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## Starting Dialysis after 75: New Outcomes Data for Shared Decision-Making

By Kurtis Pivert



n analysis of outcomes in patients initiating dialysis at 75 years or older could provide important knowledge for physicians, elderly individuals, and their caregivers in the shared decision-making process of whether to start renal replacement therapy. In their review of 5 years of data from a cohort in this age group Bjorg Thorsteinsdottir, MD, and her coworkers from the Mayo Clinic uncovered sobering results, including the frequent loss of

independent living and a high mortality rate after starting dialysis (1). Presented at Kidney Week 2013, their work fills an evidence gap and could aid physicians in delivering patient-centered care to individuals in this fast-growing segment of the U.S. population.

Thorsteinsdottir reviewed patient records for individuals 75 years or older who started any form of dialysis at the Mayo Clinic in Rochester, MN, between 2007 and 2011. The 379 patients studied were mainly male (66 percent) with a mean age of 80.8 years at time of initiation. The majority (76 percent) of patients started hemodialysis in the hospital after admission for an acute medical event or surgery. Of note, more than half (60 percent) of the patients included in the analysis began dialysis in the intensive care unit (ICU).

A precipitous early mortality rate was observed in the cohort. Of those initiating dialysis in the ICU, the 6-month mortality rate was 73 percent, with only 23 percent surviving at 1 year. The non-ICU hospital starters had a 22 percent and 41 percent mortality rate at 6 and 12 months, respectively. However, patients starting hemodialysis as outpatients did surprisingly well with only a 4 percent mortality rate at 6 months and 89 percent survival rate after 1 year. This confirms that age alone was not a good predictor of survival, and that comorbid burden and context are more important predictors of morbidity as previously shown (3), said Thorsteinsdottir. They also observed a frequent loss of independent living, with only 37 percent of patients able to return home after hospitalization. Continued on page 2

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## HOPE Act Signed into Law, Promoting Transplant Research and Access

#### By Rachel Meyer

n Tuesday, November 12, 2013, Congress passed legislation that one day could allow individuals with HIV to receive organ transplants from deceased donors with HIV, expanding the total pool of available organs and reducing wait times Nine days later, President Obama signed the act into law..

ASN made the HIV Organ Policy Equity (HOPE) Act a policy priority, and the society has aggressively pushed for passage of the bill since its introduction in February 2013.

"The HOPE Act could open up the door to hundreds more life-saving organ transplants and reduce the organ transplant waiting list for all 100,000 Americans who are on it," said co-lead House sponsor Rep. Lois Capps (D-CA). "I am incredibly proud to have authored this bill and applaud my colleagues in the House for coming together to pass this common sense, no-cost, bipartisan bill that has the potential to save lives, improve health outcomes, and save taxpayer dollars."

The HOPE Act lifts a 1980s-era ban on the acquisition or use of HIV positive organs, making it possible for researchers to study the safety and effectiveness of HIV positive transplants to people with HIV who are on the wait list. The act cre-*Continued on page 3* 

## 2013



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## Starting Dialysis after 75

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Vanita Jassal, MD, of the University Health Network in Toronto, ON, Canada, and who was not associated with the study, noted it was important to recognize the cohort of patients the authors followed are probably a mixture of two different types of patients: those who initiated dialysis having a chronic renal injury, and those who had no previous or minimal renal disease who had an acute event requiring intensive or other supportive care and an acute reason for starting dialysis.

"I think that the data are exceedingly valid and important, but I think that some of the data they're presenting represent this very acute, unwell population referred for care to a tertiary care center who we know fare quite poorly, particularly in the earlier period," Jassal said.

"The results are striking, and suggest that existing estimates of life expectancy for older adults initiating dialysis based on registry data are quite optimistic," said Ann O'Hare, MD, of the VA Puget Sound Health Care System in Seattle, WA. "This study shines a spotlight on the subgroup of older patients who initiate dialysis in the hospital and never make it into the USRDS registry, in most instances because they do not survive to discharge. While this study has important lessons for all of us, it is important to keep in mind that Mayo clinic is a tertiary referral center so it is not clear how generalizable these practices are to other centers," she said.

