ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Kidney News

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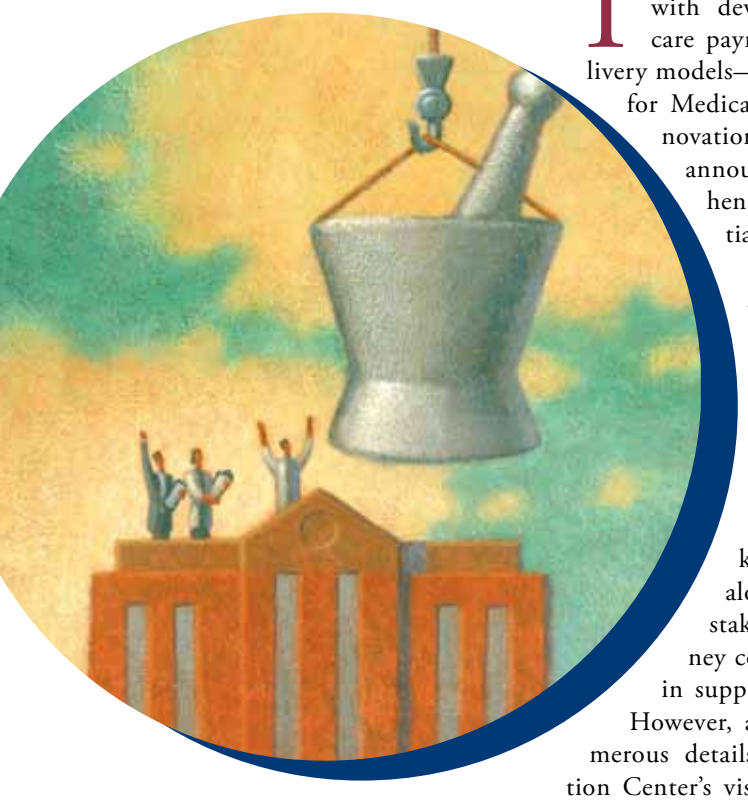
Innovation Center Announces Long-Awaited ESRD Care Model

By Rachel Shaffer



The government agency charged with developing new health care payment and service delivery models—CMS and its Center for Medicare and Medicaid Innovation (CMMI)—recently announced the Comprehensive ESRD Care Initiative.

The announcement marks the end of months of speculation about when—and whether—the Innovation Center would announce a coordinated care model for kidney care. ASN, along with many other stakeholders in the kidney community, advocated in support of such a model. However, as of press time, numerous details about the Innovation Center's vision for the program remained unclear to many in the kidney community.

CMS began accepting letters of intent for the Comprehensive ESRD Care Initiative in early February. The Innovation Center states that it anticipates that 10 to 15 so-called ESRD Seamless Care Organizations (ESCOs) will participate in the model. The first performance period for the model will begin in the fourth quarter of 2013, and interested participants must submit a letter of intent by March 15 and apply by May 1.

Yet it is unclear how many dialysis organizations, nephrology providers, and other health professionals will ultimately participate—and whether CMS will consider altering specifics of the program.

The Comprehensive ESRD Care Initiative is the first chronic disease-specific shared savings model that the Innovation Center has launched. While other fields of medicine—in-

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Online Hemodiafiltration Prolongs Life Compared with Standard Hemodialysis

Results of Prospective Randomized Trial May Change Clinical Practice

Hemodialysis is now a routine renal replacement therapy with guaranteed short-term safety, but long-term outcomes are far from ideal. Retrospective studies suggest that online hemodiafiltration (OL-HDF) may reduce kidney failure patients' risk of premature death compared with standard hemodialysis, but the results of prospective studies have failed to confirm this finding.

Hemodiafiltration differs from standard dialysis because it uses high convective transport to remove solutes over a wide range of sizes, including osteocalcin and beta2-microglobulin (Maduell F, et al. *Am J Kidney Dis* 2002; 40(3):582–589).

New results from a multicenter, open-label, randomized controlled trial demonstrate the advantages of OL-HDF (Maduell F, et al. *J Am Soc Nephrol* 2013. doi: 10.1681/ASN.2012080875).

"In view of this study's results, OL-HDF may become the first-line option in hemodialysis patients," said first author Francisco Maduell, MD, PhD, of the Hospital Clinic in Barcelona, Spain.

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Online Hemodiafiltration

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ESHOL study

A total of 906 dialysis patients were assigned to either continue hemodialysis or switch to OL-HDF, with higher convective volume than in previous prospective trials. The patients were followed up for 3 years as part of the On-Line Hemodiafiltration Survival Study, or Estudio de Supervivencia de Hemodiafiltración On-Line (ESHOL).

Compared with patients who continued on hemodialysis, those assigned to OL-HDF had a 30 percent lower risk of dying of any cause, a 33 percent lower risk of dying of cardiovascular-related causes, and a 55 percent lower risk of dying of an infection. Also, hospitalizations and dialysis sessions complicated by low blood pressure were lower in patients assigned to OL-HDF.

"The reduction in all-cause mortality associated with OL-HDF treatment observed in this trial was focused on cardiovascular and infectious diseases. Cardiovascular disease is the most common cause of mortality in chronic hemodialysis patients, and the mortality rate is still 10 times higher than in the general population," said Maduell. "Also, end stage renal disease patients have a significant risk of infectious complications, which represent the first cause of hospitalization and the second cause of death in hemodialysis patients."

The risk reductions shown in the ESHOL study suggest that switching eight patients from hemodialysis to OL-HDF may prevent one annual death.

Differences from previous studies

Results of earlier studies on hemodiafiltration were disappointing.

Two recent prospective, randomized trials failed to demonstrate a survival advantage of OL-HDF over hemodialysis. In the Dutch Convective Transport (CONTRAST) study, 714 prevalent dialysis patients were randomized to low-flux hemodialysis or OL-HDF, with an average follow-up time of 3 years. No survival difference between the groups was observed at the end of the study, (Grooteman MPC, et al. *J Am Soc Nephrol* 2012; 23:1087–1096). In the Turkish Online Haemodiafiltration Study, 782 prevalent dialysis patients were randomized to high-flux hemodialysis or OL-HDF, and, again, all-cause mortality was not affected by treatment allocation during 2 years of follow-up (Ok E, et al. *Nephrol Dial Transplant* 2013; 28:192–202).

Convective volume seems to be an important issue, based on the results of the CONTRAST and Turkish studies, Maduell said.

"The studies showed a 39 percent and 46 percent mortality risk reduction in patients receiving high convective volumes of greater than 22 and 20 liters per session, respectively," he said. "These results provide evidence of the need to deliver high convective volumes to reduce all-cause mortality. To achieve this goal, high blood flow rates and long dialysis times are required."

In the ESHOL study, the average blood flow rate was higher than in the CONTRAST and Turkish studies, whereas the average length of dialysis was longer than in the CONTRAST study and similar to that of the Turkish study. These factors led to a higher average delivered convective volume in the ESHOL study (23.7 L/session) than in the CONTRAST and Turkish studies (20.7 L).

"Our results indicate that the treatment modality could modify patient survival when a sufficient convective volume is reached," said Maduell.

Others in the field agree. Richard Ward, PhD, a professor of medicine in the kidney disease program at the University of Louisville, noted that the study is important for two main reasons: it is the first to show an unequivocal survival benefit from OL-HDF, and it confirms post-hoc analyses from the previous two studies, suggesting that the realization of a survival benefit requires the delivery of a minimum convective volume of about 24 L.

