

# Kicket Aller Aller

#### Health Care Incentives and Penalties Seek to Decrease Costs, Improve Care

By Eric Seaborg

New York City's Mount Sinai achieved through an accountable-care-style program with a 53-year-old patient on dialysis with poorly controlled diabetes and heart problems

provides a hopeful example. Esther Redd was a frequent emergency room visitor who was hospitalized seven times in the first five months of 2013. After the hospital brought to bear resources from its Preventable Admissions Care Team (PACT) during her seventh admission, Redd avoided rehospitalization at Mount Sinai for the rest of the year.

The hospital mines the electronic health records of all patients admitted and uses its own predictive algorithm to automatically calculate their risks of readmission. When a hypertensive emergency led to her seventh hospitalization in May, Redd was singled out for intervention by the PACT. Over a twoyear period, among 600 highest-risk patients, the program reduced 30-day readmissions by 43 percent and emergency room visits by 51 percent.

The incentives and penalties in the Affordable Care Act designed to improve the efficiency of care spawned the PACT as a pilot program. Although separate from Mount Sinai's accountable care organization (ACO), the PACT shares many characteristics with its ACO, and began as the organization geared up to adjust to the Affordable Care Act's new incentives, including those for ACOs. Some 10 percent of Medicare patients are in ACOs and private insurers have agreements with more than 200 ACOs, so Mount Sinai's experience is instructive.

Social worker Derrick Williams, MSW, spent more than an hour in Redd's room discussing her situation. With her multiple ailments and a 13-year-old daughter to care for, Redd was feeling overwhelmed. "When I met her in the hospital, she seemed defeated. It was spiraling out of control," Wil-

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#### Physical Activity, Even in Small Amounts, Benefits Kidney Health

E ven small amounts of physical activity may slow kidney function decline in patients with chronic kidney disease (CKD), according to two studies recently published in the *Journal of the American Society* of Nephrology. The studies, from two different teams at the same institution, suggests that exercise may have pow-

major frustration for any physi-

cian is watching a noncompli-

ant patient deteriorate, particu-

larly one with a long-term condition like kidney disease. So the turnaround

erful effects on kidney health, such as reducing the risk of developing kidney stones in the general population.

#### **Effects on kidney function**

Because few new interventions have proven useful in slowing the progression of CKD, identifying modifiable risk factors for progression is critical for reducing the morbidity, mortality, and health costs linked to the disease.

Cassianne Robinson-Cohen, PhD, an epidemiologist at the University of Washington's Kidney Research Institute in Seattle, and her colleagues previously showed that physical inactivity is linked with kidney function decline among older adults in the general population. The finding led them to question whether physical activity might help maintain CKD patients' kidney health.

"We hypothesized that physical activity might be particularly beneficial

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## Balancing risks and penalties

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liams told *Kidney News*. Williams worked to get Redd the help she needed, including finding a primary care provider and another social worker to take over after his 35-day assignment was complete.

Some problems were relatively simple: One source of noncompliance was that Redd found her multiple-medication regimen too confusing. A first step was to intervene to convince Redd's visiting nurse to organize her medications in containers that clarify when to take each.

Williams accompanied Redd to make sure she attended her dialysis appointments, and even more important, her cardiac appointments, because Redd had emotional difficulty with them. The primary care provider gave her a resource to call instead of heading for the emergency room.

The improvement has been dramatic, with Redd's only hospitalization since she met Williams being at a different hospital for previously scheduled heart bypass surgery. Driving the change has been Redd's better understanding of her conditions, along with the successful effort of Williams and his colleagues to empower her.

#### Finding the balance: better health care, lower cost

The Affordable Care Act includes provisions that allow providers to earn bonuses for better outcomes but risk penalties for yo-yo readmissions. In addition to the obvious goal of improving Redd's health and care, Mount Sinai had a strong financial motivation for trying an innovative approach because it can reap rewards as a participant in the Medicare Shared Savings Program. From the PACT, Redd passed into Mount Sinai's ACO, organizations that are being touted as a way to both improve care and lower health care costs. The hospital has invested heavily in its effort, hiring social workers and care coordinators who start their work while the patient is in the hospital. They then do what they can to improve compliancemaking home visits, helping patients keep appointments, solving transportation challenges, aiding with benefits issues, and getting involved with housing issues.

"These are the things that we have found lead patients to fall through the cracks and have their illnesses not controlled and end up in the emergency room or in the hospital unnecessarily," said Mark Callahan, MD, who heads that Mount Sinai effort that has grown into an ACO called Mount Sinai Care that serves more than 22,000 Medicare patients. One averted hospitalization can cover the cost of several months of a social worker's salary, Callahan said. And based on the success of its program, Mount Sinai received a federal grant to fund some social workers.

Over its first 16 months in the Medicare Shared Savings Program, Mount Sinai was below its cost baseline and met all of its quality metrics, Callahan said. Diabetes patients in a related Mount Sinai initiative have experienced a 1.4 percent reduction in hemoglobin A1c levels, a three-pound weight loss, and a 40 percent increase in ophthalmology screening rates.

"We have been able to leverage hospital resources in ways that we weren't initially aware of," said Joji Tokita, MD, Sinai's clinical director of nephrology. "Where we have applied resources from the ACO initiative, we have seen outcomes improve. We have seen patients stay out of the hospital. We have seen them able to avoid ER visits. We have seen improvements in patient [satisfaction]."

The Affordable Care Act contains incentives for greater adoption of electronic medical records, and Callahan and Tokita agreed that their ACO's innovations would not be possible without the ability to tap electronic data for the number crunching essential to identifying highrisk, high-cost patients for intervention. This data mining can also be used to spot patterns and problems within an organization, such as departments where care is not being delivered appropriately.

Tokita said that on the patient level, the shared access afforded by electronic records offers advantages over traditional paper charts, which can be viewed by only one person at a time. He said that the ease of seeing a social worker's notes on a meeting with a patient could lead to changing a dialysis schedule to fit better with a patient's child care needs, for example.

Whether this apparent success can continue and be duplicated in other institutions remains to be seen, but Medicare and other payers are betting heavily on ACOs. Some 250 ACOs caring for more than 4 million beneficiaries are currently under contract with Medicare, a tremendous number for a program that is just three years old.

Like Mount Sinai, most ACOs participate in the Medicare Shared Savings Program, which allows providers to share in savings without facing penalties. Medicare pays an ACO a capitated rate determined by the expected costs of treating a certain population. If the ACO can meet the quality criteria and keep the cost below an assigned benchmark, it keeps a portion of the savings.

In contrast, in a major Medicare pilot project called Pioneer ACO, participants also risk penalties for not meeting goals. The program, which began with 32 large organizations that are considered some of the most experienced with capitation programs, reported mixed first-year results.

All 32 Pioneer ACOs met the program's quality goals, exceeding industry benchmarks on 15 measures and outperforming managed-care plans on measures such as blood pressure and cholesterol control for patients with diabetes. Overall, compared with fee-for-service programs, the ACOs held down spending by half a percentage point, increasing 0.3 percent instead of 0.8 percent, and saving Medicare almost \$90 million. But most of these savings came from a few providers. Although 18 of the Pioneer ACOs lowered their costs, only 13 did so enough to reach the level for shared savings. Fourteen actually had higher costs.