#### Informing the clinical approach

Thorsteinsdottir pointed to Sharon Kaufman who, in her book *And a Time to Die: How American Hospitals Shape the End of Life* (4) highlighted "how the technological imperative to treat contributes to overtreatment near the end of life and illustrates how patients and their loved ones are often reduced to largely passive actors in the aggressive quest for life extension. Several recent studies on the ESRD population demonstrate this well, documenting that patients perceive a lack of choice and many experience regret for having started dialysis."

By contributing to increased awareness about the context and likely outcomes for very elderly patients facing the need to start dialysis, we hope to challenge the moral and technological imperative to treat everyone irrespective of their health status or prognosis, Thorsteinsdottir said. Because of the high treatment burden and poor outcomes for certain subgroups of patients, dialysis should only be started after shared decision making guided by a wellinformed patient's goals and values.

"Our study also emphasizes the importance of not being too nihilistic as evidenced by the excellent survival of the outpatient starters," Thorsteinsdottir said. "Also several patients recovered renal function despite advanced age and serious illness."

"I think that the data are quite sobering," said Jassal. "These data should be used to help engage families in the shared decision-making process that the Renal Physicians Association clinical practice guidelines suggest we use (2)." An emphasis on shared decision-making before chronic dialysis initiation was one of ASN's *Five Things Physicians and Patients Should Question* contributed to the ABIM Foundation's *Choosing Wisely* initiative.

"Overall these findings demonstrate that many older adults initiate dialysis in the setting of an acute illness, and that in these situations, survival is extremely poor," said O'Hare. "Physicians should warn their patients with chronic kidney disease about the different circumstances in which they may be faced with decisions about dialysis initiation, including acute illness."

#### A call for more research

Although this work provided important data, each physician interviewed for this article emphasized the need for more research into elderly individuals and dialysis initiation.

Jassal pointed to more research for patient-centered care. "In older individuals it's important to ask about their goals of care, but it's also important to ask if there are other treatments we should be giving them to address the other barriers to them feeling well," he said. Both Jassal and Thorsteinsdottir also called for research to help identify those patients who could do well on dialysis.

"It is imperative that we get better at preventing acute kidney injury in the elderly," said Thorsteinsdottir. "Most importantly we need early identification and early goal-directed treatment of infections and the systemic inflammatory response to avoid sepsis. We also need to develop kidney protective measures in the perioperative period and avoid nephrotoxic drugs in this population."

O'Hare emphasized more needs to be done to help patients and families anticipate the course of their kidney disease, to educate them about what to expect in the future, and to ensure that they are aware of all of their treatment options. "In particular, we should provide patients with realistic expectations about different treatment options and about positive alternatives to dialysis, such as hospice and palliative care so that they do not feel that they have no choice but to initiate dialysis should the need arise," she said.

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### Hope Act

Continued from page 1

ates an avenue for one day expanding the donor pool so that patients—both HIV positive and HIV negative—may have greater access to life-saving transplants.

"For years, arcane federal rules have restricted what could be potentially lifesaving organ transplants for HIV positive individuals," said lead Senate Republican sponsor Sen. Tom Coburn, MD (R-OK). "I applaud ... taking action to lift these rules."

Modernizing the law to reflect advances in scientific understanding and in the care of people with HIV could generate groundbreaking research.

"This is a very exciting time in the care of HIV-infected patients who need organ transplants," said ASN member Dorry Segev, MD, PhD, whose research on the population of HIV positive patients who could be suitable organ donors inspired the HOPE Act legislation. "Allowing research on HIV positive-to-HIV positive transplants positions the United States to become the world leader in understanding this extremely important treatment paradigm. We have experience with HIV positive recipients, but only using HIV negative organs."

The HOPE Act paves the way for researchers to learn how the body reacts when exposed to a new HIV strain in the context of immunosuppression, and how to minimize any risk associated with that exposure, Segev said. "We now also have the potential of understanding which strain of HIV will become dominant in the context of infection with one strain and exposure to a new strain," he said. "This has implications beyond organ transplantation, such as for seropositive couples infected with different strains."