"My hope is that this article will provide the final push to see the introduction of online hemodiafiltration in the United States," Ward said. "The three randomized trials published in

the last 12 months, together with everyday clinical experience from use of the therapy in many other countries, show that online hemodiafiltration can be performed safely. Moreover, with the blood flow rates commonly used in the United States, it should not be difficult to deliver the convective volumes associated with reduced mortality."

Enric Vilar, MD, PhD, of the department of renal medicine at Lister Hospital in England, also noted that the study provides valuable clinically relevant data. "This is an important randomized control trial with a clear message for the dialysis community," Vilar said. "The positive results confirm the findings from previous cohort studies and also the CONTRAST study, which demonstrated improved survival for the subgroup with high substitution volume hemodiafiltration."

Despite the positive findings from this trial, Maduell stressed that hemodiafiltration is far from perfect. "The main limitation is the belief that the technique solves all problems of hemodialysis. Many other aspects need to be addressed to improve overall survival in the dialysis population—for example, getting a good vascular access, avoiding volume overload, and reducing cardiovascular risks," he said.

Still, the study's results indicate that widespread use of OL-HDF could have a considerable impact on dialysis patients' health and longevity. "Mortality remains very high in dialysis patients, ranging from 15 percent to 25 percent annually. Any reduction of this mortality would be an important achievement," Maduell said.

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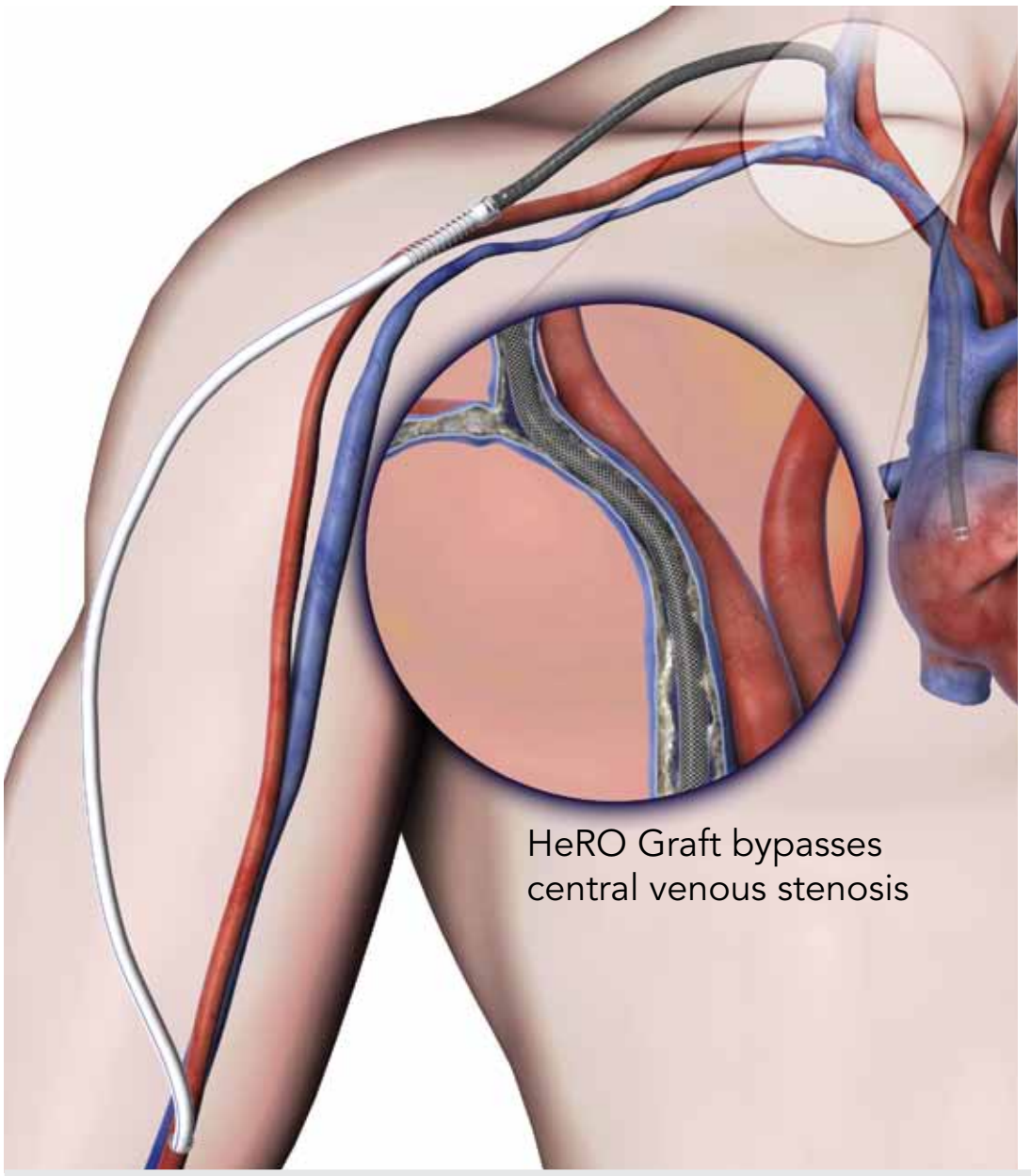

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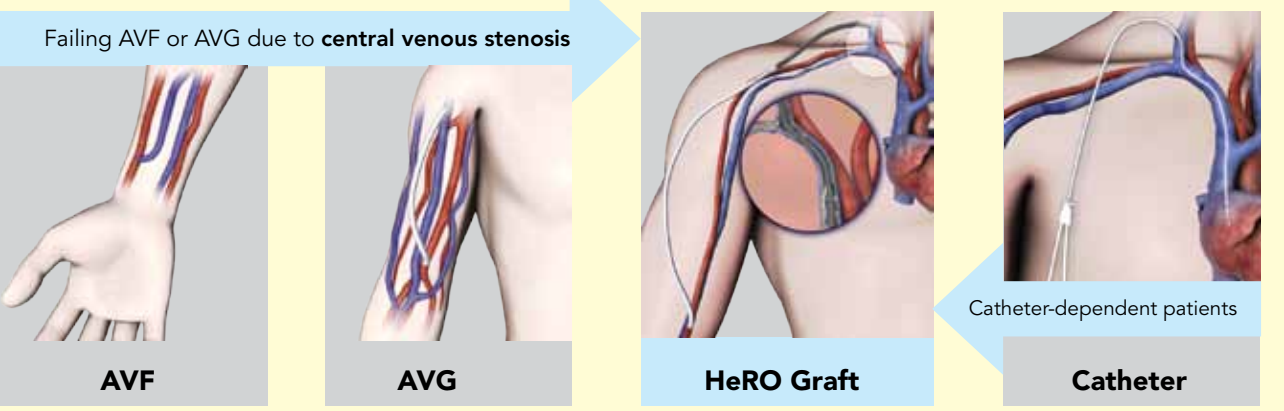

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1) Katzman et al., J Vasc Surg 2009. 2) Gage et al., EJVES 2012. 3) Dageforde et al., JSR 2012.

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ESRD Care Model

Continued from page 1

cluding oncology—have been similarly interested in a model that may improve care and reduce costs for patients with complex, high-cost conditions, nephrology is the first to pioneer the disease-specific coordinated care model. Ideally, early experiences in ESCOs could yield valuable lessons for other areas of medicine as they consider their own disease-specific shared savings models.

