers with shared governance that meet quality performance standards determined by the HHS secretary—will be eligible to receive payments for shared savings beginning January 1, 2012. Intended to promote efficient service and accountability for a patient population, the ACO program encourages investment in infrastructure and redesigned care processes. Among other things, qualified ACOs must promote evidence-based medicine and patient engagement, and meet patient-centeredness criteria specified by the secretary, such as through the use of individualized care plans.

Although the Act grants the HHS secretary discretion in further defining ACOs, it suggests that ACOs may be formed of an array of providers and organizations, including professionals in group practice arrangements, networks of individual practices, and hospitals employing ACO providers. This inclusive model would afford nephrologists numerous avenues to participate in an ACO—and potentially to improve the delivery and quality of care for patients with kidney disease at any stage of progression from stage I through dialysis.

In addition to the ACO program, the Act creates a Center for Medicare and Medicaid Innovation (CMI) within CMS, tasked with testing innovative payment and service delivery models beginning no later than January 2011. The HHS Secretary will select for testing models that address a specific population for which a care deficit exists, or a population with potentially avoidable expenditures. The patient-centered medical home (PCMH) model and Healthcare Innovation Zones (HIZ) are among possible opportunities for funding and investigation in the legislation.

The PCMH concept has received increasing attention within the nephrology community as a possible opportunity to better harmonize care (1). Potentially, nephrologists could provide care and receive payment as a "neighbor" to the medical home, or serve as the "home," for some patients. HIZs—groups of providers including a teaching hospital, physicians, and other clinical entities—would receive a comprehensive payment for delivering a full spectrum of coordinated health care services. Given the well-recognized challenges of managing chronic kidney disease and its common co-morbidities, nephrologists are likely contenders to be included in at least some test service and delivery models in the CMI.

GAO study on access under bundled payments

Although CMS has yet to release a Final Rule on the bundled rate payment system for end stage renal disease (ESRD) care, health reform legislation includes a provision requiring the Government Accountability Office (GAO) to conduct a study on the impact on Medicare beneficiary access to dialysis drugs, including drugs or biologicals for which there is no injectable equivalent or other non-oral form of administration. The report will examine providers' ability to furnish oral drugs or arrange for their provision, and their ability to comply with state pharmacy licensure requirements. Furthermore, GAO will assess whether appropriate quality measures exist to safeguard care for patients being furnished specified oral drugs by providers and renal dialysis facilities and will make recommendations to Congress.

This independent analysis of patient access under the bundled payment system will be vital to ensure quality and accessibility of care. Yet the provision is also of interest because of its relationship to the forthcoming Final Rule on the bundled payment system. One possible interpretation of this language is that Congress intended the study to be prospective—and that CMS should therefore delay implementation of bundling until it is completed. Conversely, it could be interpreted that Congress intends for all drugs without injectable equivalents—including calcimimetics and phosphate binders—in the bundle as of January 2011.

Payment

As the nephrology community prepares for implementation of the bundled rate payment system for ESRD care, the health reform bill lays groundwork for further shifts toward payment bundling. Specifically, the Act requires the HHS secretary to develop a pilot program for integrated care during an episode of hospitalization. Most important, the pilot bundle would include physicians' serv-

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Health care reform

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Table 1. Implementation timeline

Implementation Year	Legislation
2010	• Bars insurance companies from rescinding coverage when enrollees get sick • Requires insurance companies to cover preventive services (applies to plans that are new in 2010) • Eliminates lifetime limits on benefits in group health plans and bars plans from imposing pre-existing conditions on children's coverage • Provides sliding scale tax credits to help small businesses afford insurance • Reduces the Medicare prescription drug donut hole in 2010 and eliminates it by 2020 • Establishes an independent, nonprofit institute for comparative effectiveness research
2011	• Allows unused Graduate Medical Education training slots to be redistributed to increase primary care training at other sites • Increases reimbursement for primary care services under Medicare and Medicaid (2011–2014)
2012	• Establishes a "shared savings program" under which groups of providers may manage and coordinate care in "accountable care organizations" (ACOs) and receive payments for shared savings
2013	• Establishes a national pilot program on payment bundling to encourage provider collaboration and care coordination • Requires drug, device, and other medical manufacturers to routinely submit records of payments or other transfers of value to physicians to the HHS secretary
2014	• Bars insurance companies from discriminating based on pre-existing conditions, health status, age, or gender and from imposing annual limits on coverage • Increases Medicaid eligibility to 133 percent of the Federal Poverty Level for all non-elderly individuals • Provides federal matching payments to states for the cost of services to newly eligible Medicaid enrollees • Creates health insurance exchanges—competitive marketplaces where individuals and small businesses can buy affordable health care coverage • Provides sliding scale tax credits to help individuals afford insurance • Requires most individuals to obtain health insurance, or pay a fee if they do not • Prohibits health plans from dropping or denying coverage because an individual participates in a clinical trial
2015	• Establishes an Independent Payment Advisory Board to submit proposals to Congress and the private sector aimed at extending Medicare solvency, lowering costs, and improving health outcomes • Creates a value-based (rather than volume-based) physician payment program for Medicare

ices. Also included in the bundle would be payments for acute inpatient care, outpatient and emergency department, and post-acute care services. No date is set for initiation of the pilot program. However, if the secretary determines that expansion of the program would improve—or not reduce the quality of—patient care and reduces costs, he or she must develop a plan for implementation no later than January 16, 2016.

This landmark pilot program marks the first attempt to unite physician fees with other payments since the inception of the Medicare program. Theoretically, the pilot could in the long term prove to be the first step in major changes to the physician payment system.

Industry payments to physicians have long been of interest to Congress, and the Patient Protection and Affordable Care Act will begin bringing these transactions into the public eye as of March 31, 2013. All manufacturers of drugs, devices, biologicals, or medical supplies will submit to the HHS secretary detailed documentation of payments made to physicians or teaching hospitals every 90 days. The name and address of recipients, as well as the amount, date, and description of payments are among the information required for all payments or "transfers of value," including consulting fees, honoraria, gifts, education, research, and travel. The secretary will make payment information publicly available via an Internet database, plus "background information on industry-physician relationships" and "any other information the Secretary determines would be useful for the average consumer."

The Act contains a limited number of exceptions, including delayed publication of payments made related to research on a potential new medical technology or application, and of those

made in connection with a clinical investigation regarding a new drug or device. Notably, nephrologists, like other physicians, will not share any reporting burden; the Act places this responsibility solely on industry.

Workforce

The number of U.S. medical students pursuing careers in nephrology has been declining for years, and many consider the lack of student interest in internal medicine residencies to be part of the problem. Seeking to address this shortfall of general interest and other primary care physicians, Congress included numerous approaches to encourage more students to go into primary care.

In addition to multiple incentive payment programs and loan repayment options for students entering primary care, the bill also redistributes 65 percent of currently unused residency training slots and directs those slots to hospitals in certain states in July 2011. "The nation's medical schools and teaching hospitals have expressed their full support for this bill to President Obama," said Association of American Medical Colleges (AAMC) President and Chief Executive Officer Darrell G. Kirch, MD (2).

Comparative effectiveness research

"The most significant thing [in the health care bill] is comparative effectiveness research," said National Institutes of Health (NIH) Director Francis Collins, MD (3). Indeed, the legislation establishes a "Patient-Centered Outcomes Research Institute," an independent, nonprofit corporation to increase the quality and relevance of medical services and treatment through comparative effectiveness research. The institute is tasked with identifying national priorities for comparative effectiveness research, taking into account factors of disease incidence, prevalence, and burden—and emphasizing chronic conditions and gaps in evidence in terms of clinical outcomes, among other factors. In carrying out its research agenda, the institute will enter into contracts to manage funds and conduct research with federal government agencies as well as the academic and private sectors.

ASN will be actively engaged in collaborating with members of Congress, HHS (particularly the Centers for Medicare and Medicaid Services), and the rest of the nephrology community to implement these reforms and address other important aspects of the U.S. health care system not included in this historic legislation.

1. DuBose T, et al. The Nephrology–Primary Care Interface: Providing Coordinated Care for Chronic Kidney Disease. *NephSAP* 2010; 9:1–4.
2. Kirch D. "AAMC Hails Final Passage of Reform Legislation." March 21, 2010. Press Release. Available: http://www.aamc.org/newsroom/pressrel/2010/100321.htm
3. Saslow R. "Conversations: Francis S. Collins. NIH Director Sees Hits and Misses in Health Care." March 24, 2010. *The Washington Post*.