Given these results, nine ACOs left the Pioneer program. Seven of them moved to the shared savings program, but two dropped out entirely. One of the dropouts was Presbyterian Health Care of Albuquerque, NM, which issued statements explaining that, as an organization located in a low-medical-cost area, cutting costs enough to share in savings appeared to be an impractical goal.

Critics seized on these results to compare ACOs with previous experiments in cost-containment. Jeff Goldsmith, PhD, president of the consulting group Health Futures and an associate professor of public health at the University of Virginia, finds the early Pioneer ACO results comparable to those at the start of the Physician Group Practice demonstration program Medicare began in 2005. That program also provided bonuses for meeting spending reduction and quality improvement goals, but was abandoned as unworkable in 2010.

Others are more optimistic. "This is very different from the cost containment trends of the 1990s, and we see it as a sustainable change in the care delivery model," said Karoline Hilu, MD, MBA, of the Advisory Board, a health-care consulting company based in Washington, DC. "We have seen our leading health care organizations shift their approach toward the identification of at-risk populations and patients" to better allocate resources among inpatients and others.

Mount Sinai's Callahan said his organization is positioning itself for a future that may include changing financial models, but that will continue the concept of physicians and hospitals being at risk for quality measures and utilization. "Just about every major insurance company has talked with us about some kind of an ACO model for their patients," he said.



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#### Physical Activity

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in patients with CKD, a condition with a high pre-existing oxidative and inflammatory burden, and that patients with CKD may represent a group that is highly physical activity–responsive," Robinson-Cohen said.

She noted that randomized trials will be needed to evaluate exercise's safety and feasibility in the CKD population, as well as to provide estimates of its effectiveness. "However, before such trials are undertaken, we felt it wise to determine if, in a nonrandomized setting, physical activity in patients with CKD was related to retention of renal function."

Robinson-Cohen and her team studied participants in the Seattle Kidney Study for an average of 3.7 years. The analysis included 256 patients with moderate-to-severe CKD. The Seattle Kidney Study follows the health of people with kidney disease over time.

The investigators discovered that physical activity was inversely related to kidney function decline in a graded fashion and to a degree stronger than previously reported in the general population. Patients performing more than 150 minutes of physical activity per week had the lowest rate of kidney function decline. Each 60-minute increment in weekly physical activity was linked with a 0.5 percent slower decline per year in kidney function.

"This study demonstrated that even small amounts of physical activity, such as walking 60 minutes per week, might slow the rate of kidney disease progression," Robinson-Cohen said. "Physical inactivity is now emerging as one of the few risk factors for kidney disease progression that is actually amenable to intervention."

Samuel Headley, PhD, who was not involved in this study and is a professor of exercise science and sport studies at Springfield College, in Springfield, MA, noted that the findings support the notion that exercise is medicine.

"Nephrologists can use these results to encourage individuals with CKD to engage in the recommended levels of physical activity to not only enhance cardiovascular health but also preserve kidney function," Headley said. "These results also suggest that a concerted effort should be made to encourage those who are most likely to have CKD such as minority groups—to get the weekly recommended levels of leisure time physical activity."

#### Reducing kidney stone risk

Another research team at the University of Washington in Seattle found that small amounts of physical activity may also decrease the risk of developing kidney stones in the general population, while consuming too many calories may increase risk.

The prevalence of kidney stones has increased dramatically, especially in

women. Research in recent years has revealed that kidney stones may lead to systemic problems: their links with obesity, diabetes, metabolic syndrome, and cardiovascular disease demonstrate that the process of stone formation extends beyond the kidney.

Mathew Sorensen, MD, led a team that sought to evaluate whether energy intake and energy expenditure relate to kidney stone formation. Sorensen is assistant professor of urology at the University of Washington and director of the Comprehensive Metabolic Stone Clinic at the Puget Sound Department of Veterans Affairs.

The researchers studied 84,225 postmenopausal women participating in the Women's Health Initiative, which has been gathering information such as dietary intake and physical activity in women since the 1990s.

After adjusting for multiple factors including body mass index, the researchers found that physical activity was associated with up to a 31 percent decreased risk of kidney stones. The intensity of the activity did not seem to matter—even mild-to-moderate weekly activity was protective against stones.

Women could get the maximum benefit by performing 10 metabolic equivalents per week, which is the equivalent of about three hours of average walking (2 to 3 mph), four hours of light gardening, or one hour of moderate jogging (6 mph).

The researchers also found that consuming more than 2200 calories per day increased the risk of developing kidney stones by up to 42 percent. Obesity was also a risk factor for stone formation. "Even taking into account dietary intake, calorie intake, and activity, we also found that BMI/obesity remained a risk factor for stone formation," Sorensen said. "Thus the increased risk of stones linked to BMI is not primarily due to dietary choices, or macronutrient intake."

He noted that being aware of caloric intake, watching one's weight, and making efforts to exercise are important factors for improving health overall, and for reducing kidney stone risk.

Additional research is needed to verify the findings, as noted in an accompanying editorial by John Lieske, MD, of the Mayo Clinic in Rochester, NY. Lieske said that because the study focused on postmenopausal women only, similar research is needed in other populations. He added that it is possible that women who exercise regularly have other healthy habits that decrease stone risk. "Nevertheless, conservative (nonpharmacologic) counseling for patients with stones often centers almost exclusively on diet, stressing increased fluid intake, normal dietary calcium, lower sodium, moderate protein, and reduced dietary oxalate," he wrote. "The results of Sorensen et al. suggest that a recommendation for moderate physical activity might reasonably be added to the mix."





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#### **Kidney Care Innovations at the VA**

## **Innovations in Kidney Care within the Veterans Health Administration**

By Susan T. Crowley and Rudolph Rodriguez

The United States military veteran population is one that is characterized as predominantly male and with a high prevalence of diabetes mellitus and hypertension. In addition, the mean age of veterans is older than that of the U.S. population, and a substantial minority of veterans are either Hispanic or of nonwhite, non-Hispanic background. Enriched with such risk factors for kidney disease, it is not surprising that the unadjusted prevalence of chronic kidney disease (CKD) and end stage renal disease (ESRD) is higher among veterans than it is in the general U.S. population. In fact, the crude ESRD prevalence rate of the veteran population is nearly twice that of the general population.



The Veterans Health Administration (VHA) is the branch of the Department of Veterans Affairs (VA) charged with the responsibility to "care for him who shall have borne the battle," in all its facets, including the management of kidney disease. With over 150 medical centers, and more than 1200 non-hospital venues at which veterans receive care, the VA is the largest integrated health care system in the nation. In addition, with over 8 million enrollees and an estimated prevalence of stage 3 and 4 CKD in nearly 11 percent of patients using VHA health services, the VHA can also be viewed as the largest provider of chronic kidney care in the United States. With an increasing number of veterans turning to the VA for some, if not all, of their ESRD care, and with a continuing growth in the veteran population of obesity and diabetes, the VHA is facing similar challenges to the containment of kidney disease as are being witnessed globally.