The Comprehensive ESRD Care model does not reflect all of ASN's goals for the program—including that patients with late-stage chronic kidney disease be included in the model. But several key goals were addressed, including highlighting the importance of a nephrologist-led interdisciplinary care team.

The stated purpose of the model is to "improve outcomes for Medicare beneficiaries with ESRD and reduce total per capita expenditures by creating financial incentives for dialysis facilities, nephrologists, and other Medicare providers of services and suppliers to collaboratively and comprehensively address the extensive needs of the complex ESRD beneficiary population." In other words, ESCOs are responsible for all Medicare Part A and B care, with the exception of costs that might be incurred related to kidney transplant surgery.

At a minimum, ESCOs must include a dialysis provider, a nephrologist, and "at least one other Medicare enrolled provider or supplier." Beyond that, CMS anticipates that an extended interdisciplinary team would support the care of ESRD patients, including general internists, endocrinologists, cardiologists, vascular surgeons, podiatrists, psychiatrists, nurse practitioners, physician assistants, registered nurses or licensed practical nurses, and health educators.

The Innovation Center's Request for Applications (RFA) points out that the care needs of beneficiaries with ESRD are typically complex owing to multiple co-morbidities and polypharmacy, requiring care coordination services that many of them do not routinely receive today. It specifies that ESCOs must emphasize coordination across a range of providers and settings, observing that "this may be best achieved through the establishment of an interdisciplinary care team—led by a nephrologist."

The comprehensive care model includes three possible payment arrangements. One of these arrangements applies to ESCOs that contain one or more large dialysis organization (LDO) participant-owners, and the other two are options for ESCOs that do not have any LDO participant owners. The extent to which the ESCOs may share in savings or losses will vary according to which payment arrangement they select. Like many other payment and service delivery models, the Innovation Center is testing—including Accountable Care Organizations (ACOs)—ESCO quality measure reporting will be a key mechanism CMS and the Innovation Center will use to asses patient outcomes, care coordination, and clinical improvements. CMS will factor ESCOs' quality scores into the calculation of shared savings and losses—and ESCOs will be required to meet a minimum threshold score to be eligible to receive shared savings.

However, the RFA did not include specific quality measures that ESCOs will be judged upon, nor a scoring methodology. CMS stated that it will "provide ESCO applicants/selected participants with more information regarding quality scoring before they have to commit" to participating in the model. CMS has stated that it will select quality measures "in consultation with national ESRD experts, including patient advocates and nephrologists," and suggested that the priorities outlined in Table 1 will influence its decision-making.

ASN leaders said they look forward to collaborating with other health professional and patient organizations to recommend measures for ESCOs that are based on strong scientific evidence, would have a meaningful impact on care from a patient perspective, and do not create an undue reporting burden for dialysis facilities. The society also looks forward to working with these groups to recom-

mend other considerations for optimal implementation of ESCOs.

Another aspect of the RFA that has raised some concern in the community is the minimum 500 patient threshold for an ESCO. Given CMS' stipulation that the area that an ESCO defines may be no larger than two contiguous Medicare core-based statistical areas, it may be hard for some smaller—and even potentially some larger—dialysis organizations to meet that threshold. Related to the threshold concern is the fact that beneficiaries who have already been matched to a Medicare ACO or another Medicare program/demonstration/model involving shared savings at the date of initial matching for the ESCO program are ineligible for the ESCO. In markets with one large ACO or multiple ACOs, the possibility that patients have already matched and are ineligible is a real possibility.

As more clarity around the RFA and more news of the community's reaction unfolds, look for additional coverage and analysis of ESCOs in *ASN Kidney News*.

Table 1

CMS priorities for determining quality measures

- Appropriate to the health issues of dialysis patients
- Effective for quality of care monitoring and program oversight
- Inclusive of process and outcome measures that will enable a robust evaluation of patient–provider and delivery system outcomes
- Conducive to use across clinical methods, modalities, and care settings
- Effective for incentivizing better care, better health, and lower costs across Medicare Part A, Part B, Part D, and Medicaid programs
- Inclusive of measures for appropriate medication utilization
- Straightforward to operationalize and measure
- Inclusive of other CMS ESRD quality initiative data

Journal View

Daily Dialysis Linked to Increased Mortality

Patients receiving daily in-center dialysis have a higher risk of death than those receiving conventional three-times-weekly dialysis, according to a report in *Kidney International*.

Using an international registry, the researchers identified 556 patients in France, the United States, and Canada who received daily hemodialysis (more than five times weekly) between 2001 and 2010. Propensity score techniques were used to match 318 patients receiving daily hemodialysis with 575 patients receiving conventional hemodialysis (three times weekly) during the same period. Mortality on the two dialysis schedules was compared by Cox proportional hazards.

The daily hemodialysis group received dialysis nearly twice as often as the conventional group: mean 5.8 sessions per week. The mean weekly dialysis times were 15.7 hours versus 11.9 hours, respectively.

There were 170 deaths over 1382 patient-years of follow-up. The mortality was substantially higher for patients receiving daily hemodialysis: 15.6 versus 10.9 deaths per 100 person-years, hazard ratio 1.6. The results were similar in matched and unmatched adjusted analyses and in specified subgroup analyses. There was also evidence that daily hemodialysis was poorly tolerated—30 percent of patients switched to conventional hemodialysis after a median of 10 months.

Previous reports have suggested improvement in health-related quality of life and other outcomes for patients undergoing daily hemodialysis. This cohort study, how-

ever, finds that mortality is actually higher for patients receiving daily hemodialysis compared with the conventional schedule. Although daily dialysis may have quality-of-life benefits, it cannot be recommended on the basis of improved survival [Suri RS, et al. A multinational cohort study of in-center daily hemodialysis and patient survival. *Kidney Int* 2013; 83:300–307].

Conservative Kidney Management: Quantity and Quality of Life

For patients with advanced kidney failure, conservative kidney management (CKM) is associated with shorter survival compared with dialysis, with no decrease in quality of life, reports a study in the *Clinical Journal of the American Society of Nephrology*.

The prospective study included 170 elderly patients with advanced, progressive chronic kidney disease: late stage 4 or stage 5. After standard assessments and discussions with patients and family members, 80 patients began to undergo (or were planned for) hemodialysis and 44 received peritoneal dialysis. Thirty patients opted for CKM, which consisted of ongoing medical treatment and multidisciplinary support. The remaining 16 patients remained undecided.

Patients underwent assessments of quality of life, anxiety and depression, and satisfaction with life for as long as 3 years. Quality of life and survival were compared among groups.

Patients selecting CKM were older, had more dependency needs, and had more comorbidity. Patients in the CKM group

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Journal View

Conservative Kidney Managment

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also had poorer physical health and higher anxiety than did those choosing dialysis. Most quality-of-life measures showed no significant change over time, regardless of treatment choice. The exception was life satisfaction, which decreased after the start of treatment in the dialysis groups but remained unchanged in the CKM group.

Survival was shorter for patients choosing CKM, after comorbidity, performance status, age, physical health, and propensity score were controlled for. Patients in the dialysis groups survived a median of 1317 days after enrollment, compared with 913 days in the CKM group.

Conservative kidney management may be considered by elderly patients with advanced kidney failure, for whom the benefits of dialysis are questionable. This study shows that quality of life tends to be maintained in patients opting for CKM, compared with those starting dialysis. This must be weighed against substantially shorter survival with CKM. [Da Silva-Gane, et al. Quality of life and survival in patients with advanced kidney failure managed conservatively or by dialysis. *Clin J Am Soc Nephrol* 2012; 7:2002–2009].