Budget Priorities

Continued from page 1

Medicare and Medicaid, and "discretionary" spending, such as CDC and AHRQ. Each year, Congress must decide whether to appropriate funds for discretionary programs. Following development of the congressional budget, House and Senate Appropriations Committees allocate discretionary funding to programs and agencies within function areas. With the exception of the Medicare End-Stage Renal Disease (ESRD) Program, the majority of agencies and programs of interest to the nephrology community rely on discretionary funding.

Proposed budget includes robust funding for medical research

Requesting a $1 billion increase in discretionary NIH funding for FY 2011—a 3.2 percent increase from FY 2010 levels—President Obama clearly prioritizes scientific research in this year's budget (Table 1). Of the total $32.2 billion requested for NIH for FY 2011, approximately $1.96 billion is targeted toward the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a 2.6 percent jump from FY 2010. Similarly, the budget includes a 2.9 percent increase over last year for both the National Heart, Blood, and Lung Institute (NHLBI) and the National Institute on Aging (NIA), nearly $3.1 billion and just over $1.1 billion, respectively.

NIH Director Francis Collins, MD, recently outlined five "exceptional opportunities" for the agency to pursue that could reap substantial downstream benefits. In developing the budget, NIH mapped the portfolio of each institute or center against these five themes and then adjusted to reflect other area- or institute-specific contingencies:

- Applying high-throughput technologies to understand fundamental biology and to uncover the causes of specific diseases.
- Translating basic science discoveries into new and better treatments.
- Putting science to work for the benefit of health reform.
- Encouraging a greater focus on global health.
- Reinvigorating and empowering the biomedical research community.

Collins also emphasized medical research as a sound investment in the economy. NIH data show that each dollar of NIH funding creates more than two dollars in state economic output per year, and each grant generates approximately seven jobs.

Although pleased with the proposed increase, the Ad Hoc Group for Medical Research, on whose executive committee ASN serves, had recommended that NIH receive a $35 billion budget in FY 2011. This figure reflects the FY 2010 budget adjusted for medical inflation, plus half the value of funds that were awarded as part of the American Recovery and Reinvestment Act (ARRA, better known as the economic stimulus package), to ensure continuation of ongoing research.

Last year, Congress appropriated the Department of Veterans Affairs (VA) approximately $47.5 billion in discretionary funding for medical care and an additional $581 million for health research. For FY 2011, the Obama administration proposes a nearly 8.5 percent boost in medical care spending totaling over $51.5 billion.

VA health research also stands to gain—if somewhat more modestly—at 1.5 percent over FY 2010 levels, or just shy of $600 million. ASN serves on the executive committee of the Friends of the Veterans Affairs Medical Care and Health Research (FOVA), which has recommended a $700 million research budget to support returning veterans from Iraq and Afghanistan and to bring VA research facilities into the 21st century.

Table 1. Federal budget comparison, FY 2010 versus FY 2011

Federal agency	FY 2010 actual	FY 2011 proposed	Proposed increase/decrease	Percent increase/decrease
NIH	$ 31,247,200,000	$ 32,247,200,000	$ 1,000,000,000	3.20%
NIDDK	$ 1,957,364,000	$ 2,007,589,000	$ 50,225,000	2.57%
NHLBI	$ 3,095,812,000	$ 3,187,516,000	$ 91,704,000	2.96%
NIA	$ 1,109,800,000	$ 1,142,337,000	$ 32,537,000	2.93%
VA Medical Care	$ 47,505,000,000	$ 51,533,000,000	$ 4,028,000,000	8.48%
VA Health Research	$ 581,000,000	$ 590,000,000	$ 9,000,000	1.55%
AHRQ	$ 397,900,000	$ 610,900,000	$ 213,000,000	53.53%
FDA	$ 3,284,066,000	$ 4,031,658,000	$ 747,592,000	22.76%
NSF	$ 6,872,110,000	$ 7,424,000,000	$ 551,890,000	8.03%
CDC	$ 6,742,760,000	$ 6,611,478,000	$ (131,282,000)	-1.95%

Abbreviations: NIDDK = National Institute of Diabetes and Digestive and Kidney Diseases; NHLBI = National Heart, Lung, and Blood Institute; NIA = National Institute on Aging; AHRQ = Agency for Healthcare Research and Quality.

Comparative effectiveness research gets likely boost

With a proposed budget increase of 54.4 percent above FY 2010 funding, AHRQ receives the largest budget boost of any health-related agency in the president's budget. The $611 million outlined in the request is nearly $214 million more than AHRQ saw last year. Given the administration's focus on health reform, AHRQ—which supports research to improve health care quality, reduce costs, and broaden access to essential services—is a high funding priority.

If the president's proposal is enacted, a substantial portion—approximately $272.5 million—of the total $611 million AHRQ budget will likely be targeted to expand comparative effectiveness research. Other priority areas of research within AHRQ slated to see funding gains include hospital-acquired infections (HAIs)—$34 million—and health information technology (HIT). ASN serves on the executive committee of Friends of AHRQ, a coalition of more than 200 health-related organizations dedicated to supporting the agency, and strongly endorses the president's request for the agency.

Also poised for significant budget growth in 2011 is the Food and Drug Administration (FDA), receiving a nearly 23 percent budget increase in the president's proposal. This funding would elevate the FDA's budget to just over $4 billion in 2011, up nearly $1 billion from 2010. Although the administration has identified increasing food safety as the major priority for the FDA in 2011, the proposed budget also includes $25 million dedicated to modernizing regulatory science.

The proposed $25 million for regulatory science dovetails a recently announced initiative between NIH and FDA to accelerate the process from scientific breakthrough to the availability of new, innovative medical therapies for patients—including new RO1 grant funding for regulatory science investigators.

Like most programs and agencies related to medical research, the National Science Foundation (NSF) received a proposed increase in the president's budget. Specifically, NSF would receive an 8 percent boost to nearly $7.5 billion in 2011. The budget calls for doubling funding for multidisciplinary research on next-generation information and biological technologies intended to fuel job and industry creation. The president also highlights a 14 percent increase in funding for a new consolidated program aimed at building the science and technology workforce by recruiting and retaining undergraduate students from underrepresented groups.

The CDC is the only health-related agency slated for a decrease in funding under the Obama administration's budget request. Unobligated balances from the FY 2009 pandemic influenza supplemental enabled CDC to request fewer resources, and this decrease is reflected in the $133 million reduction from FY 2010 levels.

Amid a challenging economic climate and a declared freeze on most discretionary spending, medical research has nonetheless triumphed in President Obama's proposed budget for FY 2011. "The administration clearly recognizes the potential of research funding to enhance patient care, improve quality of life, reduce health care costs, and strengthen the U.S. economy," said ASN Public Policy Board Chair Thomas Hostetter, MD.

The beneficial impact of increased NIH funding is evident nationwide. For example, Oregon Health & Science University (OHSU) received approximately $58 million in ARRA awards from NIH as of December 2009. These funds fueled 112 projects spanning a wide spectrum, from studies to improve how we identify cancer-causing changes in genes to research aimed at restoring limb movement in stroke victims to projects on improving how providers use health information technology tools to reduce medical errors and costs.

Moreover, OHSU estimated nearly 300 full- and part-time jobs added or retained as a result of increased funding from NIH through ARRA. "Our own analysis, as well as that of the National Institutes of Health, has demonstrated that biomedical research is a powerful stimulant for the local economy," said OHSU President Joe Robertson, MBA, MD. "Few investments directly benefit so many citizens while at the same time creating sustainable, highly skilled jobs and economic activity."

ASN will continue to press lawmakers to support the president's research focus as the budget and appropriations processes move forward. The society's advocacy activities include having the ASN Council, Board of Advisors, and Public Policy Board visit Capitol Hill last month, in honor of World Kidney Day, for a series of meetings with members of Congress, their staff, and other key policymakers.