The VHA Kidney Program operates 69 VA hospital-based and four freestanding hemodialysis units. With 837 dialysis stations, the current treatment capacity is approximately 3500 hemodialysis patients. In addition, over half of the dialysis programs offer home dialysis options. In terms of number of patients, the size of the VHA Dialysis Program ranks among the top 10 dialysis organizations in the United States. Despite this in-house capacity, many veterans are not able to utilize VA-based units due to geographic constraints; therefore, the VHA pays for approximately 13,000 patients to receive in-center hemodialysis or home dialysis in the community. Kidney transplantation is also offered within the VA at five sites across the nation (Portland, OR, Nashville, TN, Birmingham, AL, Iowa City, IA, and Pittsburg, PA) with plans to expand to seven kidney transplant centers.

The VHA Kidney Program is part of the Office of Specialty Care within the Office of Patient Care Services. It is supported by a field advisory committee consisting of nephrology experts. As a collective effort, the VHA recently developed a strategic plan to address advanced kidney disease and guarantee access for Veterans to dialysis care. Consisting of the expansion of cost-effective VA dialysis services, the development of a streamlined national dialysis contract service, and a reinvigoration of the pursuit of innovative health service delivery options, the ultimate goal of the strategic plan is to promote CKD prevention and delay the onset of ESRD.

The VHA transformed itself over the past 2 decades from a hospital-based caredelivery system to that of a patient-centered, home-based care model. Implementing a patient-aligned care team and using the revolutionary power of health information technology—including arguably the world's best electronic health record system and an extensive array of teletechnologies—the VHA seeks to consistently "provide the right care, at right time and at right place." To provide a structured way to identify, fund, and test further new health care system proposals, the VA established the VA Center for Innovation (VACI). In 2010, the VACI held the second of its new annual innovation initiative (VAi2) competitions, this time highlighting kidney disease as one of the six preidentified priority areas. Issuing a broad agency announcement, the VA solicited submissions from industry and academia for new models of kidney disease treatment that would leverage VA strengths to improve the quality and cost effectiveness of, and access to, kidney disease care for veterans. Four VAi2 proposals pertaining to kidney disease were selected for piloting, each of which targeted at least one of the facets of the VHA dialysis strategic plan:

- VA e-Kidney Clinic—The Medical Education Institute (MEI, Inc.) was selected to assist in the development a virtual kidney clinic with the goal of creating an easily accessible, standardized, veteran-customized kidney disease education portfolio.
- Renal Video Teletechnology—Investigators from VA Minneapolis submitted a proposal to test the feasibility of providing advanced care management of veterans with CKD using clinical home-based video technology provided by American Telecare (ATI, Inc.). Outcomes of this novel application of existing VA teletechnology will include measures of care coordination including hospitalization rates and urgent start dialysis.
- VA CKD VA Renal Information System—The University of Michigan Kidney Evaluation Center (KECC), will develop a national comprehensive VA kidney database, thereby permitting the evaluation of the epidemiology of acute kidney injury, CKD, ESRD, and renal transplantation in a large national integrated health care system.
- Automated Wearable Artificial Kidney (AWAK)—AWAK, Inc. will be piloting the use of a novel wearable "home" peritoneal dialysis device, the automated wearable artificial kidney.

The results of these pilot awards will be the topic of future articles in *ASN Kidney News*. For further information about kidney health and disease prevention resources, as well as CKD and ESRD treatment options and other federal benefits available to veterans, readers are encouraged to visit the VHA Kidney Program website at http://www.medi-calsurgical.va.gov/kidney.program.asp.

Susan T. Crowley, MD, FASN, is the VHA National Program Director for Kidney Disease, Chief of the Renal Section at the VA Connecticut Healthcare System, and Associate Professor of Medicine at the Yale University School of Medicine in New Haven, CT. Rudolph Rodriguez, MD, is the VHA Renal Field Advisory Chairperson, Chief of Nephrology at the VA Puget Sound Healthcare System, and Professor of Medicine at the University of Washington, Seattle, WA.

#### VAi2 Projects: VA eKidney Clinic and Renal Video Teletechnology

#### By Devasmita C. Dev and Areef Ishani

The U.S. Department of Veterans Affairs (VA) established the VA Center for Innovation (VACI) to identify, fund, and test new health care system proposals. During the second annual innovation initiative (VAi2) competition a total of four VAi2 proposals pertaining to kidney disease were selected. Two of these focused on the implementation of telemedicine in nephrology—creation of a virtual kidney clinic and development of clinical home-based video technology.

#### **VA eKidney Clinic**

The team-based approach to chronic kidney disease (CKD) management often involves patient visits to a variety of providers, including the physician or physician extender, renal nurse, renal dietician, renal social worker, and pharmacist. Disease symptoms and treatment options are frequently discussed at various levels specific to the particular provider and topic. However, many patients and their family members seem to misunderstand the gravity of a kidney disease diagnosis because the information can be overwhelming.

Disease and treatment education are consistently the main "ace in the hole" for prolonged chronic disease management. To that end, the VA has taken a lead in providing a virtual kidney clinic website—the eKidney Clinic (http://www.medicalsurgical.va.gov/ kidney/program.asp). This website allows the patient to personalize their understanding of kidney failure. A patient with kidney disease can pace his or her understanding, repeat information as necessary, test their disease comprehension, reflect on the disease process, and frame questions for their online providers. The virtual providers also remain impartial when conveying and explaining symptoms that can and do occur. Information about common medications that patients with CKD may need is reviewed by a virtual pharmacist. A visit with a virtual dietician answers questions about highpotassium foods, clarifies why they should be avoided as kidney function worsens, and provides advice on how to help manage foods that can taper a high phosphorus load. Patients can search the virtual learning site for specific terms and unfamiliar jargon used by the medical team. A virtual social worker discusses various choices for renal replacement, including hemodialysis (home, in-center, or nocturnal), peritoneal dialysis, renal transplantation, as well as the option to be managed conservatively with no dialysis.

A chronic progressive and lingering disease is understandably difficult for patients and their caregivers. The eKidney Clinic teaching website gives veterans and other patients with CKD, and their families and caregivers, some support away from the physician's office or clinic providers. The site is easy to navigate and has many accessibility features, including the ability to enlarge the font size as necessary, listen in on the virtual messages for each room that the patient chooses to enter to learn about the different aspects of CKD and its progression, or read the messages associated with representative pictures discussing the topic at hand for the visual learner or those who are hearing impaired. The website is mindful of the diversity of individuals with CKD and

carefully tailors the ethnicities presented to ensure visual integrity and reduce bias in the presentation of the disease process for any particular group of individuals not presented. Overall, this VA initiative is an excellent addition in improving care not only for the veteran patient with CKD but also for all patients suffering from CKD.

#### **Renal video teletechnology**

Patients with kidney disease often have a multitude of chronic comorbid conditions that require careful and close management by several different health care providers. Some veterans with CKD live far from VA facilities that provide subspecialty nephrology care, which may impede their access to this important care. Multidisciplinary case management with telemonitoring has been demonstrated to improve outcomes in chronically ill populations without CKD, but it has not been as frequently applied to vulnerable elderly populations with CKD, such as veterans.