Hypertension Carries Higher Stroke Risk in Black Patients

At a given level of blood pressure, the risk of stroke associated with hypertension is higher for black than in white patients, according to a report in *JAMA Internal Medicine*.

The study included data on nearly 28,000 black and white participants 45 years and older in a population-based follow-up study of stroke risk factors. The study oversampled blacks and residents of the "stroke belt" of the southeastern United States. Proportional hazards models were used to assess differences in stroke risk factors and outcomes for black and white participants in three age groups (less than 65 years, 65 to 74 years, and 75 years and older) and three systolic blood pressure levels (less than 120 mm Hg, 120 to 139 mm Hg, and 140 to 159 mm Hg).

The analysis included 715 incident strokes over 4.5 years of follow-up. Black participants were more likely to be taking antihypertensive drugs. They also had higher rates of diabetes and left ventricular hypertrophy but lower rates of atrial fibrillation, smoking, and heart disease.

Per 10 mm Hg increase in systolic blood pressure, stroke risk increased by 24 percent for black participants versus 8 percent for white participants. This racial disparity was still significant after adjustment for other risk factors. The racial difference was greatest for participants 45 to 64 years. In this age group, the odds ratio for stroke among black participants was 1.38 for those with prehypertension and 2.38 for those with stage 1 hypertension. (For those with normal blood pressure, the racial difference was nonsignificant.)

The results show a greater increase in stroke risk associated with hypertension in black versus white patients, at similar ages and blood pressure levels. The authors note that black patients are more likely to have hypertension and less likely to have it under control, with uncontrolled blood pressure leading to a higher risk of incident stroke. Blood pressure may help to explain the recognized higher risk of stroke among black Americans, particularly during middle age [Howard G, et al. Racial differences in the impact of elevated systolic blood pressure on stroke risk. *JAMA Intern Med* 2013; 173:46–51].

NIDDK Director Speaks with *ASN Kidney News*

NIDDK Director Griffin Rodgers, MD

KN:

You have led the NIDDK for more than 6 years. Tell us about the institute and your vision of NIDDK's role in promoting scientific endeavor.

Rodgers:

As the NIDDK's director, I want to underscore the institute's commitment to vigorous, multipronged research efforts. In particular, I want to respond to two questions I have been asked at recent meetings with NIDDK constituency groups: "How will NIDDK research move forward now and in the future?" and "How will the institute meet the challenges of the current budget landscape?"

Clearly, at all levels of the NIDDK we will continue to pursue the most compelling research to combat the many debilitating and costly chronic diseases within our mission: kidney and urologic diseases, diabetes and other endocrine and metabolic diseases, liver and other digestive diseases, nutritional disorders, obesity, and hematologic diseases. Moreover, we will remain firmly committed to basic, translational, and clinical research; research training and career development; and the dissemination of health information to improve the lives of patients, their families, and those at risk for these diseases.

Together, we at NIDDK will build upon the emerging opportunities that are the fruits of past research investments. Through careful planning and analysis, we will meet the challenge of deploying our budgetary resources in the most effective and efficient ways to sustain research momentum and fully capitalize on research achievements. In moving research forward, several overarching principles will guide my leadership and that of the NIDDK extramural division directors:

- **Maintaining a vigorous investigator-initiated research portfolio.** The innovations and problem-solving skills of individual investigators are crucial for research progress. Therefore, NIDDK will maintain funding of investigator-initiated grants at the highest possible level. We will also maximize our investments by supporting cross-cutting science that is broadly applicable to many disease-specific research issues. Examples include identification of biomarkers that can aid in disease diagnosis and assessment of new treatments in clinical trials, development of cell-based therapeutic approaches for repairing damaged tissues, and the use of cutting-edge research methods to identify new candidate drugs.
- **Supporting pivotal clinical studies and trials**. Clinical studies will continue to be an integral component of research on the broad spectrum of diseases for which NIDDK has research responsibility. We have supported large epidemiologic studies of chronic kidney disease (CKD) in adults through the Chronic Renal Insufficiency Cohort (CRIC), and in children through the Chronic Kidney Disease in Children Prospective Cohort (CKiD). Shortly, NIDDK will fund new clinical studies and trial initiatives in glomerular diseases, CKD, and end stage renal disease (ESRD). Because many of these diseases disproportionately affect minority populations, we will continue to seek insights and answers to health disparities. For example, we will continue to ensure substantial minority participation in clinical trials relevant to these diseases. We are also maximizing our investments by expanding the investigative community's access to the valuable research resources accrued in our major clinical trials. We are doing this by funding ancillary studies to these trials and by supporting a central repository for biologic materials from clinical trials.
- **Preserving a stable pool of talented new investigators.** The ideas and fresh perspectives of new investigators invigorate the research community. We will strive to ensure that today's generation of young scientists can realize their potential for contributing to biomedical research and will view research as a viable career. We will foster mentorship through our K Awardee (career development) workshops and New PI workshops for first-time RO1 investigators, and promote special consideration for funding of talented new investigators through the use of differential paylines and special emphasis.
- **Fostering exceptional research training and mentoring opportunities.** Maintaining an NIDDK-focused pipeline of outstanding investigators is critically important to our research progress. We will continue to support significant opportunities at the graduate and postdoctoral levels, as well as through research career development awards and undergraduate research educational opportunities. To ensure that we are deploying our research training resources most productively, we are analyzing data to determine the most effective aspects of training programs so that we can share them with our entire community.
- **Ensuring knowledge dissemination through outreach and communications.** We are continuing efforts to ensure that the science-based knowledge gained from NIDDK-funded research is imparted to health care providers and the public for the direct benefit of patients and their families. Examples include the National Kidney Disease Education Program (NKDEP), the National Diabetes Education Program (NDEP), the Weight-control Information Network (WIN), and new programs to promote celiac disease awareness and the prevention of obesity in children.

As we plan for the future, we will continue to seek and value external advice from investigators, professional scientific organizations, patient advocates, and the public. Key sources of input will continue to be our National Advisory Council, Interagency Coordinating Committees, strategic planning processes like the Kidney Research National Dialogue (KRND), ad hoc planning groups, and scientific conferences and workshops. This input will provide a useful scientific guidepost as we make resource allocation decisions. Active collaboration with other components of the NIH and other federal agencies will also remain a cornerstone of NIDDK planning efforts

Ever-increasing knowledge and the advent of new technologies bring new scientific opportunities for alleviating and conquering the many chronic diseases within the NIDDK's mission. Our continuing goal will be to seize and maximize these opportunities to reduce the burden of disease and improve the public health. To this end, I look forward to working with the NIDDK's many stakeholders now and in the future.

Together, we at NIDDK will build upon the emerging opportunities that are the fruits of past research investments. Through careful planning and analysis, we will meet the challenge of deploying our budgetary resources in the most effective and efficient ways to sustain research momentum and fully capitalize on research achievements.

–Griffin Rodgers

KN:

What are the most important things you take into account when allocating funds, and how much discretion do NIH and NIDDK have in allocating research dollars?