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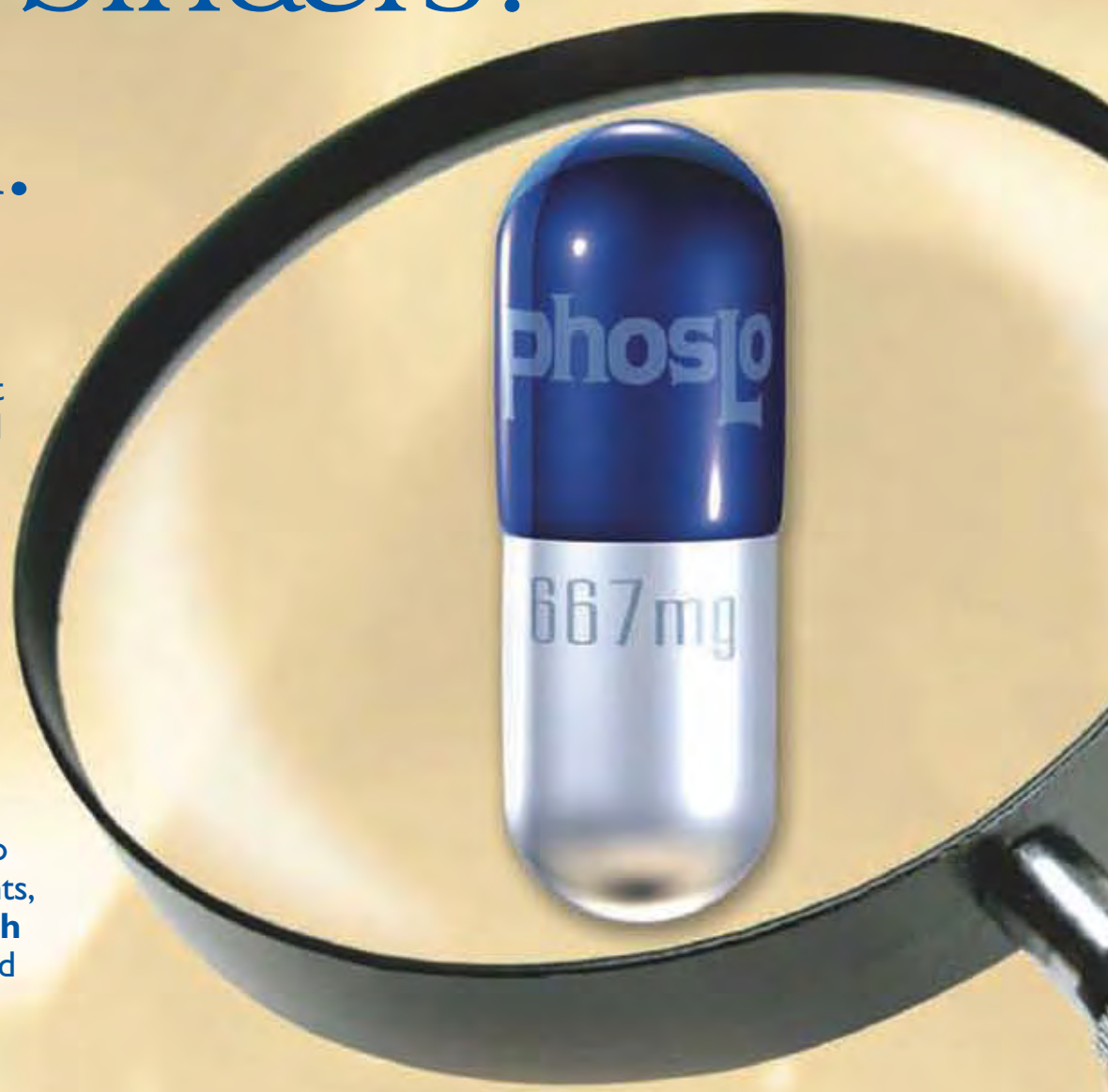

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1. Qunibi WY, Hootkins RE, McDowell LL, et al. Treatment of hyperphosphatemia in hemodialysis patients: The calcium acetate renagel evaluation (CARE Study). *Kidney International* 65:1914-1926, 2004. 2. Qunibi WY, Moustafa M, Kessler P, et al. Coronary artery calcification in hemodialysis patients: Preliminary results from the calcium acetate renagel evaluation-2 (CARE-2) study. Poster session presented at the International Society of Nephrology/World Congress of Nephrology Meeting in Rio de Janeiro, Brazil: April 21-25, 2007. 3. Suki WN, Zabaneh R, Cangiano JL, et al. Effects of sevelamer and calcium-based phosphate binders on mortality in hemodialysis patients. *Kidney International* Aug 29, 2007. 4. Young EW, Albert JM, Akizawa T, et al. Sevelamer vs. calcium-containing phosphate binders and mortality in the dialysis outcomes and practice patterns study (DOPPS). *J Am Soc Neph.* 16: Abstract, 2005. American Society of Nephrology Renal Week. Pennsylvania Convention Center, Philadelphia, PA. November 8-13, 2005. 5. PhosLo [prescribing information]. Fresenius Medical Care, Waltham, MA: January 2007. 6. Mehrotra R, Kopple JD, Wolfson M. Metabolic acidosis in maintenance dialysis patients: clinical considerations. *Kidney International* 64(suppl 88):S13-S25, 2003. 7. Drug Topics Redbook (Montvale, NJ: Thomson Healthcare), 2007.

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Interdisciplinary Care of the CKD Patient

Historically, care for chronic kidney disease patients in the United States has been provided by strong interdisciplinary teams. The 2008 Medicare Conditions for Coverage for dialysis and kidney transplant teams firmly legislates this type of care provision. The Conditions now require that every dialysis and transplant team have a physician, nurse, master's level social worker, registered dietitian, certified patient care technician, and most importantly, a focus on patient-centered care that encompasses making patients the most important member of these teams.

In this special section of *ASN Kidney News*, we are fortunate to have these interdisciplinary team members discuss ways that these professionals can uniquely contribute to patient care, and bring up important issues related to interdisciplinary barriers to chronic kidney disease outcomes.

Lori Hartwell, a kidney patient and advocate, presents the critical patient perspective and discusses ways that teams can work with patients to help them become active members of interdisciplinary teams. Anthony Messana examines the function of the patient care technician on teams, and Rita Solomon-Dimmitt discusses the critical role of nutrition in kidney disease patients. Teri Browne explores the psychosocial barriers to patient outcomes, and Dori Schatell and Joseph Merighi review nonmedical obstacles to fistula use in dialysis patients.

Together, these interdisciplinary experts present information relevant to all chronic kidney disease care providers that can help maximize the care provided to patients.

Teri Browne, PhD, MSW, is assistant professor of health social work services at the University of South Carolina College of Social Work in Columbia, and Sheila O'Day, MSN, is a nurse practitioner with the University of Nebraska Medical Center.

PARTNERING IN CARE—A PATIENT'S PERSPECTIVE

By Lori Hartwell

One of my earliest memories of having a health care professional empower me to become a partner in my own care occurred when I was eight years old. My pediatric nephrologist, Dr. Richard Fine, was determined that I learn how to take my own blood pressure and that I fully understand the medications I was taking. I had been under his care since the age of two, and he finally challenged me to take a more active role in managing my disease. His confidence in my ability to monitor my own status inspired me to learn more about kidney disease and to strive to be the best patient that I possibly could be.

When I was a teenager there were exciting developments in the treatment of kidney disease. Many of the therapies that people now take for granted were in their infancy, and I was often one of the first persons to try a new treatment. Although I trusted my doctor's knowledge, I still felt like I needed to understand the new therapies or procedures so that I did not feel like a guinea pig. I believe that my interest in being involved with my own care led to a better relationship with my nephrologist.

Throughout the process he treated me as an equal partner. His expectation that I would be interested and involved in my own care helped me understand how my actions could help maximize the benefits of therapies, ultimately leading to a more successful outcome.

Based on my own lifelong experience with kidney disease, I believe that patients of all ages can become active partners with their health care providers. When you hear the phrase "partner in care," it may seem like a very abstract expression, and many patients (and health care professionals) may ask, "Does becoming a partner in care really matter?" The answer is a definitive yes! A partnering relationship between the patient and physician is essential for patient empowerment, which has been repeatedly demonstrated to yield better outcomes—especially for patients with a chronic disease.

So let's assume that physicians want to build partnering interpersonal relationships with their patients. How can they pursue that goal? Encouraging patient empowerment often has more to do with the physician's nonverbal communication skills than with the information conveyed. Based on my 40-year (and counting) lifelong experience living with chronic kidney disease, I would like to offer the following tips to physicians who want to partner with and empower their patients.

Invest the time to partner with your patients

I feel very fortunate because I've had a good relationship with my present nephrologist for the past 20 years. He knows me and I know him. We have gotten to know each other's quirks and personalities and are comfortable communicating with each other. He realizes that to be an empowered patient I need to understand and make my own decisions regarding my care. He routinely provides me with information about my current status, and I reciprocate by providing ongoing and proactive updates of my status from my perspective.

[My nephrologist's] expectation that I would be interested and involved in my own care helped me understand how my actions could help maximize the benefits of therapies, ultimately leading to a more successful outcome.