The VAi2 renal video teletechnology initiative, led by the Minneapolis VA health care team in collaboration with American TeleCare, focuses on providing advanced care management to veterans with moderate to severe CKD in the Minneapolis or St. Cloud VA Health Care System or an affiliated Community Based Outpatient Clinics. The advanced care management consists of tools, equipment, and education that allow veterans to self-monitor their CKD from home. For example, the telehealth device contains peripherals for patients to monitor their vital signs (blood pressure, weight, and glucose) and enables a patient education session to be done in the patient's home at their pace. Further, this management plan will connect the highest risk veterans with CKD to a VA care team that has expertise to manage major risk factors (e.g., diabetes and hypertension) as well as other associated comorbid conditions and psychosocial complications. This technology allows video visits with the interprofessional VA-based team (nephrologist, nurse practitioner, nurse, renal dietician, renal social worker, clinical PharmD, and psychologist) and provides educational modules to the veteran at home (on such topics as kidney disease, diet changes, and diabetes). The interprofessional team has helped patients achieve lifestyle goals, assisted with patient education and activation, managed each patient's chronic conditions (hypertension, diabetes, depression, and others), and helped identify and resolve acute conditions.

To date, 601 veterans have already been enrolled in this advanced care management plan. A clinical trial is being conducted to compare the impact of this technology with usual care for veterans with CKD. In addition to slowing CKD progression, it is anticipated this intervention will reduce emergency room visits and hospitalizations, and thereby reduce health care costs. Preliminary findings from this trial should be available in the near future.

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#### Quality and Safety Initiatives at the Veterans Health Administration

#### By Michael J. Fischer, Karen B. Sovern, and Wissam M. Kourany

The delivery of high-quality and cost-effective chronic hemodialysis care is a daunting challenge as evidenced by ongoing poor health outcomes and high costs across the United States. The prevalence of end stage renal disease (ESRD) among veterans is quite high, approximately double that of nonveterans, owing in part to high rates of predisposing comorbid illnesses (e.g., diabetes or hypertension) and other sociodemographic risk factors. Similar to their non-VA counterparts, veterans receiving chronic hemodialysis experience an annual mortality rate in excess of 15 percent and more than 30 days hospitalization annually. Such poor outcomes highlight the critical need to improve quality of dialysis care.

A variety of recent steps have been taken within the VA to improve quality of dialysis care nationally for our veterans: 1) determination of clinical performance measures that assess quality of dialysis care; 2) establishment of data collection procedures needed to assess clinical performance measures; and 3) analysis and reporting of clinical performance measures for the facilities at the local, regional, and national level.

#### Clinical performance measures for quality of hemodialysis care

Beginning in July 2012 and concluding in February 2013, a transparent, stakeholderdriven process was launched to identify clinical performance measures for chronic hemodialysis in the VA. Clinical performance measures are defined as tools to assess compliance with standards for clinical care, and their purpose is to measure, report, and compare quality of care, and to improve clinical performance. At the direction of Susan Crowley, MD, FASN, Veterans Health Administration National Program Director for Kidney Disease and Dialysis, a VA committee with representation from diverse domains of leadership, operations, clinical services, and research within VA was created to review, discuss, and select clinical performance measures for this evaluation. The sources for our measures included several organizations that develop, implement, review, endorse, and adopt measures, such as the Centers for Medicare & Medicaid Services and the National Quality Forum.

The committee agreed upon several key criteria that would be important requirements for measures to be adopted by the VA, including that they must be mature vetted measures, designed as facility-level measures, and that they address distinct aspects of ESRD care. Other criteria included that they have a solid evidence base and be timely, clinically relevant, feasible and usable to improve quality. In addition to an in-person meeting, a series of conference calls and interval web-based Share-Point commenting and voting procedures were utilized by the committee to review and adopt clinical performance measures. Out of a total of 78 measures reviewed and discussed, 11 measures were adopted. The performance measures encompass dialysis adequacy, vascular access, anemia, bone and mineral metabolism, infection, and immunization.

#### Establishment of data collection procedures

A particular strength of VA is its fully integrated national electronic medical record (EMR), which includes all VA dialysis units across the United States. Data colllected to calculate the chosen hemodialysis quality measures are predominantly extracted from laboratory and medication data available via the corporate data warehouse. These data elements are extracted and synchronized nightly from the EMR. Some data elements that cannot be obtained from the EMR are self-reported data by personnel at the hemodialysis facilities. An interdisciplinary collaboration between the working group, VHA Support Service Center (VSSC), and VA Inpatient Evaluation Center led to the development and design of a new web-based electronic interface available to facilitate reporting. When this process is complete, we will be able to capture and report data on a monthly basis and examine trends over time.

#### Analysis and reporting of hemodialysis clinical performance measures

The chief goal of analyzing and reporting hemodialysis performance measures is to have a "real-time" method of monitoring and improving quality of care to veterans. None of the measures has absolutely identified performance targets (i.e., prespecified goal targets). Rather, measure scores or percentages will be evaluated on a numerical score from 0 to 100. For some measures, a higher or increasing value (percentage) is desirable, whereas for others a lower value/ percentage is desirable. Measures will be reported via a new national VA hemodialysis quality measure dashboard, which was constructed in collaboration with VSSC. This dashboard can be viewed by VA operations and clinical dialysis staff, and thereby furthers quality assurance and improvement at the facility level. The dashboard enables dialysis providers to navigate to patient-level details and generate a list of patients not meeting the desired target for given measures at their facility. For example, one of the measures collects and reports information on bloodstream infections in hemodialysis patients at each facility. If there was a noticeable increase in infections at any given facility, this would trigger further examination at the patient, facility, and national level.

#### **Future directions**

Improving quality of care for veterans receiving chronic hemodialysis is a top priority in VA. Establishing and reporting quality measures is one of many recent initiatives in VA that aims to further this goal. Recognizing the constant evolution in the dialysis evidence base, the VA working group continues to meet regularly to review and discuss revisions and additions to the current quality measures. An additional future direction of this working group that has recently begun is to internally pilot less mature, yet innovative and novel, hemodialysis quality measures to further improve quality of care.

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#### SCAN-ECHO Program Provides "Telenephrology" Care for Veterans

By Bessie A. Young, Raimund Pichler, Richard Treger, and Robert Safirstein

ephrology care is increasingly difficult to provide in rural and medically underserved areas. Because of the need for more invasive procedures, imaging, and monitoring, nephrology care tends to be clustered in larger academic and urban settings, forcing some patients to travel long distances for nephrology care. At a cost of roughly \$50 billion, the Department of Veteran Affairs (VA) provides primary care for more than 8 million veterans, more than 41 percent of whom live in rural or medically underserved areas without access to specialty care, particularly nephrology care. Given the number of rural veterans and those in medically underserved areas, the VA implemented the Specialty Care Access Networks-Extension for Community Health Outcomes (SCAN-ECHO) program, a provider-toprovider telehealth program sponsored by the Office of Specialty Care Transformation. The SCAN-ECHO program is designed to afford greater access of primary care providers to specialty care using the extensive VA telemedicine infrastructure and videoconferencing equipment.