Rodgers:

A substantial percentage of budget allocation is dedicated to investigator-initiated grants, in accordance with the available NIDDK payline. The proportion that goes to kidney disease thus depends on the number of applications and how well they score in review. The institute also has a process for larger (more costly) initiatives, although this has become smaller with the flattening of the NIH budget. Initiatives are proposed by KUH (kidney, urologic, and hematologic diseases) program staff and are then

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NIDDK

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reviewed for scientific opportunity by the NIDDK Council. Finally, kidney investigator–initiated applications have competed successfully for Common Fund, T1D, and large-scale genetics projects. Topics include "Kidney on a Chip," "Metabolomics in CKD," "Systems Biology Approaches for Diabetic Nephropathy," a cluster randomized trial in patients on dialysis that is part of an NIH health systems collaboratory, and a clinical trial to determine the value of APOL1 screening.

KN:

NIDDK spearheaded the Kidney Research National Dialogue (KRND). How has the information NIDDK gathered altered the planned Blueprint for Kidney Research?

Rodgers:

NIDDK has completed the first phase of KRND and is working on the development of the individual chapters for the "Blueprint for Kidney Research," which also will be published as a series of individual commentaries in the *Clinical Journal of the American Society of Nephrology (CJASN)*. Responses to the question, "What are the critical questions and objectives in kidney research?"—which numbered over 270—were broad ranging and insightful. Upon review, the collection of questions in a particular kidney research area captured the distinctiveness of each field's critical questions. However, it has become clear that more discussions are needed to refine the content of the individual topic discussions to truly capture the current state of each field and provide high-impact conceptual models, recommendations, and potential "roadmaps." These second-level discussions are now being completed through a hybrid structure of electronic discourse and telephone conferencing. We have taken postings from the KRND and the individual chapter commentaries into consideration during the development of current initiatives.

KN:

What will the KRND mean to individual investigators?

Rodgers:

The KRND is a good source of ideas for trainees, early stage investigators, and seasoned, established investigators who wish to think more deeply about their own research trajectory. We hope it will stimulate innovative directions that advance kidney research and aid in establishing research collaborations. Our hope is that the *CJASN* commentaries will effectively communicate these ideas to the broadest community possible.

KN:

Has the focus on translational research at NIH changed funding goals at individual institutes?

Rodgers:

NIDDK's research portfolio supports a broad range of science, including patient-oriented clinical research, basic and translational research, clinical trials, pragmatic clinical trials, public health, and translation to the clinic. Translational research serves as an evolving source for new ideas and thoughtful future directions, but is only one part of the portfolio.

KN:

What do you consider the most promising translational opportunities in kidney research and practice?

Rodgers:

The most promising translational opportunities at the moment are those that pertain to glomerular disease, CKD, dialysis, and acute kidney injury (AKI). We have put forth recent funding announcements in all of these areas. We also encourage investigators and associated small start-up companies working on innovative devices, tools, and drugs to submit Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) applications, as congressionally mandated funding has increased in these areas.

KN:

The percentage of funded grant applications is decreasing, and automatic spending cuts may take effect between 2013 and 2021. If automatic spending cuts go into effect, how should investigators and research institutions prepare?

Rodgers:

This is quite difficult to predict, yet it goes without saying that the high quality of research must be maintained in the face of any future spending cuts. We are attempting to support all five of our core principles as strongly as possible during periods of fiscal uncertainty.

KN:

How does NIDDK balance approaches to retain established researchers with the need to attract new researchers to the field?

Rodgers:

The NIDDK tries very hard to do both, largely through a special emphasis on funding and bridge awards for established investigators who just missed the payline, and via concerted efforts to entice undergraduate, medical school, and doctoral students to consider nephrology as a research career. We also give a special advantage to early stage investigators with a differential payline, as well as particular consideration of those who just missed the payline. We have recently hosted a mentoring workshop for our first-time R01 investigators (New PI Workshop) and are actively planning a similar one for our career development awardees (K Awardee Workshop). Finally, we just set up a Facebook page for our training and career programs (http://www.facebook.com/NIDDKKUHtrainee). We need to attract new researchers' talent and ideas to sustain nephrology research in the future.

KN:

Many scientists and clinicians struggle to help resolve disparities in kidney disease. What are the most important recent gains in this area?

Rodgers:

There have been gains in the identification of genetic markers for risk of glomerular disease and CKD in African Americans, but significant disparities remain in outcomes. The rate of CKD in African Americans is not greater than the rate for whites, but the rate of ESRD is much higher for African Americans. I think the new genetic findings hold potential promise, but we still do not know how to operationalize them. This is an active area of investigation that may provide clinical benefits. Perhaps this will help resolve a paradoxical finding in the ESRD literature that showed despite decreased access to care and increased socioeconomic challenges, African American hemodialysis patients survive longer than white patients—an unresolved mystery that if solved could provide public health insights. The NKDEP program has been very active in finding ways to get the message out to minority communities and others with increased risk of CKD and to the providers who serve them.

KN:

In 2007 the NIDDK wrote about the economic imperative to conquer diabetes. Doesn't the same kind of imperative exist for kidney disease?

Rodgers:

It absolutely does. The NIDDK supports a wide range of studies:

- Basic science, including physiology, pathophysiology, development, injury, repair, and regeneration
- Epidemiology research, such as the aforementioned CRIC and CKiD studies, and the Assessment, Serial Evaluation and Subsequent Sequelae of Acute Kidney Injury (ASSESS-AKI)
- Translational research, including the Diabetic Complications Consortium (DCC) and the CKD Biomarker Consortium
- Clinical trials, including new RFAs in 2013 for glomerular, CKD, and ESRD clinical study initiatives

KN:

What do you consider the greatest opportunity for kidney researchers over the next decade? Could antifibrotic research not only point toward better management of kidney disease, but lead to actual regression? If so, how?

Rodgers:

I believe that over the next 10 years, we will see significant strides in the treatment of fibrosis, whether the fibrosis is a result of glomerular disease, slowly progressive CKD, or follows a bout of AKI. Recent research in animal models has pointed to many potential targets to limit, if not reverse progressive fibrosis in the kidney and other organs. We are designing a future initiative that has a long-term aim to find agents that reverse established disease—through repair, regeneration, or reversal of fibrosis.

Policy Update

World Kidney Day 2013 Highlights Acute Kidney Injury

By Sarah Faubel, MD; Stuart Goldstein; and Bertrand Jaber on behalf of the ASN Acute Kidney Injury Advisory Group

Acute kidney injury (AKI) is a serious and growing public health problem that is encountered in the hospital setting. AKI is associated with a higher short-term risk of in-hospital death, and AKI-associated costs have been estimated at $10 billion annually in the United States, due in part to extended hospital length of stays and use of renal replacement therapies. Survivors of episodes of AKI remain at increased risk of development and progression of chronic kidney disease, end stage kidney failure, and death. Unfortunately, at present, there exist no specific therapies aimed at preventing or treating AKI and its associated complications with the exception of supportive care, including renal replacement therapies.

Launched in 2006, World Kidney Day broadcasts an annual message about kidney disease to the public, government health officials, and health care providers, including general practitioners. Over the past seven years, this effort has focused on early detection of kidney disease, kidney protection measures, and kidney organ donation. This year, World Kidney Day—March 14, 2013—focuses on AKI to raise awareness and promote discussion, education, and policy development with the hope of improving prevention and treatment of this condition.