I believe that my understanding of my disease and the ability to recognize the different "danger signs" that occasionally arise have helped in his assessments and led to an improvement in my own care and outcomes. We work as partners in determining treatment plans. He lets me know the options (including the positives and negatives), helps me understand the decisions that I have to make, and provides his medical perspective of the route to the best care. Ultimately, however, I am the decision maker.

In contrast, I also receive care from a number of physicians from other disciplines with whom I don't have either that rapport or that partnership—yet they are responsible for some very important aspects of my health.

Patients and physicians both need to understand the other's communication style. Physicians should realize that patients communicate differently—some

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Partnering

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verbally and some nonverbally. I recommend that at the initial visit between a doctor and patient, the physician take the lead by having a frank discussion on how the two parties will communicate. For example, the physician could provide a short bio or a personal philosophy video that would help the patient get to know him.

If physicians devote the time to letting patients know that they want them to become partners in their own care, it will go a long way toward encouraging patient involvement. Physicians might also provide a list of what kind of communication they encourage from patients. This list should include not just what to do in an emergency, but also how patients can become educated and active participants, and the kind of information that they should track and share with the physician at each office visit.

It is never too late to open up or change the lines of communication. I encourage physicians to surprise your current patients by adapting a similar approach and investing the time to show them you care about their input and opinions. I believe the short- and long-term outcomes that will result will more than make up for the time investment.

Be mindful of the tone of your communications

One thing that can make or break a partnership is the doctor's tone of voice and body language. If a doctor seems to be distant and "not there," or is condescending, the patient frequently just shuts down, leaving the physician wondering why a message is not getting through. Conversely, a partner-in-care relationship is fostered when the physician's voice and body language make it clear that he or she sincerely wants the patient to be involved and do better.

Patients have a tendency to dissect and remember whatever communications they have with the doctor in detail. Remember that although the physician has dozens of interactions with patients a day, for the patient these interactions with a crucial individual in their lives happen infrequently. It is not uncommon for me to remember almost word for word a conversation I had with my physician weeks earlier.

Even a minor tonal shift by the doctor that is misinterpreted or accompanied by conflicting body language can result in the doctor's intended message being totally missed or misunderstood. Although a physician tells me one thing, I may focus more on his facial expressions or body language and "hear" something totally different. It is therefore very important that the physician ask the patient for input, ask him to repeat back the information that was provided, and clarify any questions. It is also vital that the physician review the decisions that were jointly made to ensure that the intended messages were actually heard.

Encourage the use of peer resources

Because doctors must deliver good news and bad news on a daily basis, these messages are most effectively received by the patient when delivered with compassion, care, and a good dose of hope.

It is difficult and challenging to care for patients in such a way that you are honest in delivering the hard facts while simultaneously providing the patient with a sense of shared purpose, partnership, and hope for a worthwhile future. What makes this even harder is limited resources that do not allow physicians to spend unlimited time with each patient.

One factor that can significantly help a doctor achieve these challenging goals is leveraging outside resources. Such resources can complement the physician's message and prepare patients to be more knowledgeable and educated partners with their caregivers.

In 1993, I founded the patient-run Renal Support Network (RSN), which offers several programs that reach out to patients and provides substantial resources to develop hope, knowledge, and partnership skills. These include a dynamic website (RSNHope.org) that offers online support including a patient-run bulletin board (Kidney Space), educational patient meetings, a patient-run radio program (KidneyTalk), essay contests, and written articles.

RSN offers a one-of-a-kind nationwide toll free support program called HOPEline, (1-800-579-1970), where patients can call in and interact at length with experienced and trained patient peers. The peers' primary mission is to share their experience, strength, and hope, as well as to direct callers to other helpful resources.

Learning about such peer resources and directing patients to them helps physicians demonstrate that they care about more than just clinical issues and are truly concerned for the patient's emotional well-being. This attention to treating the patient as a complete person helps build trust that, in turn, leads to a stronger physician-patient partnership and mutual respect. Fostering such a relationship may help improve patient quality of life and better overall outcomes.

Lori Hartwell is president of the Renal Support Network.

Contribution of the Dialysis Technician to Patient Outcomes

By Anthony Messana

Over the years, the evolution of dialysis technology has enabled us to measure delivered adequacy of dialysis, precisely predict and remove fluid volume, and perfect the patient monitoring process during treatment. Another area of evolution is the expanded collaborative role of the multidisciplinary team providing care to kidney patients and their families. In years past, patient care was provided primarily by licensed medical professionals. Over time the multidisciplinary team has expanded to include unlicensed professionals in a collaborative effort to provide holistic care to a patient population that is growing in number, age, and co-morbidities.

Who are these multidisciplinary team members and what attributes are required of each member? The team consists of the nephrologist, registered nurse, patient care technician (PCT), dietitian, and social worker. Each team member must be a professional who, based on their education, skill sets, and scope of practice, is committed to providing safe and competent care to patients. Because the attributes of the team members differ, the definition of care provided by each member will differ. A true multidisciplinary team results when these varying definitions of care are brought together.

The new Medicare Conditions for Coverage (CfC) have broadened the care provider focus to include all the members of the patient care team. The conditions set forth qualifications and roles for the medical director, nurse manager, nursing staff in both home and in-center modalities, dietitian, social worker, PCT, water treatment and reprocessing technician, and CEO/administrator. Defining the team in a broader scope has allowed Medicare to better define the education and training requirements for each team member and to identify expected competencies for each team member.

In the new CfC, each patient is required to have an individualized patient assessment by nursing and social and dietary services in addition to the nephrologist's medical documentation. The conditions help those caring for kidney patients move from an isolated and sequential assessment process into the required collaborative interdisciplinary "plan of care." In their surveying process, Medicare is examining the collaborative nature of these plans and will be citing facilities if they fall short in meeting this requirement.

An integral member of the multidisciplinary team is the PCT. With growth of the dialysis patient population, the role of the PCT has expanded to one of caregiver. As a result of this expanded role, Medicare and the dialysis community have recognized the importance of measuring the clinical competence of the PCT. The new CfC require all PCTs to have a minimum of a high school diploma or to have worked as a PCT for at least four years prior to October 2008. Also included is a new condition requiring all PCTs to pass a nationally recognized certification exam and to maintain the certification through continuing education or retesting.

In the day-to-day activities of the dialysis facility, the PCT interacts with the patient more frequently than other care providers. The PCT initiates the dialysis treatment, monitors the patient response to treatment, and discontinues the treatment. As a result of these frequent and close interactions, the patient develops a bond of trust with the PCT. This opens up communication and allows the patient to discuss problems and concerns. The PCT, in turn, shares this information with the multidisciplinary team and provides valuable input to the care planning process. Clearly, the PCT is an important and valuable member of the team.

Anthony Messana is executive director of St. Joseph Hospital in Orange, CA.

OPTIMAL NUTRITION IN CKD

By Rita Solomon-Dimmitt

The role of the registered dietitian in renal care is to help those with chronic kidney disease (CKD) maintain adequate nutritional status. Maintaining nutritional status needs to be considered a lifestyle change rather than a diet with limitations and overwhelming restrictions. Optimal renal nutrition provides the opportunity to live a longer life with renal replacement therapy (RRT) as it is indicated.

Prior to RRT, the primary goal is to limit excess uremic toxins and prevent protein-energy malnutrition. The Kidney Disease Quality of Life Index (KDOQI) recommends that individuals with chronic renal failure [glomerular filtration rate (GFR) < 25 mL/min] who are not undergoing maintenance dialysis follow a low-protein diet providing 0.60 g protein/kg/day. For individuals who will not accept such a diet or who are unable to maintain adequate daily energy intake with such a diet, an intake of up to 0.75 g protein/kg/day may be prescribed (1).

The registered dietitian needs to work with the patient at regular intervals to ensure adequate protein intake. Greene et al. documented reduced intake of protein as GFR declined. Adequate calorie intake is recommended to protect protein and to reduce the risk of catabolism. The calorie goal is 35 kcal/kg for those younger than 60 and 30–35 kcal/kg for those 60 and older. The registered dietitian can assess the patient's typical intake and develop a plan for the patient to coordinate the reduced protein levels, while achieving the additional caloric requirements. Tools such as Protein Nitrogen Appearance (PNA) and subjective global assessment (SGA) can assist in quantifying the patient's risk of malnutrition.