Telemedicine, which is defined as the exchange of medical information using electronic means to improve patient health, utilizes many electronic applications to provide medical care. "Telenephrology" is defined as the use of these measures to evaluate and treat patients with kidney disease. The VA uses a variety of telemedicine applications, ranging from the online personal health record—called My HealtheVet—to the electronic consults available through the VA electronic medical record (EMR) available to all clinicians across the country for any veteran enrolled within the VA. The SCAN-ECHO program uses all the above telemedicine applications to improve nephrology specialty access for rural veterans.

SCAN-ECHO is based on Project ECHO, a community outreach program initially developed to address disparities in hepatitis C treatment in rural New Mexico. Project ECHO, led by Sanjeev Arora, MD, developed primary care–specialty partnerships that facilitate education and collaboration between primary care providers and an interdisciplinary primary care team located at a tertiary facility. Using weekly telemedicine clinics that include 20- to 30-minute didactic presentations on essential clinical topics, virtual clinics are conducted during which providers received regular education and case-based consultations on patients actively being treated for hepatitis C. The results showed primary care providers were able to achieve similar outcomes in hepatitis C treatment compared to specialists, and that telemedicine could be used to provide specialty care remotely.

The VA currently has five renal SCAN-ECHO programs that partner with primary care within a defined geographic area to increase primary care provider access to nephrology specialty care for patients with severe chronic kidney disease (CKD). During the SCAN-ECHO conference, primary care providers are given education on a relevant topic and receive case-based consultation on clinical cases presented using telemedicine videoconferencing equipment. A few of these programs are highlighted here.

#### **VISN 20 SCAN-ECHO**

Veterans Integrated Health Care System 20 (VISN 20) is the largest VISN by geographical area, accounting for 23 percent of the U.S. land mass, including Alaska, Washington, Oregon, Idaho, and parts of Montana and California. Specialty care is provided by two major medical center hubs: the Seattle VA Puget Sound Health Care System in Seattle, WA, and the Portland VA Medical Center in Portland, OR. The VISN 20 SCAN-ECHO site consists of nephrologists Raimund Pichler, MD, and Bessie Young, MD, MPH, who receive consults from primary care providers located in Alaska, eastern and western Washington, and Idaho. A 30-minute didactic is presented, followed by case-based presentation of consults that lasts from 30 to 45 minutes. Clinicians are linked by videoconferencing technology, provided by secure PC meeting equipment or videoconferencing equipment, which allows for presentation of patients and viewing of secure clinical information. Consults were initiated in early 2013 and are derived primarily from electronic consults (e-consults). The program has expanded to include CKD education classes for patients at remote sites who are approaching the need for dialysis.

#### VISN 1 SCAN-ECHO

The VISN 1 SCAN-ECHO program encompasses most of Connecticut, Rhode Island, and adjacent areas of Massachusetts and New York. Additionally, partnerships with VISN 2 and 3 have been forged. The program began with a strong emphasis on hepatitis C therapy and pain management. The latter program provided the infrastructure to expand beyond our geographic boundaries. Under the leadership of Susan Crowley, MD, FASN, director of nephrology at the West Haven VA, each member of the renal division participates in monthly hour-long didactic/case-discussion lectures directed toward a primary care audience. This model is being used to address consults received from primary care and embed them in the lectures as SCAN-ECHO consults in real-time face-to-face presentations and case discussions.

#### **Greater Los Angeles SCAN-ECHO**

The Greater Los Angeles Healthcare System (GLAHS) SCAN-ECHO program commenced in May of 2012 and is led by nephrologist Richard Treger, MD. GLAHS has a diverse patient population located in distant geographic sites, stretching as far north as Bakersfield and as far west as San Luis Obispo. Nephrology consults initiated by primary care providers are handled by videoconference, facilitating the subspecialty care of patients at distant sites. During a typical 60-minute session two cases are discussed, including recommendations for further clinical care and follow-up, and a 20- to 30-minute didactic is presented. The goal of the program is not only to handle the specific cases, but to augment the ability of primary care providers to care for nephrology patients. As such, an online nephrology curriculum has been created with topics available for review by primary care providers, covering such common disorders as CKD, hypertension, electrolyte disorders, and kidney stones.

#### **Denver VA SCAN-ECHO**

The Denver SCAN-ECHO program initiated their program in April of 2012 by providing education to primary care providers. A nephrology team at the Denver VA provides a kidney disease curriculum for primary care provider education. To date, over 39 sessions with over 600 participants from 206 sites covering three VISNS (VISN 15, VISN 19, and VISN 23) have been conducted. After initiation of continuing medical education credit, participation increased significantly and has expanded to VISN 16.

SCAN-ECHO is an exciting new tool in the health information technology armamentarium that allows nephrologists to partner with primary care providers in order to facilitate improved nephrology care for rural and medically underserved veterans. SCAN-ECHO aims to improve the care of veterans with all stages of kidney disease, providing direct patient and provider education to combat the growing epidemic of kidney disease in the United States. The extensive VA EMR and videoconferencing infrastructure will allow VA to continue to be at the forefront of providing nephrology specialty care for all veterans.

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#### **Journal View**

#### Reduced Kidney Function Linked to Increased Cancer Risk

People with low levels of estimated GFR (eGFR) have higher cancer mortality, suggests a report in the *American Journal of Kidney Diseases*.

The researchers analyzed follow-up data on 4077 predominantly white participants from the Australian, populationbased Blue Mountains Eye Study. Baseline eGFR was analyzed for association with the risk of cancer death, including the kidney function threshold at which the excess risk of death begins. Reduced eGFR was also assessed as a prognostic factor for death after cancer diagnosis.

Three hundred seventy cancer deaths occurred during a median follow-up time of 12.8 years. With adjustment for other factors, for each 10 mL/min per 1.73 m<sup>2</sup> reduction in eGFR, the hazard ratio (HR) for cancer-specific mortality was 1.18. Compared with an eGFR of 60 mL/min per 1.73 m<sup>2</sup>, the HR associated with eGFR less than 60 mL/min per 1.73 m<sup>2</sup> was 1.27.

Hazard ratios increased further at lower levels of kidney function. The excess risk was highest for breast and urinary tract cancers: HR 1.99 and 2.54, respectively. On analysis limited to participants in whom cancer developed, the overall cancer mortality was more than twice as high at an eGFR less than 45 mL/min per  $1.73 \text{ m}^2$ .

Cancer risk is known to be increased in patients with chronic kidney disease. However, the association between reduced kidney function and cancer mortality has been unclear.

This study finds that an eGFR less than 60 mL/min per 1.73 m<sup>2</sup> is associated with an increased risk of death from cancer, and that reduced kidney function predicts poor outcomes among older patients with cancer. The authors call for further studies of the association between eGFR and cancer, including intervention and prevention strategies [Iff S, et al. Reduced estimated GFR and cancer mortality. *Am J Kidney Dis* 2014; 63: 23–30].