"Research . . . will allow us to learn

whether this form of transplantation will provide the same benefits to recipients as [do] organs from non-HIV donors," said ASN Transplant Advisory Group chair Michelle Josephson, MD. "It will also provide us with an opportunity to see whether anti-retroviral therapy can prevent super-infection with a different HIV strain. Enactment of the policy will ultimately give us the necessary data to determine whether we should continue forward with transplanting HIV positive kidneys into HIV positive recipients."

In advocating for the HOPE Act, ASN collaborated with other organizations in the HIV and transplantation fields-including the HIV Medicine Association, the American Society of Transplant Surgeons, and the American Society of Transplantation-underscoring the broad cross-community support for the bill. In total, ASN met with more than a third of the members of the U.S. House of Representatives who cosponsored the bill. The society commended Rep. Capps and her lead House Republican sponsor Rep. Andy Harris, MD, and Sen. Coburn and Senate Democratic lead sponsor Sen. Barbara Boxer (D-CA) for their visionary leadership on this legislation and for the bipartisan support they built.

There have been 200 or more transplants for HIV positive recipients each year in recent years, all of whom were matched with HIV negative organs," said United Network for Organ Sharing CEO Brian Shepard. "If the needs of future candidates with HIV can be met with more HIV positive donor organs, that will also create more opportunities for the rest of the patients who are waiting. UNOS is committed to working with transplant programs to protect the safety of their patients and prevent disease transmission, through a robust system of verifying key clinical information for organ donors and recipients."



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#### ASN Kidney News Editor-in-Chief Call for Applications

The American Society of Nephrology (ASN) seeks candidates for the position of Editor-in-Chief of *ASN Kidney News*. The monthly news-magazine examines research findings and policy changes, pinpoint-ing emerging trends in industry, medicine, and training that affect practitioners in kidney health and disease. *ASN Kidney News* provides a venue to highlight scientific and clinical advances with more commentary and speculation than is possible in scientific journals.

Candidates should be ASN members who possess wide knowledge of and broad experience in nephrology, a thorough understanding of technology and modern communications venues, as well as an understanding of the requirements of writing and editing skills, time commitment, and general effort required to produce a monthly newsmagazine. Candidates should possess strong leadership qualities, intellectual vision, organizational abilities and experience relevant to editing this leading newsmagazine. The term will start January 1, 2015, and continue for a 3-year renewable term.

The editor's primary responsibility is to continue to enhance the newsmagazine's reach, reputation and voice in the community. The editor should be prepared to build on current achievements, strengthen ASN Kidney News' competitive position, technological achievements, develop editorial initiatives that represent the full spectrum of issues important to kidney professionals and others in the kidney community, and take full advantage of the electronic publishing environment. The editor should also work with ASN staff to assure that ASN Kidney News activities are carried out in a fiscally responsible manner.

The editor must maintain ASN Kidney News editorial policies and procedures and establish new policies and procedures as appropriate to reflect relevant changes in medical publishing.

The editor recommends an editorial team to help promote excellence in content and advance editorial initiatives and reports to ASN through the ASN Communications Committee.

Detailed information on duties and the process for applying for the editor-in-chief position is available at http://www.asn-online.org/news/2013/1113\_KN\_Call\_for\_Applications.pdf

Letters of interest must be received by 01/15/14. Candidates selected for in-person interviews will be interviewed in early May of 2014.



#### Labor of Love

ASN Kidney News turns 5 years old in January. This magazine has grown and matured over those years, just like an infant becomes a toddler. Now it is time for the publication to get new guidance. 2014 will be my last year as editor, and the search has begun for the new leader.

At this time, *Kidney News* is published as a traditional hard copy magazine, an app for mobile devic-

es, and online forms available on the ASN web site. As time goes on, the focus will move more and more to electronic versions of the tabloid. The next editor needs not only strong writing and editing skills, but also familiarity with online media. Curiosity and a desire to learn about new things are imperative; as new tools and media become available, the magazine should be ready to explore these frontiers.