The team must be alert to signs of inadequate intake or uremic symptoms, which may indicate the need for initiation of dialysis or a renal transplant. Earlier intervention with RRT may correct a decline in nutritional status. The registered dietitian can assess weight trends, appetite, and ability to acquire and prepare appropriate foods, as Leon determined (2). The recommended protein for clinically stable peritoneal dialysis patients is 1.2 to 1.3 g/kg body weight/day; and for maintenance hemodialysis patients, 1.2 g/kg/day. The calorie goals continue to be generous to protect the protein and prevent catabolism; however, peritoneal dialysate calories should also be considered.

Kaysen suggested that inflammation contributes to anorexia, reduces the effective utilization of dietary protein and calorie intake, and contributes to catabolism of the key somatic protein, albumin (3). Nephrologists can potentially improve the nutritional status of patients by arranging permanent dialysis access placement.

A large study of over 4000 patients showed that central venous catheters can contribute to the inflammatory state and decreased albumin levels (4). Caregivers providing and overseeing dialysis can also reduce the risk of inflammation and infection with attention to access care and dialysate preparation. Implementation of quality process flow to assure timely intervention with erythropoiesis stimulating agents and bone mineral metabolism can improve appetite and reduce risk of inflammation, respectively.

Adequate food intake may be impeded by an individual's inability to function independently. The nephrology social worker can assist in assessing the support systems available and appropriate coping skills.

Nutritional intervention to improve oral intake may include calorie dense foods, small, frequent meals, and possibly oral supplements. The use of oral supplements during hemodialysis has been studied in 85 patients with significantly improved albumin, prealbumin, and SGA during six months of supplementation compared to the three months of baseline nutrition intervention alone (5). Appetite stimulants have been shown to be beneficial (6), and in extreme cases, intervention with tube-feeding or total parenteral nutrition can be instituted for the nonworking gastrointestinal tract.

The American Dietetic Association has taken the position that access to adequate amounts of safe, nutritious, and culturally appropriate food at all times is a fundamental human right. Food is a basic human need. Many patients, however, reside in "food deserts" with little or no access to fresh foods or lower cost grocery options. The registered dietitian can assist with recommending organizations and programs that address food insecurity. Assistance in teaching patients methods for preparing less costly cuts of meat is necessary to achieve the goal of 50 percent high biological value protein. Recommending use of lower potassium seasonal fruits and vegetables as less costly nutritional sources or reducing the sodium content of canned vegetables are methods to help accommodate a limited food budget.

Transplantation offers an alternative to the regimen of dialysis and has the benefit of less strenuous protein needs. The primary nutritional goals emphasize maintenance of desirable body weight and use of poly- and monounsaturated fats. Patients are encouraged to exercise and maintain healthy weight ranges. A team approach is the most effective method to achieve the lifestyle changes needed.

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References

1. KDOQI: Nutrition in chronic renal failure. *Am J Kidney Dis* 2000; 35:6, suppl 2.
2. Leon JA, et al. Can a nutritional intervention improve albumin levels among hemodialysis patients? A pilot study. *J Renal Nutr* 2001; 11:9–15.
3. Don BR, Kaysen G. Serum albumin: Relationship to inflammation and nutrition. *Seminars in Dialysis*; 17:432–7.
4. Thijssen, S, et.al. Determinants of serum albumin concentration analyzed in a large cohort of patients on maintenance hemodialysis. *J Renal Nutr* 2007; 17:70–74.
4. Cagler K, et al. Therapeutic effects of oral nutritional supplementation during hemodialysis. *Kidney Int* 2002; 62:1054–1059.
5. Burrowes J. The role of pharmaceutical agents in appetite stimulation in patients with end-stage renal disease. *J Renal Nutr* 1996; 6:127–133.

Psychosocial Barriers to Chronic Kidney Disease Patient Outcomes

By Teri Browne

The current paradigm for the provision of chronic kidney disease (CKD) care mandated by the 2008 Conditions for Coverage requires an interdisciplinary approach to outcomes-driven patient care. In CKD, dialysis, and kidney transplant centers, master's level social workers can work with these interdisciplinary teams to help patients ameliorate psychosocial barriers to optimal outcomes.

Social workers can be of particular help in the areas of patient self-management of diet, fluid restriction, medications, treatment recommendations, and modality selection. Social workers are often the team expert on palliative care, and can help maximize patient satisfaction and physical and mental functioning.

There are psychosocial barriers to CKD patients' self-management of all laboratory values and to medication self-management. Social workers can help teams understand these barriers to patient self-management as they relate to food security, health beliefs, denial, and coping.

Take, for example, patients with a high phosphorus level. From a psychosocial perspective, patients may have high phosphorus because they live in areas without easily accessible large grocery stores (this occurs in many poor urban neighborhoods, as well as in very rural areas). The only way such a patient can access groceries is through a small convenience store that may only stock processed foods high in phosphorus. Or a patient's phosphorus may be high because the patient wants to "fit in" with his friends. He may be in denial about his CKD and too embarrassed to carry around or take the phosphorus binders that would help lessen the effects of the phosphorus-rich fast food he routinely eats with his friends.

Another reason that a patient may not follow the prescribed diet is a low income that precludes purchase of fresh vegetables and high quality proteins or reliance on a "Meals on Wheels" program that does not accommodate a renal diet.

A patient's phosphorus level may also be high because she has a low health literacy. Despite having completed high school, she may have difficulty reading and understanding the letters and numbers on her prescription bottle. Or because she is burdened with taking numerous pills every day as a CKD patient, she may not be able to afford even a nominal copayment for her medications. Or she may not want to use her strict fluid allowance in swallowing so many pills.

Because a high phosphorus often doesn't have immediate, tangible symptoms and phosphorus binders do not provide any noticeable relief (as a pain reliever would for a sore back), patients may not comprehend why maintaining a low phosphorus is so important. This is especially true when the team uses complicated medical terminology like "phosphorus," "hyperphosphatemia," "bone disease," and other jargon.

Social workers can assist patients with all of these psychosocial barriers to optimal patient laboratory outcomes by exploring and addressing health beliefs, pill burden, literacy, community resources, social network influence, and socioeconomic factors.

The nephrology social worker is often the expert in palliative care on CKD teams and can help patients explore starting and stopping treatment, pain, advance care planning, and coping with the losses associated with kidney disease and its treatments.

All dialysis patients now must be assessed for their physical and mental functioning. The Clinical Performance Measurements require that patients' Kidney Disease Quality of Life (KDQOL) be measured routinely by social workers. Patient quality of life has been empirically linked to patient mortality and morbidity. It is a critical area for patient assessment and intervention that should be an important part of any dialysis unit's Quality Assessment and Performance Improvement program.

Eighty-nine percent of kidney disease patients report experiencing significant lifestyle changes from the disease (1). Researchers including Auslander, Dobrof, and Epstein (1), Burrows-Hudson (2), and Kimmel et al. (3) have found that psychosocial issues negatively impact health outcomes of patients and diminish quality of life. Because of the importance of these factors, every dialysis and kidney transplant center must have a master's level social worker on its interdisciplinary team to help patients with psychosocial barriers to CKD outcomes.

Teri Browne, PhD, MSW, is assistant professor of health social work services at the University of South Carolina College of Social Work in Columbia, SC .

References

1. Auslander G, Dobrof J, Epstein I. Comparing social work's role in renal dialysis in Israel and the United States: the practice-based research potential of available clinical information. *Social Work in Health Care* 2001; 33:129–151.
2. Burrows-Hudson S. Mortality, morbidity, adequacy of treatment, and quality of life. *ANNA J* 1995; 22:113–121.
3. Kimmel P, et al. Psychosocial factors, behavioral compliance and survival in urban hemodialysis patients. *Kidney Int* 1998; 54:245–254.
4. Kaitelidou D, et al. Implications of hemodialysis treatment on employment patterns and everyday life of patients. *Dial Transpl* 2005; 34:138–147, 185.

BARRIERS TO FISTULA PLACEMENT AND USE: The Patient Side of the Equation

By Dori Schatell and Joseph Merighi

Fistula First aims to increase arteriovenous fistula (AVF) use in prevalent hemodialysis patients from 32.4 percent (2003) to 66 percent, while reducing central venous catheter (CVC) use.

Stakeholder efforts ranging from vascular surgeon collaborations to restructuring reimbursement have driven the AVF rate up to 52.6 percent in 2009. But gaps remain in new AVF creation and in cannulation afterward. In-center continuous quality improvement protocols focusing on AVF processes are necessary, but not sufficient. Considering the patient side of the AVF equation may help us to reach—or exceed—that 66 percent goal.