#### Fractures in Dialysis Patients Have High Morbidity and Mortality

Hemodialysis patients experience a high incidence of fractures and resulting adverse outcomes, reports a study in *Kidney International*.

The incidences of fracture events and postfracture morbidity and mortality were evaluated in an international cohort of 34,579 hemodialysis patients from the Dialysis Outcomes and Practice Patterns study. Fractures requiring hospital treatment occurred in 3 percent of participants overall, including 491 hip fractures and 643 other fractures. The incidence of fracture ranged from 12 per 1000 patientyears in Japan to 45 per 1000 patientyears in Belgium; the rate in the United States was 30 per 1000 patient-years.

Across countries, fracture rates were higher in hemodialysis patients than in the general population. With some variation between countries, postfracture mortality was greater than 500 per 1000 patient-years, and the combined rates of death and rehospitalization exceeded 1500 per 1000 patient-years. In comparison with hemodialysis patients without fracture, those sustaining fractures had a 3.7-fold increase in risk of death and a fourfold increase in the combined risk of death and rehospitalization. The rates of mortality and rehospitalization were highest in the month after fracture.

Relatively few studies have examined fracture rates and outcomes in the frail dialysis population. The new results show a high incidence of fractures in hemodialysis patients around the world, with high resulting rates of death and rehospitalization. "Fracture prevention strategies should be identified and applied broadly in nephrology practices," the researchers conclude [Tentori F, et al. High rates of death and hospitalization follow bone fracture among hemodialysis patients. *Kidney Int* 2013; 85:166–173].

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#### **Journal View**

#### ACEIs/ARBs Show Renoprotective Effect in Stage 5 CKD Linked to Increased Cancer Risk

In patients with advanced predialysis chronic kidney disease (CKD) and stable hypertension, treatment with a renin-angiotensin-aldosterone system blocker reduces the risk of long-term dialysis or death, reports a study in *JAMA Internal Medicine*.

The prospective cohort study included 28,497 hypertensive adults in Taiwan with predialysis stage 5 CKD. Eligible patients had serum creatinine greater than 6 mg/dL and hematocrit less than 28 percent, and they were being treated with erythropoiesis-stimulating agents. Of those, 14,117 patients were receiving an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker (ACEI/ARB); the remaining 14,380 patients were not. The rates of long-term dialysis and all-cause mortality were compared by the use of Cox proportional hazards regression models.

At a median follow-up time of 7 months, 70.7 percent of patients had started long-term dialysis, and 20.0 percent had died before progressing to ESRD. Patients receiving ACEIs/ARBs had a small but significant reduction in the risk of long-term dialysis: hazard ratio 0.94. There was a similar reduction in a composite outcome of long-term dialysis and death.

The renoprotective effect of ACEI/ ARB use was apparent in most patient subgroups; benefits were also observed with ACEI or ARB treatment. The risk of hospital admission for hyperkalemia was higher among ACEI/ARB users. However, there was no increase in predialysis mortality caused by hyperkalemia.

There are few data on the benefits of ACEI/ARB therapy in patients with stage 5 CKD. In Taiwan, the prevalence and incidence of ESRD are very high, and dialysis is typically started late.

The new data suggest that ACEI/

ARB therapy has renal benefits for patients with advanced predialysis CKD. The risk of long-term dialysis or death is reduced by about 6 percent, with no increase in all-cause mortality. The researchers write, "We estimate that, every year, ACEI/ARB use could prevent 5.5 percent of the patients with advanced CKD from commencing long-term dialysis" [Hsu T-W, et al. Renoprotective effect of renin-angiotensin-aldosterone system blockade in patients with predialysis advanced chronic kidney disease, hypertension, and anemia. JAMA Intern Med 2013 Dec 16. doi: 10.1001/ jamainternmed.2013.12700].

#### **Clarithromycin plus Calcium Channel Blockers Increase AKI Risk**

An interaction between calcium channel blockers and clarithromycin is associated with an increased risk of acute kidney injury (AKI), according to a study in the *Journal of the American Medical Association*.

The population-based study included two groups of older adults in Ontario, mean age 76 years, who were newly prescribed a macrolide antibiotic during treatment with a calcium channel blocker—mainly amlodipine. Adverse outcomes were compared for 94,083 patients receiving clarithromycin, an inhibitor of cytochrome P450 3A4 (CYP3A4), and 96,226 patients receiving azithromycin.

The primary outcome of hospitalization for AKI occurred in 0.44 percent of patients who were prescribed clarithromycin versus 0.22 percent of those taking azithromycin: odds ratio (OR) 1.98. The risk of AKI was highest for patients taking dihydropyridines, especially nifedipine: OR 5.33. Patients taking the combination of clarithromycin and a calcium channel blocker were also at a higher risk of admission for hypotension, OR 1.60, and all-cause mortality, OR 1.75.

Calcium channel blockers are metabolized by CYP3A4, a process that raises the possibility of harmful blood drug concentrations in the presence of CYP3A4 inhibition. Clarithromycin is a CYP3A4 inhibitor, whereas azithromycin is not.

The new results strongly suggest that many older patients are coprescribed

clarithromycin with a calcium channel blocker, and this combination is associated with increased risk of AKI, hypotension, and death. The researchers write: "Our results suggest it is possible that hundreds of hospitalizations and deaths in our region may have been associated with this largely preventable drug-drug interaction" [Gandhi S, et al. Calciumchannel blocker-clarithromycin drug interactions and acute kidney injury. 2013; 310:2544–2553].

#### **CORAL Study Finds No Benefit of Stenting in Renal Artery Stenosis**

A worldwide, multicenter trial shows no reduction in clinical events with renal artery stenting for patients with atherosclerotic renal artery stenosis, reports the *New England Journal of Medicine*.

The "Cardiovascular Outcomes in Renal Atherosclerotic Lesions" (CORAL) study included 947 patients with atherosclerotic renal artery stenosis. Eligible patients were taking two or more antihypertensive drugs, had chronic kidney disease, or both. The open-label study randomly assigned patients to medical therapy alone or medical therapy plus renal artery stenting. The main outcome of interest was a composite of death resulting from cardiovascular or renal causes, myocardial infarction, stroke, hospitalization for congestive heart failure, progressive renal insufficiency, or renal replacement therapy.

At a median follow-up time of 43 months, the primary outcome rates were almost identical between groups: 35.1 percent with renal artery stenting and 35.8 percent with medical therapy alone. The individual component outcomes and all-cause mortality were similar as well.

Stenting also showed no benefit in patients with global renal ischemia or in other high-risk subgroups. The lack of clinical benefit was observed despite a reduction in systolic blood pressure in the stenting group: 2.3 mm Hg lower than with medical therapy alone.

There is a long history of uncertainty over the role of stenting in treatment of renal artery stenosis related to atherosclerosis. The CORAL results show no improvement in outcomes with renal artery stenting, compared with medical therapy alone, for patients with renal artery stenosis and hypertension or chronic kidney disease. "From this result, it is clear that medical therapy without stenting is the preferred management strategy for the majority of people with atherosclerotic renal-artery stenosis," the researchers conclude [Cooper CJ, et al. Stenting and medical therapy for atherosclerotic renal-artery stenosis. *N Engl J Med* 2013; 370:13–22].