Creating and editing *Kidney News* has been challenging, but it has also been fun. I highly recommend this fun, rewarding job.

Pascale Lane, MD Editor-in-Chief, ASN Kidney News

## Meet ASN's New President: Sharon M. Moe



Sharon M. Moe, MD, FASN, FACP, FAHA, began her term as ASN President November 10, 2013. Dr. Moe is Director of the Division of Nephrology at Indiana University School of Medicine, as well as the Stuart A. Kleit Professor of Medicine and an Adjunct Professor of Anatomy & Cell Biology. She is also Section Chief of Nephrology at the Roudebush Veterans Administration Medical Center in Indianapolis.

Dr. Moe received her medical degree from the University of Illinois College of Medicine at Chicago and completed her residency in the Department of Internal Medicine at Loyola University Medical Center in Maywood, IL. She was a clinical fellow and a research fellow at the University of Chicago. At Indiana University Dr. Moe chaired the Department of Medicine Clinical Trials Program from 1997 to 2007 and was the Assistant and then Associate Dean for Research Support from 2001 to 2005. She then became the Vice Chair for Research in the Department of Medicine from February 2005 to June 2011. In 2011 she became the Director of the Division of Nephrology at Indiana University.

In addition to serving on ASN Council for the past 5 years, Dr. Moe served on the ASN Postgraduate Education, Program, and Nominating Committees as well as the Media Relations Task Force. She has served as co-director of the society's Annual Meeting Professional Development Symposium, as a speaker at the society's Board Review Course and Update, and as an abstract reviewer and session coordinator.

### Dr. Moe, what are your areas of research study?

I study the relationship of kidney disease, vascular calcification, bone, and disorders of mineral metabolism (CKD-MBD). Work in our lab has used in vivo, ex vivo, and in vitro techniques to investigate the pathophysiology of arterial medial calcification and the relationship between calcification and bone. We are now investigating this pathway using a naturally occurring rat model of CKD-MBD to understand how therapies for bone alter cardiovascular disease and how cardiovascular disease is altered by drugs we use to treat bone and mineral disorders. We are also interested in how the dietary source of phosphate alters bioavailability and how this alters CKD-MBD.

#### Why did you become a nephrologist?

Nephrology offers a little bit of everything. Patients with kidney disease offer complex challenges; each patient is a little bit different. I chose nephrology because taking care of otherwise healthy patients didn't seem to offer as much professional satisfaction or intellectual stimulation. Nephrologists take physiology to the bedside; not every specialty has that connection, and I was also interested in opportunities to pursue my research and administrative interests.

#### Fewer students are choosing nephrology. Can ASN make a difference?

While ASN is making a difference, workforce concerns remain a problem for nephrologists. We haven't done a good enough job "marketing" the joys of nephrology; we don't convey to students the range of careers available, the range of patients nephrologists take care of, and the real difference kidney professionals make to their patients' lives.

In medical school, students may most often see patients with kidney disease in the emergency room or late in their disease course. They don't get a full picture of the wide spectrum of practice, or of how energizing and motivating our work can be—as an example, I have a patient who came to me to start dialysis 15 years ago, and together we have managed his care so that he still hasn't had to start dialysis. And we fail to emphasize the miraculous nature of dialysis itself—while undergoing dialysis is tough, without dialysis, patients would die.

In 2011, ASN established the ASN Workforce Committee and this group is very active. This year ASN launched a very successful program to introduce medical students to renal physiology and connect them with nephrology mentors, as well as a program to involve patients in community screenings. The ASN Foundation for Kidney Research is helping young faculty achieve independent careers. However, we have to focus more on building diversity within the ranks of kidney professionals, supporting the entire care team, creating more flexibility for those who want to work part time or job share, and making sure that students understand how much nephrology offers to those who want to make a real difference in health care.

### You have selected health disparities as a focus of your presidential term. Why?

In the United States, nephrologists see a disproportionately high number of patients who are African American, Hispanic, and Native American. We don't understand enough about the reasons for this. ASN is uniquely positioned to give voice to all types of patients with kidney disease, and the society has committed a number of resources to advancing care for vulnerable populations, and to the basic and clinical research that will help us really understand the underlying causes of these disparities.