Walk a mile in a patient's shoes

Many patients who start dialysis are poorly informed of their treatment choices and unaware of what "treatment" entails. Among 109,321 incident ESRD patients, only 50 percent had nephrology care in the 24 months before dialysis (1). Dialysis is a tremendous mental, physical, and psychological blow even when patients are prepared. They are asked to change schedules, diets, fluid intake, and medications. They may lose jobs, homes, or relationships. One third may have intradialytic hypotension, with painful muscle cramps, headaches, dizziness, nausea, and vomiting.

With CVCs in place, patients can observe their chair neighbors who have fistulas. From the patient's perspective, the sight of a fistula may create concerns or even fears. The following quotes are from patients who participated in a public dialysis-support email listserv and commented with their concerns about getting a fistula.

"At dialysis, I could see everyone's accesses from a distance, but didn't want to see them up close as I sensed they looked pretty bad. Some patients had very scarred up looking arms from afar."

"My biggest fear is being all scarred up. I like my body the way it is, whole and unaltered. The hardest part for me is knowing that my arm will look different and have scars."

"I have a very large fistula on my left arm—about six inches long and two inches thick. I work with young children. One day I made the mistake of wearing a short-sleeved shirt, and one of the kids got so scared he started to cry."

Have you seen those needles?

Needle fear is an underrecognized cause of refusal to have an AVF or permit one to be cannulated. Among the general population, an estimated 10 percent have needle phobia that triggers an involuntary vasovagal response—dizziness, nausea, fainting, even cardiac arrhythmias (1).

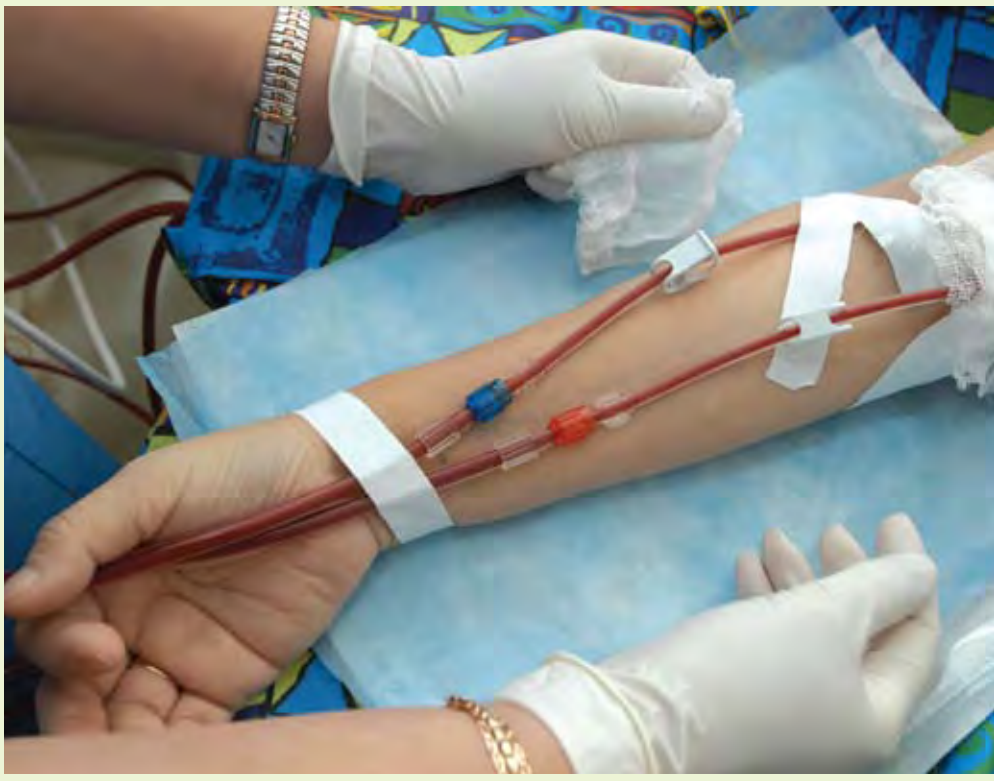
In 2007, 341,264 Americans used hemodialysis. If 52.6 percent of patients have AVFs, this represents more than 56 million cannulations per year, with 17 to 14 gauge dialysis needles. A PubMed search of "hemodialysis needle fear" found just two studies, both only peripherally addressing the topic (3,4). Yet for patients, needles can be a deal-breaker. Below are two quotes taken from a public dialysis-support email listserv that highlight needle-related concerns reported by some dialysis patients.

"Dialysis with my neck catheter was a piece of cake compared to using my arm. I've had bruising and trouble with bleeding after treatment. I still dread the stick, too…I catch myself worried about things that could happen, even lying awake at night with this on my mind."

"When my kidneys shut down, I went from the subclavian cath right to PD because I am, quite frankly, afraid of needles. Last year, I got a bad case of peritonitis and went onto hemo. I've been on a subclavian since. Over the year, I had six replaced. My doctor has been urging me to get a fistula because this subclavian is really too risky and hard on the vessels. Here's my problem: a friend showed me her fistulas, and I was horrified because they sliced her arms up and down. I'm also terrified of those needles. I don't know what to do."

Moving forward with fistulas

It is important that the entire dialysis care team recognize that new dialysis patients may have no intrinsic motivation to proceed with fistula creation and use. Improving patient motivation requires an interdisciplinary dialysis team approach. For example, the team can support the choice to have a fistula by:



- **calming fears.** Address needle fear with hypnosis referral, instruction to squeeze leg and non-access arm muscles during cannulation (prevents syncope), and by offering pain relief. Topical lidocaine (EMLA®, Topicaine®, LMX®, and Less-N-Pain® avoid additional needles, but must be applied one to two hours prior to treatment.
- **addressing body image concerns.** Acknowledge that dialysis causes losses to be grieved. Some patients choose to view their accesses as "battle scars." The Buttonhole Technique may reduce unattractive aneurysms and reduce needle pain (3).
- **educating patients.** The interdisciplinary team knows that fistulas provide optimal outcomes, but patients may not. Start by asking them to tell you what they know about access, so you can correct myths and start a dialog.

In the end, the responsibility of helping patients overcome their concerns about getting or using an AVF cannot be left to one member of the dialysis team. Nephrologists, in collaboration with social workers, nurses, patient care technicians, and dietitians, can provide a unique solution to this multifactorial problem. Understanding the patient's perspective is central to improving the U.S. fistula success rate.

Dori Schatell is executive director of Medical Education Institute in Madison, WI. Joseph Merighi, PhD, is associate professor of human behavior at Boston University School of Social Work.

References

1. Khan SS, et al. Does predialysis nephrology care influence patient survival after initiation of dialysis? *Kidney Int* 2005; 67:1038–46.
2. Hamilton JG. Needle phobia: A neglected diagnosis. *J Fam Practice* 1995; 41:169–75. Full text article available free on-line at: http://www.findarticles.com /p/articles/mi_m0689/is_n2_v41/ai_17276569
3. van Loon MM, et al. Buttonhole needling of haemodialysis arteriovenous fistulae results in less complications as compared to the rope-ladder technique. *Nephrol Dial Transplant* 2010; 25:225–30.
4. McLaughlin K, et al. Why patients with ESRD do not select self-care dialysis as a treatment option. *Am J Kidney Dis* 2003; 41:380–5.

Kidney Disease Patient Education Classes Now Reimbursable by Medicare

By Caroline Jennette

Kidney Disease Education (KDE) classes are now reimbursed by Medicare. Patient education services were mandated by the Medicare Improvements for Patients & Providers Act of 2008 and became effective January 1, 2010.

Who is allowed to administer KDE classes?

KDE services may be delivered by a physician, physician assistant, nurse practitioner, clinical nurse specialist, or if in a rural area (defined by Metropolitan Statistical Area), KDE services may be provided by a hospital, critical access hospital, skilled nursing facility, outpatient rehabilitation facility, home health provider, or hospice. Under no circumstances can a dialysis unit provide or bill for Medicare KDE sessions, even if it resides within a hospital.

Who is eligible for KDE services?

Medicare Part B beneficiaries with stage 4 chronic kidney disease can be referred for KDE classes. Beneficiaries with an estimated glomerular filtration rate of under 15 or over 30 are ineligible for services.

Is there a set curriculum for the KDE classes?

There is no standardized curriculum except that sessions must cover all topics listed in the regulations (see Table 1). The National Kidney Foundation has developed a curriculum that fits the regulations and is available for free from www.kidney.org/YTYC

How will KDE classes be measured for effectiveness?