#### Statins and Diuretics May Increase Diabetes in High-Risk Patients

Patients with impaired glucose tolerance who take diuretics or statins may be at increased risk of new-onset diabetes, reports a study in the *British Medical Journal*.

The authors reanalyzed serial data on glucose levels from the "Nateglinide and Valsartan in Impaired Glucose Tolerance Outcomes Research" (NAVIGATOR) trial. The rates of new-onset diabetes were assessed for patients with no baseline history of treatment with  $\beta$ -blockers (5640 patients), diuretics (6346 patients), and statins (6146 patients). Another 6294 patients with no history of treatment with calcium channel blockers were studied as a "metabolically neutral" control group.

At a median follow-up time of 5 years, treatment with  $\beta$ -blockers was started in 16.2 percent of patients, diuretics in 20.7 percent, statins in 22.0 percent, and calcium channel blockers in 18.6 percent. After adjustment for baseline factors and time-varying confounders, both diuretics and statins were associated with an increased

risk of new-onset diabetes: hazard ratio 1.23 and 1.32, respectively.

The risk of diabetes was not increased for patients starting treatment with  $\beta$ -blockers or, as expected, calcium channel blockers.

Impaired glucose tolerance may be a risk factor for the development of diabetes during treatment with certain classes of medication. This reanalysis of randomized trial data shows a significant increase in the risk of new-onset diabetes with diuretics and statins.

Although there is no significant association with  $\beta$ -blockers, the authors term this effect "indeterminate." They conclude: "Our findings suggest that glycaemia should be better monitored when these drugs are initiated in high risk patients" [Shen L, et al. Role of diuretics,  $\beta$  blockers, and statins in increasing the risk of diabetes in patients with impaired glucose tolerance: Reanalysis of data from the NAVI-GATOR study. *BMJ* 2013; 347:f6745].



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#### **Practice Pointers**

## **Hemodialysis Access Rupture**

#### By Mohamed Sekkarie

#### How common is access rupture?

According to data reported to the Centers for Medicare & Medicaid Services, fatal rupture of arteriovenous (AV) dialysis access accounts for close to 0.4 percent of all hemodialysis deaths, which translates into about one death per 1000 hemodialysis patient years. A recent retrospective review of cases reported to the medical examiner in the District of Columbia, Maryland, and Virginia suggested that there is significant underreporting of such deaths (1). The incidence of nonfatal rupture is harder to estimate due to lack of data and no uniform definition of "rupture."

#### Is any type of AV access more likely to rupture?

Gortex grafts are more likely to rupture than fistulae probably owing to higher risk of infection and lack of tunica media. Due to the higher prevalence of fistulae in the recent years, however, it is likely that rupture of fistulae as an absolute number may exceed that of grafts.

#### What is the difference between an aneurysm and a pseudoaneurysm?

Aneurysms are a bulging in the vein wall that has been weakened by repeated needle insertions. Pseudoaneurysms are a result of leaking blood, and have disrupted muscular layer.

#### What are the warning signs?

Possible signs of an impending rupture include the following: evidence of disruption of access wall; signs of infection; a persistent clot (scab); unhealthy skin; pseudoaneurysms that exceed twice the diameter of the graft or those that are increasing in size; and excessive access bleeding after dialysis, around needles, and between treatments (2). Close to 60 percent of patients who die due to a ruptured access experience an access complication event in the 6 months preceding death.

#### What is the role of access physical examination and when should it be performed?

Physical examination is best done before cannulating the access where tape and needles are not obstructing the view. One should look for the above signs. Nurses and patient care technicians should look for these signs at every dialysis session. The examination before dialysis should also be done by the nephrologist periodically.

#### What are the best preventive measures?

Primary prevention of rupture should concentrate on avoiding erosion of the access wall. In addition to measures to prevent infections, cannulation techniques are extremely important to prevent the formation of thin walled areas, including aneurysms and pseudoaneurysms. Rotating sites, including the rope ladder technique, make use of the whole length of the access and prevent wearing certain areas. Buttonhole technique in fistulae may have an advantage but good data are lacking. Cluster sticking, the tendency to stick in one general area, should be avoided (3). Lower risk of rupture is another reason why fistulae are preferred over grafts. Overanticoagulation should be avoided.

#### How urgent is the need for referral when these warning signs occur?

The presence of one or more of the above warning signs constitutes an urgent, and even at times emergent, situation (4). Direct verbal communications between the nephrologist and surgeon are critical. Active and recurrent bleedings and skin erosion require immediate surgical intervention.

#### What should the surgeon do?

Except in cases of infected grafts or uncontrollable bleeding, the surgeon should try to preserve the access by repairing the high risk area through aneurysmorrhaphy (Figs. 1 and 2) (5). Not all access surgeons are familiar this technique. In the case of graft pseudoaneurysms, endovascular repair with a stent is a good alternative (6).



Figure 1. Photographs of a fistula damaged by cluster cannulation with evidence of wall thinning: the skin is shiny and discolored.



#### Figure 2 . The fistula was prophylactically repaired using aneurysmorrhaphy.

#### How should access ruptured be managed?

Patients, members of their household, and caretakers should be instructed on how to apply pressure if access bleeding occurs. They should call for immediate help even if the bleeding stops. Immediate surgical consultation in a hospital setting is warranted. All dialysis providers should be familiar with pressure techniques on the bleeding area and its arterial flow.

#### What is the prognosis?

Owing to lack of uniform definition and lack of data, the prognosis is hard to determine. Severe bleeding in the home setting is probably fatal in most circumstances. Most deaths from access ruptures occur at patients' residences.

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#### **Industry Spotlight**

#### **Acceleron Tests Drugs for Renal Patients**

Acceleron Pharma (Cambridge, MA), focuses on designing protein therapeutics for cancer and rare diseases. Two of its new products under development involve patients with renal conditions.

Acceleron and Celgene Corp., based in Summit, NJ, are jointly developing a drug candidate called sotatercept, a fusion protein that acts by increasing the production of mature red blood cells into circulation, which may benefit patients with advanced chronic kidney disease.

Recently, Acceleron reported that it was about to receive a \$7 million milestone payment under a collaboration agreement with Celgene, which recently opened a phase 2 clinical trial of sotatercept in patients undergoing hemodialysis.

In previous clinical studies, sotatercept has shown "encouraging activity by increasing red blood cells as well as bone mass in patients," said Matthew Sherman, MD, Acceleron's chief medical officer. "We believe that the distinct profile of sotatercept could benefit many patients, including those who have end stage renal disease, the most advanced stage of chronic kidney disease." He noted that the compound is also being studied in phase 2 trials in people with several rare hematologic diseases, including  $\beta$ -thalassemia and myelodysplastic syndromes.

A year ago, Acceleron started a phase 2 study of dalantercept, a novel blood vessel inhibitor that targets the activin receptor-like kinase 1 (ALK1) pathway. The two-part, randomized phase 2 study is a study of dalantercept in combination with axitinib (Inlyta by Pfizer). Axitinib is a vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor, intended to treat patients with metastatic renal cell carcinoma.