The AKI Advisory Group is leading ASN's efforts to commemorate the day. In preparation for World Kidney Day 2013, the AKI Advisory Group conducted a large systematic review and meta-analysis aimed at estimating the worldwide incidence of AKI and its stages of severity and associated mortality. The review also aims to describe geographic variations according to countries, regions, and their economies. The advisory group also completed a narrative review on the importance of transitions of care following hospital episodes of AKI calling for studies aimed at identifying patients at risk for developing chronic kidney disease and in need of targeted interventions. To further raise awareness of AKI, on World Kidney Day, the AKI Advisory Group will conduct a survey of nephrologists to determine the number of cases of AKI seen in the United States on one particular day. This survey may help assess the burden of AKI as a function of the overall practice of nephrology (see more below).

The epidemiology of AKI has undergone a dramatic shift in the past two decades. Medical providers increasingly understand that AKI is independently associated with poor patient outcomes. The major clinical contexts studied have included those in which the timing of AKI is known and predictable (e.g., cardiopulmonary bypass) or when mortality is very high, such as in patients admitted to the intensive care unit with septic shock.

Numerous studies such as RIFLE and AKIN, as well as improved criteria for assessing AKI (KDIGO) have demonstrated that AKI may manifest as a secondary syndrome associated with another system illness and/or its treatment. Recently, increased attention has focused on nephrotoxic agents used for diagnostic purposes, including iodinated contrast agents required for imaging studies, as well as the multiple nephrotoxins prescribed to treat underlying illness or symptoms, which range from non-steroidal inflammatory drugs, antimicrobials, to chemotherapeutic agents.

Recent data show that over 80 percent of hospitalized patients are exposed to at least one nephrotoxic medication. Nephrotoxic medication–associated AKI is often non-oliguric, so clinicians should monitor kidney function closely in the at-risk patient receiving a nephrotoxin. Given the increased evidence that AKI can lead to CKD, increased awareness of AKI risks and outcomes by non-nephrologists, and their collaboration with nephrologists, can improve outcomes.

On World Kidney Day 2013 ASN will conduct a survey of its U.S. members to provide a snapshot of AKI on this one day. Participants will be asked to keep track of the number of patients with AKI they see in the hospital relative to the total number of cases seen.

As understanding of the epidemiology of AKI has emerged, so too has the importance of characterizing the public health burden of AKI, particularly in regard to its daily impact. Therefore, on World Kidney Day 2013 ASN will conduct a survey of its U.S. members to provide a snapshot of AKI on this one day. Participants will be asked to keep track of the number of patients with AKI they see in the hospital relative to the total number of cases seen.

Although much is known about the epidemiology of AKI, virtually nothing is known about the burden of AKI from a nephrologist's practice perspective. A picture of a "day in the life of AKI" will include an estimate of the number of cases of AKI, the number requiring renal replacement therapy, and the amount of in-hospital nephrology practice devoted to the care of patients with AKI.

All U.S. nephrologists are encouraged to participate, whether or not they see patients on World Kidney Day, as questions regarding overall practice related to AKI will also be asked. The information obtained in this survey will further raise awareness of AKI and its impact on public health. In summary, AKI continues to present a formidable challenge to health care providers and patients, and requires innovation in the prevention and treatment of this condition. With the launch of its new 2013 campaign, the AKI Advisory Group hopes to galvanize health care professionals and policy makers, in close collaboration with the public, to design better and safer health care delivery systems that focus on preserving kidney health through prevention and early detection and treatment of AKI, with the goal of mitigating the long-term costly burden of chronic kidney disease.

Sarah Faubel, MD, is affiliated with the Division of Nephrology, University of Colorado and Denver Veterans Administration Medical Center. Stuart Goldstein, MD, is affiliated with the Center for Acute Care Nephrology, Cincinnati Children's Hospital Medical Center. Bertrand Jaber, MD, FASN, is affiliated with the Department of of Medicine, Division of Nephrology, Kidney and Dialysis Research Laboratory, St. Elizabeth's Medical Center, Boston, and the Department of Medicine, Tufts University School of Medicine.

Paving the Way for Veterans' Health: A VA Research Primer

By Grant Olan

With a budget of $1.95 billion last year, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the largest source of federal funding for kidney research, but certainly not the only one. The U.S. Department of Veterans Affairs (VA) has a comprehensive research portfolio aimed at advancing the treatment of kidney failure, as well as preventing and slowing the progression of kidney disease.

Like the National Institutes of Health (NIH), VA research grant proposals are subject to a peer review process. Only the most promising proposals based on objective, evidence-based science are funded. Unlike NIH, the VA does not have an extramural research program. Consequently, all VA-funded investigators must hold a VA appointment such that at least five-eighths of their work time is with the agency.

Last year the VA released a report on "The State of VA Research" that highlights some significant kidney-related research, including a 2011 study that found cystatin C (a blood marker of kidney function) is significantly more accurate than the standard blood marker (creatinine) in predicting serious complications of kidney disease. "Among adults who were identified as having kidney disease by high creatinine levels, the researchers found that only patients who also had abnormally high levels of cystatin C were at high risk for death, cardiovascular disease, heart failure, or kidney failure. People with high creatinine but normal cystatin C levels had risks similar to those with normal creatinine levels."

VA researchers also demonstrated in a large 2008 multisite clinical trial that more intensive treatment for acute kidney injury (the rapid loss of kidney function over a few hours or a few days)—e.g., dialysis six times

Continued on page 14

Policy Update

VA Research Primer

Continued from page 13

instead of three times per week—may not result in any added benefit.

One of ASN's top policy priorities is advancing support for medical research within federal research agencies, including the VA. ASN is on the Executive Committee of the Friends of VA Medical Care and Health Research (FOVA), and works closely with a number of other medical research advocacy coalitions.

FOVA was founded more than 20 years ago to ensure that America's veterans receive high-quality health care. Today, FOVA is a diverse coalition representing national academic, medical, and scientific societies; voluntary health and patient advocacy groups; and veteran-focused associations. FOVA works in concert with "The Independent Budget." The Independent Budget is a recommendation released annually by veterans' service organizations around the same time the President releases his annual budget recommendations. The recommendation is highly regarded and used by Congress to determine VA budget needs.

This year FOVA and The Independent Budget are recommending a $611 million increase for the VA's Medical and Prosthetic Research account in Fiscal Year 2014, a $30 million, or 5.2 percent, increase over 2012 levels. FOVA estimates that $17 million, or 2.9 percent, of that total is needed to keep pace with the rising cost of medical research. The additional $13 million is needed to support new research into conditions veterans returning from Iraq and Afghanistan face, including polytrauma, or multiple traumatic injuries such as a serious head injury in addition to a serious burn.

Thanks in part to the work of FOVA, the VA released a congressionally requested report last year detailing an in-depth survey and analysis of the physical condition of all VA research facilities (www.aamc.org/varpt). The survey and analysis evaluated and documented deficiencies in five areas and prioritized those deficiencies from 1 (life-threatening issues such as a chemical shower over electrical cords) to 5 (items that should be fixed but pose no threat to the health and safety of personnel are not required immediately). Altogether, the deficiencies total $774 million to correct.

In response to this report, for the first time, FOVA and The Independent Budget are also making specific budget requests for VA research construction and infrastructure needs. Construction and infrastructure funding for VA research needs currently competes with funding for VA clinical needs like patient beds and elevators, which typically take precedence. As a consequence, many VA facilities have run out of adequate research space, or existing space is unable to meet current research standards and safety codes.