There is not a standardized tool for outcomes measurement yet, but the Department of Health and Human Services is "considering working with organizations that are developing outcomes assessments as they work to develop a standardized assessment tool." However, outcomes assessments are supposed to be administered to the beneficiary during a KDE session and available to CMS by request.

How are the classes supposed to be formatted?

Sessions may be done individually or in a group, and each beneficiary may receive a maximum of six sessions. Sessions are billed at one hour. Group sessions may accommodate two to 20 people. All sessions must be "face to face."

How are the classes billed?

Two separate billing codes can be used depending on whether the sessions are done individually or in groups:

- HCPCS G0420 (CPT 97082): face-to-face, educational services related to the care of chronic kidney disease; INDIVIDUAL, per session, per one hour
- HCPCS G0421 (CPT 97804): face-to-face educational services related to the care of chronic kidney disease; GROUP, per session, per one hour

Caroline Jennette is legislative liaison at the University of North Carolina Kidney Center.

Table 1. Content standards for Kidney Disease Patient Education Services

Management of co-morbidities including for the purpose of delaying the need for dialysis

- Prevention and treatment of cardiovascular disease
- Prevention and treatment of diabetes
- Hypertension management
- Anemia management
- Bone disease and disorders of calcium and phosphorus metabolism management
- Symptomatic neuropathy management
- Impairments in functioning and well-being

Prevention of uremic complications

- Information on how the kidneys work and what happens when the kidneys fail
- Understanding if remaining kidney function can be protected, preventing disease progression, and realistic chances of survival
- Diet and fluid restrictions
- Medication review, including how each medication works, possible side effects and minimization of side effects, the importance of compliance, and informed decision-making if the patient decides not to take a specific drug

Therapeutic options, treatment modalities, and settings, including a discussion of the advantages and disadvantages of each treatment option and how the treatments replace the kidney

- Hemodialysis, both at home and in-facility
- Peritoneal dialysis (PD), including intermittent PD, continuous ambulatory PD, and continuous cycling PD, both at home and in-facility
- All dialysis access options for hemodialysis and peritoneal dialysis
- Transplantation

Opportunities for beneficiaries to actively participate in the choice of therapy and to help tailor it to meet their needs including

- Physical symptoms
- Impact on family and social life
- Exercise
- The right to refuse treatment
- Impact on work and finances
- The meaning of test results
- Psychological impact

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ASN News

ASN In-Training Examination for Nephrology Fellows

The second annual ASN In-Training Exam (ITE) was given on April 8 and 9, 2010, at 122 different institutions nationwide. The ITE is an Internet-based test administered by the National Board of Medical Examiners that closely mimics the American Board of Internal Medicine's initial certifying exam in nephrology. The results of the exam allow nephrology training program directors (TPDs) to compare their fellows both internally and with all other fellows in the country who took the exam. It also allows TPDs to identify subject areas that are lacking and need further attention as well as individual fellows who may need more direction in a certain subject.

For fellows, ITE offers an opportunity to assess their knowledge about all areas of nephrology. The exam was created and is maintained and updated by a subgroup of the ASN Training Program Directors Executive Committee led by Mitch Rosner, MD, associate professor of medicine at the University of Virginia.

ASN saw a substantial increase in registrants in one year—from 689 in 2009 to 754 in 2010. This number includes almost every first and second year nephrology fellow in the country. The test consists of 150 multiple-choice questions and takes about six hours to complete.

The exam, open to any nephrology fellow who is a member of ASN, will be an annual event. For more information, please contact ASN Senior Policy Coordinator Susan Owens at sowens@asn-online.org or (202) 416-0668, or visit the ITE Frequently Asked Questions website at http://asn-online.org/training/ite-faq.aspx. The results of the exam will be mailed to TPDs approximately six weeks after the test date.

Journal View

High Rate of AKI Even in Non-Severe Pneumonia

Acute kidney injury occurs in up to one-fourth of patients with uncomplicated pneumonia, in association with increased mortality and an elevated immune response, according to a study in *Kidney International*.

The prospective study included 1836 hospitalized patients with community-acquired pneumonia (CAP). The overall rate of AKI in CAP patients was 34 percent. Fifty-two percent of the patients with AKI had severe sepsis, while 48 percent had non-severe sepsis. In 63 percent of cases, AKI was already present at the time of hospital admission.

Among patients with non-severe CAP, the rate of AKI was 16 to 25 percent, depending on subgroup classification. Patients with AKI were older, more likely to be white, and had more preexisting comorbidity and more severe CAP. They also had increased levels of biomarkers, including interleukin-6, tumor necrosis factor, and D-dimer—even in the absence of severe sepsis.

The risk of death associated with AKI was highest in the first 100 days after presentation. However, the increase in mortality remained significant through one-year follow-up. For non-severe CAP patients with AKI, one-year mortality ranged from 17 to 34 percent. Mortality was increased even among patients who were never admitted to the ICU: hazard ratio 1.29.

Sepsis is the main cause of AKI in critically ill patients, but relatively little is known about AKI in patients with less severe illness. Most patients with CAP are not severely ill and do not receive intensive care.

This study documents the occurrence of AKI in one in three patients with CAP overall, including up to one in four patients with non-severe CAP. The development of AKI is associated with an increased risk of death and with increased levels of immune and fibrinolysis markers, even in the absence of severe sepsis. The authors call for increased awareness of the high incidence of AKI after pneumonia and for the development of new prevention and treatment strategies, especially for patients with non-severe CAP [Murugan R, et al. Acute kidney injury in non-severe pneumonia is associated with an increased immune response and lower survival. *Kidney Int* 2010; 77:527–535].

Across eGFRs, Proteinuria Linked to Increased Mortality

Proteinuria is an independent predictor of mortality and progressive kidney disease at all levels of estimated glomerular filtration rate (eGFR)—including normal kidney function, according to a report in *The Journal of the American Medical Association*.

Alberta laboratory registry data were used to evaluate relationships among eGFR, proteinuria, and adverse clinical outcomes. The analysis included more than 920,000 adults who had at least one outpatient serum creatinine measurement between 2002 and 2007 and were not receiving renal replacement therapy at baseline. Proteinuria was assessed by both dipstick and albumin-to-creatinine ratio (ACR).

Eighty-nine percent of patients had a normal eGFR (60 mL/min/1.73 m^2 or greater). On adjusted analysis, all-cause mortality was higher in patients with lower eGFR or higher proteinuria. Adjusted mortality per 1000 person-years was 7.2 for patients with heavy dipstick-measured proteinuria but normal eGFR, compared to 2.9 for those with decreased eGFR (45 to 59.9 mL/min/1.73 m^2) but normal protein excretion.

Proteinuria measured by ACR showed a similar effect on mortality. Heavy proteinuria was also independently associated with progressive kidney disease, including end stage renal disease and doubling of serum creatinine, and with acute myocardial infarction.

Current guidelines for kidney disease staging rely on eGFR but do not address the presence or severity of proteinuria—an important CKD marker that is also associated with adverse outcomes. Many patients with low eGFR do not have proteinuria, and vice versa.

This study shows increased rates of death and other adverse outcomes in patients with heavy proteinuria, regardless of eGFR. In fact, outcomes appear worse for patients with normal eGFR and heavy proteinuria than for those with decreased eGFR but normal proteinuria. "These findings suggest that future revisions of the classification system for CKD should incorporate information from proteinuria," the researchers write [Hemmelgarn BR, et al. Relation between kidney function, proteinuria, and adverse outcomes. *JAMA* 2010; 303:423–429].

Hospital-Associated Hyponatremia: High Costs and Consequences

Hyponatremia, whether community- or hospital-acquired, is a common problem that is associated with increased mortality and resource utilization, according to a report in *Archives of Internal Medicine*.

The cohort study included more than 53,000 adult hospitalizations at one tertiary care hospital between 2000 and 2007 for which an admission sodium level was available. The researchers analyzed the rates and outcomes of community-acquired hyponatremia (CAH), defined as an admission serum Na+ of less than 138 mEq/L; hospital-aggravated hyponatremia, in which community-acquired hyponatremia worsened during hospitalization; or hospital-acquired hyponatremia, in which serum Na^+ was normal at baseline but fell to less than 138 mEq/L in the hospital.

About 38 percent of patients had CAH. This group was at increased risk of in-hospital death, adjusted odds ratio (OR) 1.52. Patients with CAH were also more likely to be discharged to a long-term or short-term care facility, OR 1.12; and had a 14 percent increase in length of hospital stay.

Hospital-aggravated hyponatremia occurred in 5.7 percent of patients who had hyponatremia at admission. The OR for in-hospital mortality was 2.30 for this group, compared to 1.46 for patients with CAH but no further decrease in serum Na^+.