"Many patients with renal cell carcinoma respond to treatment with a VEGF inhibitor yet their disease subsequently progresses," said Michael B. Atkins, MD, deputy director of the Georgetown Lombardi Comprehensive Cancer Center, Georgetown University Medical Center. "My colleagues in the kidney cancer research community and I are optimistic that combining two therapies with distinct anti-angiogenesis (anti-blood vessel growth) mechanisms....can provide a more effective and durable antitumor response in these patients."



Acceleron, its partners, and its collaborators have initiated seven phase 2 studies across three of Acceleron's programs—dalantercept (known first as ACE-041), sotatercept (ACE-011), and ACE-536—since November 2012.

#### Merck and GSK Team on Renal Cancer Combo Drug

 $P_{\rm harmaceutical giant}$  Merck announced that it has launched a clinical trial that evaluates a combination of its own drug with one of Glaxo-SmithKline's oral drugs to fight advanced renal cell cancer.

Merck's new offering is an investigational anti-PD-1 immunotherapy called MK-3475, along with Glaxo SmithKline's orally administered kinase inhibitor, pazopanib.

Iain Dukes, senior vice president for licensing and external scientific affairs at Merck, said, "We look forward to initiating further collaborations to investigate MK-3475 in combination with other anticancer agents across a range of tumor types." Industry website Fierce Biotech said the anti-PD (programmed cell death) drug would be a "badly" needed commodity, if successful. "Under growing pressure from Wall Street, which has come to expect . . . disappointment, delay and failure from Merck over the past few years, the pharma giant is circling its best research wagons around this PD-1 immunotherapy drug," Fierce Biotech stated on its website.

By blocking PD-1, MK-3475 allows the body's immune system T cells to act against cancer cells.

Glaxo SmithKline's pazopanib, marketed as Votrient, was approved by the U.S. Food and Drug Administration for the treatment of patients with advanced renal cell carcinoma in October 2009 and is now approved in more than 80 countries.

Renal cell carcinoma is one of the targets that Merck is tackling in an ambitious series of clinical trials. According to a profile of the drug published by Fierce Biotech, MK-3475 is being studied in 10 clinical trials that are estimated to enroll more than 4000 patients across a broad range of cancer types. In 2014, these include renal cell, bladder, colorectal, gastric, head and neck, melanoma, non-small cell lung, triple-negative breast, pancreatic, and hematologic cancers. For information on Merck's clinical trials, visit http://www.merck.com/clinical-trials/.

#### **Disasters Keep Dialysis Facilities and Companies Planning**



A toxic leak into water sources in West Virginia and extreme winter weather over Canada and the United States had people working hard to keep dialysis facilities safe and operational in recent weeks.

A sudden leak of a chemical used in coal processing affected patients in and around Charleston, WV. The chemical had overflowed around the tank run by Freedom Industries. It then migrated over land and through soil into a river, about a mile from the affected West Virginia American Water Company plant, CNN reported. Tap water was affected in nine counties for several days, and customers had to stop all use of tap water.

The so-called polar vortex that descended over much of the United States in January also was a cause for reminders to people receiving dialysis to be prepared as road conditions worsened and utilities and deliveries were threatened. Dialysis providers updated websites with disaster preparedness plans. Fresenius North America provided this checklist for patients:

- Create a disaster kit with emergency supplies and at least one extra 3-day supply of medicines.
- Store a 3-day supply of food based on your emergency meal plan. Speak with your health care team about when to begin following your emergency plan. Limit fluid intake to 2 cups per 24 hours.
- Patients with diabetes should ask their doctor how to adjust their insulin dosage if severe flooding or storms are forecast.
- Make backup plans for rides to the local dialysis center.

#### **Policy Update**

#### **2014 NIH and VA Research Budgets a Mixed Bag**

#### By Grant Olan

t the tail end of one of the least productive years in congressional history, Congress managed to pass a bipartisan budget deal for 2014 that President Barack Obama signed into law on January 17. The deal capped a long year of budget showdowns, including the 16-day government shutdown in October. Like most federal budgets, there is both good and bad news: the deal reinstated some funding—but not all to budget cuts in 2014.

The 2014 budget includes \$29.9 billion for the National Institutes of Health (NIH)—a \$1 billion increase over 2013. But before jumping with joy, keep in mind that the total is still \$723 million less than in 2012. Likewise, the budget includes \$1.7 billion for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—the biggest federal funder of kidney research—which is \$51 million less than in 2012 (Table 1).

"ASN thanks Congress for passing a budget that provides NIH an additional \$1 billion in 2014," ASN President Sharon M. Moe, MD, FASN, said. "Investments in medical research by NIH pay off big dividends: in lifesaving treatments for patients with serious illnesses like kidney disease, in more efficient and effective care, and even cures that result in long-term federal health care savings. Because of recent breakthroughs, like the discovery of the *APOL1* gene as a risk factor for kidney disease progression in African Americans, we are on the cusp of some amazing new advances in medicine. However, the budget does not reverse all the harmful cuts to NIH. Cuts to NIH funding will slow down progress, which is why ASN urges Congress to restore all funding for NIH."

The research budget for the Department of Veterans Affairs (VA) fared better, receiving \$585 million, an increase of a little more than \$4 million over 2012. However, this growth is not sufficient for the VA to keep up with the cost of inflation, making it challenging to invest in new opportunities such as the Million Veteran Program, the largest longitudinal study in history. The goal of the Million Veteran Program is to collect health information from 1 million veterans to learn more about how genes affect health, which could lead to improved screenings, diagnoses, prognoses, and personalized therapies.

ASN leaders are meeting with leaders from the VA's Office of Research and Development in February to discuss opportunities for leveraging the genetic information collected in the Million Veteran Program to better understand kidney disease. ASN leaders also have February meetings at NIH to discuss opportunities for addressing health disparities, and with congressional offices to discuss the best

strategies for reducing the burden of kidney disease.

These efforts are part of ASN's aggressive new research advocacy strategy. The society is also engaging partners in the kidney community to develop a unified advocacy message to promote the public health burden of all kidney diseases and benefits of federal investments in kidney research.

"More than 20 million Americans have kidney disease, placing them at increased risk for serious adverse health conditions such as cardiovascular disease and kidney failure," said ASN Treasurer-Secretary and Research Advocacy Committee Chair John R. Sedor, MD, FASN. "ASN thanks Congress for providing additional funding for NIH and VA research in the 2014 budget, and is committed to working with the VA, NIH, and Congress to explore every possible avenue for preventing the progression of kidney disease."

#### Table 1. Federal research funding

	2012	2013	2014
NIH	\$30,623,000,000	\$28,926,000,000	\$29,900,000,000
NIDDK	\$1,795,348,000	\$1,693,315,000	\$1,744,274,000
VA	\$581,000,000	\$582,700,000	\$585,664,000

NIDDK = National Institute of Diabetes and Digestive and Kidney Diseases; NIH = National Institutes of Health; VA = Department of Veterans Affairs.

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