FOVA believes specifically designating funds as a line item in the VA's budget to address these deficiencies is the only way to break this stalemate. Consequently, as a down payment for the $774 million cost to correct all the deficiencies, FOVA is recommending $50 million or more in Fiscal Year 2014 for up to five major VA research facility construction projects and $175 million in non-recurring maintenance and minor construction funding to address priority 1 and 2 deficiencies identified in the 2012 VA research facility report.

"VA research has led to countless discoveries and innovations that have advanced health care not just for our nation's veterans, but for all Americans. Now the architecture that made this possible is languishing, and in some cases literally falling apart around the investigators that work in VA research facilities," said John R. Sedor, MD, ASN Research Advocacy chair. "If we don't make the necessary investments to bring these facilities up to current code and standards, the VA will have a tough time attracting new investigators, and research will suffer as a consequence. ASN supports the important work that FOVA is doing to advance the VA research program."

Do Health Apps Yield Patient Results?

By Pascale Lane

"There's an app for that."

It seems like everything can now be managed from a smartphone. Apps abound to help us shop and work and play. Pets can even be fitted with GPS collars so we can track their travels over the Internet. More than 20,000 apps also claim to manage our health, including the most popular diet method in a *Consumer Reports* annual survey. Some may be revolutionary, while others may be useless.

Diet diaries and pedometers have made way for devices that chart workouts using GPS and accelerometers to directly measure activity. Other services let participants earn workout rewards or log miles for charities. Wi-fi chipped blood pressure cuffs and bathroom scales can send data straight to an online logbook, showing the health results of those efforts in the gym and kitchen.

On the provider side, apps make it easier to get up-to-the-minute data to help with diagnosis and treatment. Accessing the latest treatment guidelines just requires pulling out a smartphone and tapping its screen. Integration of electronic records into mobile devices helps us keep track of what is going on with our patients, rather than relying on our (faulty) memories for after-hours calls. Choosing these sorts of apps requires little thought; they are clearly useful.

Things get trickier for patients. How can they know which apps provide useful health management, as opposed to others that may provide bad advice? Dedicated patient groups, the e-patients, may test and review apps for each other. At least one health app boutique service, Happtique (www.happtique.com), gathers apps for member review. Providers can use the platform to prescribe apps to their patients, even creating their own virtual app store. The platform also provides a secure environment for transmitting data from services such as glucose trackers to health care records.

Diabetes tracking may be the most advanced health app area. Glucose monitors and insulin pumps can send their data directly to online information hubs. Add in diet and activity tracking, and these services become a way to look at all aspects of glycemic control and effect over time.

What is missing for apps? Results. While these apps should provide patients better health support, we do not have data to show better outcomes yet.

We also do not have the comprehensive apps for kidney patients that we do for diabetes. Where is the app that charts blood pressure, diet, and activity? Where is the diet tracker that can tell the user phosphate and potassium content of their food choices? Where is the dialysis tracker with blood pressure, weight, and dialysis settings automatically charted to look for trends?

Managing chronic disease means keeping track of all aspects of an illness. Treatment includes medications and diet, as well as monitoring signs and symptoms. Apps may help patients do this better, perhaps improving health outcomes. That is our goal, and there will be an app.

Pascale Lane, MD, is editor-in-chief of ASN Kidney News.

Something to Say?

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

Time out.

Let’s take a moment to look at the current state of the lab industry.

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Industry Spotlight

Amgen Fourth Quarter Profits Drop, Revenue Up for 2012

Amgen finished 2012 with lower fourth-quarter profits—reporting a net income of $788 million—despite an 11 percent increase in revenue for the quarter to $4.42 billion. Increased spending on research and development and other administrative costs led to the 16 percent decline for the quarter compared to 2011.

For 2012, revenues at the biotechnology company also rose 11 percent for the year, totaling $17.3 billion. This performance also reflects the costs of Amgen's acquisition of deCODE Genetics—a biotechnology company based in Iceland that focuses on identifying genetic risk factors for disease development—which was finalized in December of last year.

Amgen's anemia drugs contributed to the weak fourth-quarter performance, with Aranesp (darbepoetin alfa) and Epogen (epoetin alfa) sales falling by 9 percent and 1 percent, respectively. For 2012, Aranesp and Epogen sales declined 11 percent and 5 percent, respectively, driven by changing practice patterns and reduced dosing. Introduction of new drugs to treat anemia in patients receiving dialysis could lead to a more competitive environment for this therapeutic area, and possibly pose additional challenges to sales.

Demand for other medications in Amgen's nephrology portfolio remained strong. Sales of Sensipar (cinacalcet), a treatment for secondary hyperparathyroidism, were up 19 percent in the fourth quarter of 2012 and 18 percent for the year.

Looking ahead to 2013, Amgen's chairman and CEO Robert A. Bradway announced several new phase III trials, including one for AMG 145 for individuals with high LDL cholesterol levels. "We enter 2013 with good momentum, a broad late-stage pipeline, and a continued focus on building our business internationally," he said. However, the company announced plans in January to lay off 160 employees, or 1 percent of its workforce.

New Hyperphosphatemia Treatment Meets Phase III End Points

Keryx Biopharmaceuticals recently announced that the phase III clinical trial of its drug Zerenex (ferric citrate) successfully met its predetermined end points. Conducted under a Special Protocol Agreement, the study assessed the oral ferric iron–based compound for the treatment of hyperphosphatemia in patients with ESRD who are receiving dialysis.

The multicenter, randomized, open-label trial involved 441 patients with ESRD who were undergoing either hemodialysis or peritoneal dialysis. The study was conducted in two stages, a 52-week safety assessment phase and a 4-week efficacy assessment phase, preceded by a 2-week washout interval.

Zerenex met the primary end point of significantly reducing serum phosphorus levels compared to placebo in the efficacy assessment phase. The drug also met all secondary end points during the 52-week safety assessment, including maintenance of serum phosphorus in the normal range (with a noninferiority comparison with Renvela [sevelamer carbonate]), increasing ferritin and transferrin saturation levels, and reducing intravenous iron and erythropoiesis-stimulating agent use compared with the active control.

Based in New York City, Keryx also reported plans to file a New Drug Application for Zerenex with the Food and Drug Administration (FDA) and a Marketing Authorization Application with the European Medicines Agency in the second quarter of 2013.

The results of this trial follow the January 2013 announcement that Zerenex was submitted for approval in Japan by Japanese Tobacco, the company that sublicenses the drug from Keryx.

Current therapies for the treatment of hyperphosphatemia include Renvela and Renagel (sevelamer hydrochloride), both of which are manufactured by Sanofi.

Keryx has also initiated phase II development of Zerenex for the management of phosphorus and iron deficiency in patients with stage III–V CKD who are not receiving dialysis.

Canadian Biotech Merger Puts Focus on Nephrology Drugs

Two Canadian biotechnology firms—the publicly traded Isotechnika Pharma and privately held Aurinia Pharmaceuticals—will combine forces to concentrate on the nephrology therapeutic market. The companies will join together under the Aurinia banner to focus on developing the calcineurin inhibitor voclosporin, an immunosuppressant, for approval.

Although the merger is based in Canada, the deal has international overtones. If approved, the South Korean ILJIN Life Science—which owns the rights to voclosporin—will take a 25 percent ownership stake in the new Aurinia.

Vifor Pharma, the Swiss pharmaceutical company held by the Galenica Group, is also involved. In 2012 it signed a development and commercialization agreement with Isotechnika to market voclosporin for treatment of lupus and all proteinuric nephrology indications in the United States and other countries outside of Canada.