Of patients who stayed in the hospital for more than one day and had an admission serum Na+ of 138 to 142 mEq/L, 38 percent developed hospital-acquired hyponatremia. This group also had increased in-hospital mortality, OR 1.66; and increased risk of discharge to a facility, OR 1.64. Patients with hospital-acquired hyponatremia also had a 64 percent increase in length of stay. The consequences of hyponatremia tended to be greater at lower Na^+ levels.

The adverse prognostic impact of hyponatremia is well known, but few studies have included the full range of patients with hospital-associated hyponatremia or examined outcomes other than mortality. This large, unselected series finds that both CAH and hospital-acquired hyponatremia are common conditions associated with increased in-hospital mortality and increased resource use.

A significant percentage of patients with CAH have further drops in Na+ while hospitalized. Regardless of the nature of the associations, "hyponatremia is a compelling prognostic marker of adverse outcomes," the investigators conclude [Wald R, et al. Impact of hospital-associated hyponatremia on selected outcomes. *Arch Intern Med* 2010; 170: 294–302].

Letters

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

Policy Update

FDA and NIH Collaborate to Bring New Treatments to the Public

American Society of Nephrology (ASN) public policy staff recently participated in a briefing on a new partnership between the U.S. National Institutes of Health (NIH) and the Food and Drug Administration (FDA). The two agencies will work together to improve the processes for bringing new drugs and treatments through the approval process, thus making new therapies publicly available and improving public health.

NIH Director Francis Collins, MD, and FDA Commissioner Margaret Hamburg, MD, established the Joint NIH FDA Leadership Council, which will work to improve regulatory tools, make regulatory considerations part of biomedical research planning, and integrate the latest science into the regulatory review process.

NIH and FDA also issued a Request for Applications to encourage research in regulatory science on February 24, 2010. According to Health and Human Services Secretary Kathleen Sebelius, "much more can be done to speed the progress from new scientific discoveries to treatment for patients. Collaboration between NIH and FDA will go a long way to foster access to the safest and most effective therapies for the American people."

ASN enthusiastically supports this collaboration. The society's major legislative priorities include funding medical research in kidney disease and improving the success of kidney transplants. Designing research studies with a proactive approach to navigating the regulatory process, and improving the ability to carefully and efficiently evaluate the efficacy of new treatments, will help address the significant needs of millions of Americans who suffer from chronic kidney disease.

The jointly issued press release is available at http://www.nih.gov/news/health/feb2010/od-24.htm

Patients in the Public Safety Net: A Blind Spot in Medical Care?

Addressing profound health care disparities is a major legislative priority of ASN in 2010. As part of its commemoration of World Kidney Day on March 11, ASN highlighted the recently published work of Yoshio Hall, MD, Andy Choi, MD, Glenn Chertow, MD, and Andrew Bindman, MD. Their study, titled *Chronic Kidney Disease in the Urban Poor* (*Clinical Journal of the American Society of Nephrology*, doi 10.2215/CJN.09011209), emphasizes the need to better understand and address the burden and progression of chronic kidney disease (CKD) in underserved populations. Safety net medical settings provide care to millions of Americans who cannot afford medical care or are not eligible for health insurance.

Hall and his colleagues examined data from 15,353 adults with nondialysis-dependent CKD stages 3 to 5 who were cared for in safety net settings in San Francisco. The patients were followed for periods ranging from 12 months to 9.4 years. The vast majority were indigent (73 percent had annual incomes less than $15,000), 6 percent were homeless, and 46 percent unemployed. Forty percent were uninsured or enrolled in Medicaid, and one-third spoke a primary language other than English. The vulnerable populations studied are highly underrepresented in prior U.S.-based studies of kidney disease.

In this public health care setting, the study authors found that moderate to severe CKD afflicted a large fraction of younger adults, most of whom were members of racial-ethnic minority groups. They further observed that poor minority adults with moderate to severe CKD were two to four times more likely to progress to kidney failure than non-Hispanic whites. The authors concluded that additional research is vital to assess the extent and burden of kidney disease in other safety net settings, particularly as the nation contemplates how to enhance access to effective care for uninsured and underinsured Americans.

World Kidney Day and Beyond: ASN Advances Key Priorities in Kidney Care

World Kidney Day is a global health awareness campaign designed to inform lawmakers and the public about the prevalence of kidney disease and the importance of improving the lives of millions who suffer from kidney disease worldwide.

ASN leaders gathered in Washington, DC, on Thursday, March 11, 2010, and visited members of Congress and their staff. In visits to congressional offices and a series of radio interviews with national media, ASN leaders reviewed the four major legislative priorities for ASN in 2010:

- Address Profound Health Care Disparities
- Improve the Success of Kidney Transplants
- Fund Medical Research that Improves Kidney Health
- Fix the Flawed Sustainable Growth Formula

Several ASN leaders were invited to more informal sessions hosted by U.S. senators and representatives and discussed with them the issues noted above and the effect of kidney disease on individuals and their caregivers.

In collaboration with the National Kidney Foundation and Dialysis Patient Citizens, ASN hosted a reception for members of Congress, patient advocates, and kidney professionals at which speakers discussed how kidney disease affects Americans and what is being done in the professional and public arenas to address this growing health threat.

Throughout the year, ASN advocates for these important legislative goals. For example, ASN recently joined with 14 other organizations representing professionals in organ donation and transplantation to urge President Obama and Congress to extend Medicare funding for immunosuppressive drug coverage. The current 36-month limit on Medicare coverage of these drugs often causes patients to reduce or stop using them, and can result in transplant failure. Extended coverage would prolong the lives of millions of transplant recipients, reduce taxpayer costs, and allow more dialysis patients to consider transplant.

ASN President Sharon Anderson, MD, FASN, recently wrote U.S. Senate Majority Leader Harry Reid urging him to rescind the 21 percent Medicare physician payment cut. Millions of seniors and military veterans rely on government-supported health care, and drastic physician payment cuts affect the ability of clinics and hospitals to sustain operations to care for these individuals. At press time, the House of Representatives and Senate were working to address this issue.

ASN urges its members to visit the policy section of the ASN website and learn how to become involved in supporting these important priorities in kidney care.

Index to Advertisers

Industry Spotlight

Hemodialysis Product Recall

A hospital-use hemodialysis machine has been recalled by its original manufacturer, Edwards Lifesciences Corp. U.S. distributor Baxter International operates the public contact line at 888-736-2543 for those with questions.

The machine, Aquarius Hemodialysis System, cleans waste products and extra fluid from a patient's body after kidney failure. The machine also monitors all the fluid going in and out of the body. The product model numbers are GEF08200, GEF09500, GEF09600, GEF09700, and GEF09800, using software version 6.00.04.

According to Dow Jones News, Edwards Lifesciences spokeswoman Amanda Fowler said the company hadn't received any reports of adverse reactions associated with the problem as of March 2009. The company sold the Aquarius product line to Baxter in September 2009 for $56 million. Edwards still assists Baxter with quality and regulatory affairs issues for the product, Fowler said. The recall is "voluntary," Fowler said.

The product was designed to trigger an alarm when a certain level of fluid imbalance is reached in a patient's body, the FDA said. However, patients can override the alarm, which could put them in danger of a fluid imbalance.

The product is mainly used in the intensive care setting and was part of Edwards'Critical Care business line. The product line represented approximately $50 million in sales in 2008, primarily in Europe, according to Edwards.

Baxter's peritoneal dialysis cyclers get class I recall

The FDA imposed a Class I recall on Baxter's HomeChoice and HomeChoice PRO peritoneal dialysis (PD) cyclers because the cyclers could overfill a patient's abdominal cavity, a condition referred to as increased intraperitoneal volume (IIPV).

The FDA noted that although Baxter is not removing the HomeChoice and HomeChoice PRO from the market, "clinicians should weigh the risks and benefits to continued use of these devices by their patients versus other forms of dialysis therapy." The FDA suggested that clinicians also review the prescription settings for patients who continue to use the devices.

Baxter said on its website that it had received serious injury reports, and at least one notice of death considered to be linked to IIPV. The company sent notices to clinicians and patients to inform them of the FDA recall and is identifying steps that should be enacted to reduce the risk of harm associated with IIPV.

As for the signs and effects of IIPV, Baxter noted that children and nonverbal patients may be at increased risk because of their smaller size or inability to communicate. The company recommends increased monitoring of these patients, and others who may be vulnerable, including critically ill patients and patients with pulmonary and hemodynamic instability.

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