Aurinia itself was spun out from Vifor as a separate entity after the Swiss firm acquired Aspreva in 2008, a company that specialized in immunosuppressive therapies, investigated lupus nephritis treatments, and conducted the Aspreva Lupus Management Study (ALMS).

Previously, voclosporin has been studied in the treatment of chronic noninfectious uveitis. However, the drug was withdrawn from approval for this indication in Europe because of a failure to demonstrate that its benefits outweighed its risks.

Isotechnika recently completed a phase IIb study of voclosporin for use in solid organ transplantation that demonstrated equivalence to tacrolimus in prevention of acute rejection.

"While there have been a number of advances in the treatment of lupus nephritis, there is no question that significant unmet medical need remains," said Neil Solomons, MD, the new company's chief medical officer. "To that end, we expect to launch this phase IIB study of voclosporin in lupus nephritis in 2013," he added.

Based in Edmonton, Alberta, Canada, Isotechnika anticipates completion of the deal by the end of the first quarter of 2013, pending shareholder and regulatory approval.

New Iron Therapy Successful in Reducing ESA Dosing

A novel iron supplement therapy under development at Rockwell Medical significantly reduced erythropoietin-stimulating agent (ESA) dosing by 37 percent over the course of a recent 9-month study. A randomized placebo-controlled phase II clinical trial demonstrated that the drug—soluble ferric pyrophosphate (SFP)—met the primary end point of lowering ESA use in patients with end stage renal disease (ESRD) receiving hemodialysis.

Unlike other iron supplement therapies, which are given intravenously, SFP is mixed into dialysate and administered during dialysis. SFP's unique mechanism simulates the body's delivery of dietary iron, which could contribute to its efficacy. Upon entering the bloodstream, the drug quickly binds to apotransferrin and travels to bone marrow.

The phase II PRIME trial involved 108 patients with ESRD receiving hemodialysis randomized to receive dialysate either with or without SFP. Hemoglobin levels in both the SFP and placebo groups were similar at the beginning and end of the trial. However, the ESA dosing needed to maintain hemoglobin levels was significantly lower in the SFP group. In addition, SFP maintained iron balance without increasing iron stores in other organs and had a safety profile similar to placebo.

"We believe that SFP's unique ability to treat iron deficiency while dramatically reducing the need for ESA, without increasing iron stores, strengthens SFP's potential to become the market leading iron therapy treatment for CKD-HD patients," said Rockwell Medical President and CEO Robert Chioini. "SFP's ability to substantially reduce ESA use in the treatment of anemia should translate into significant cost savings in dialysis care while potentially lowering the serious risks associated with the dosing of ESAs."

Based in Michigan, Rockwell Medical is currently conducting a phase III trial of SFP for use in the treatment of anemia in patients with ESRD who are receiving hemodialysis. At the trial's conclusion, the company anticipates filing a new drug application with the U.S. Food and Drug Administration by the end of 2013.

Abbott Laboratories Spins Off AbbVie, Reports Dip in Fourth-Quarter Profits

Abbott Laboratories announced a 35 percent decrease in profits in the fourth quarter of 2012. Despite an increase in sales of more than 4 percent, net earnings for the quarter were $1.05 billion, down from $1.62 billion in 2011.

Early repayment of debt and costs associated with spinning off Abbott's biopharmaceutical business into a new company called AbbVie contributed to the drop at the end of the last quarter. Finalized at the beginning of 2013, the new multinational will concentrate solely on the development of pharmaceuticals to treat complex diseases that affect broad patient populations.

The *Wall Street Journal's* Market Watch recently reported that Abbott's move to spin off AbbVie was "a bid for a higher market valuation for Abbott Labs' diversified businesses, which are poised for stronger earnings growth in coming years than AbbVie."

Abbott will maintain its stable of diagnostic and endovascular devices, as well as diabetes, vision, and nutritional products.

AbbVie's focus is on drug development in therapeutic areas such as hepatitis C, rheumatoid arthritis, and multiple sclerosis. The new pharmaceutical firm also inherited several products from Abbott's nephrology portfolio, including Calcijex (calcitriol injection) and Zemplar (paricalcitol).

"In 2012, we achieved a significant milestone in Abbott's 125-year history with the creation of AbbVie while delivering another year of strong results," Abbott's chairman and CEO Miles White said. "Abbott's mix of diversified health care businesses and pipeline is favorably aligned with key health care and emerging market trends and well positioned to deliver top-tier growth in 2013."

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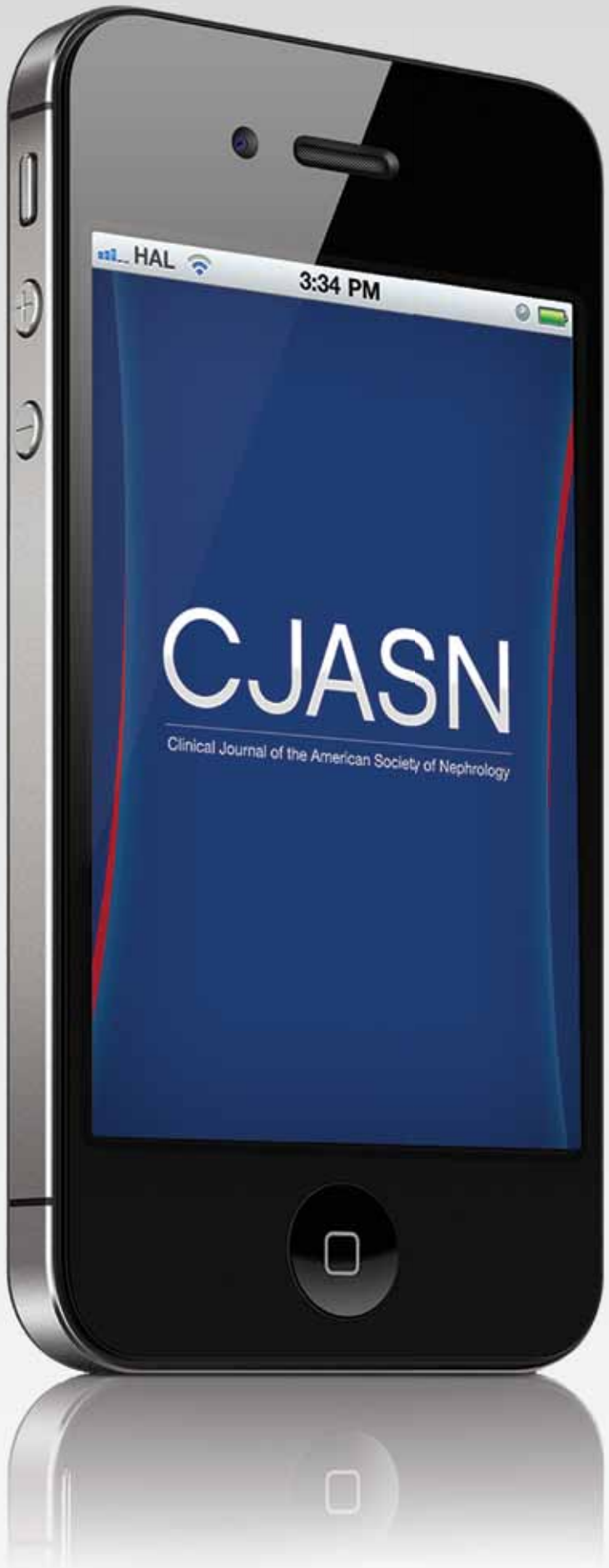

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