If funding for kidney disease research remains low, these disparities will continue. As ASN President I will work with our policy team to make sure U.S. lawmakers and other policymakers understand the full impact of kidney disease and just how much they can contribute to reducing health disparities. We also need to work with other research organizations and foundations to help us lessen the disparities.

#### You have spoken before about the need for more proactive approaches to chronic disease care. Would you elaborate on that?

Professionals who take care of patients with chronic disease experience the joy of providing real continuity of care and making huge positive differences in the lives of their patients. But a challenge for all chronic disease care involves balancing ongoing care of patients with active efforts to prevent disease. This is especially true in an area like nephrology, where kidney disease may go undiagnosed for quite a while.

We must really advance our ability to detect and prevent kidney disease. This requires raising awareness among the general population and other medical professionals, and funding innovative research that will help us detect kidney disease at earlier stages.

There has been so much emphasis on dialysis despite the fact that the therapy affects a small proportion of our patients. While truly life-saving, dialysis does not provide patients with an ideal quality of life. I am certain all nephrologists have seen patients who were told they had kidney disease 10 years ago, but never sought care because they were so afraid of dialysis and did not believe there was anything that could be done to prevent progression. And many of these patients have family members on dialysis. In my personal experience fear fuels denial, and denial limits access to care and compliance with care.

I believe the concept that over 20 million Americans have kidney disease needs to be heard loud and clear and needs to come from all kidney organizations and patients alike. The corollary is that if we don't slow progression we will have increased costs. These costs are to patient quality of life, disruption to families, and costs to the health care system. The Kidney Health Initiative is energizing the innovation needed to find therapies to slow progression, but our message to patients and Congress has to be equally energizing. Nephrologists need to send a common message of what we can do to slow progression, that preemptive transplant is ideal, and that early diagnosis is key. This positive thinking will empower patients to take care of themselves and stand up for more research to ensure that care is optimized.

## **Policy Update**

### The 2014 U.S. Budget: What You Need to Know

#### By Grant Olan

n October 16, 2013, the U.S. Congress passed a continuing resolution (CR) to fund the government, ending a 16-day government shutdown—the first in nearly two decades—that began October 1. The CR expires on January 15, 2014, when Congress must pass a budget for the remainder of fiscal year 2014 (or, alternatively, pass another short-term CR funding government beyond that date). In the absence of a budget or CR, the government would again shut down.

Congressional leaders on both sides of the aisle have stated that they do not want that to happen, and have agreed to call together a budget conference with representatives from the U.S. House of Representatives and Senate to make recommendations about long-term spending. The budget conference has until December 13 to make recommendations to Congress, leaving just enough time for Congress to act on a 2014 budget by the January 15 deadline.

At this point in time it is unclear whether the budget conference will meet the December 13 deadline. One issue of contention is the topline number for the 2014 budget. The Budget Control Act (BCA) of 2011 imposes a cap of \$967 billion in 2014 for federal discretionary spending (defense and non-defense). (Entitlement programs are not subject to budget caps, although Medicare will experience an annual 2 percent cut through 2021 unless Congress acts to stop the cuts.)

There is disagreement about whether to raise the cap for both defense and nondefense discretionary spending and how to pay for an increase in the budget. Both Republicans and Democrats agree that the cap is too low for defense discretionary spending, as it would result in a \$20 billion cut from 2013 funding levels for defense programs. Democrats, however, insist that if the cap is raised for defense discretionary spending, it should also be raised for nondefense discretionary spending, which funds medical research (including kidney research), transportation, public health, public safety, and other government programs and services.

What we do know is that the budget for the National Institutes of Health (NIH), including the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), was cut \$1.7 billion (more than 5 percent) in 2013. As a consequence, NIH awarded 1300 fewer grants (700 fewer competing grants) and 460 fewer training grants.

"When adjusted for inflation, NIH's budget is less today than it was in 2003, and the percentage of grants NIH funds is at an all-time record low," said ASN President Sharon M. Moe, MD, FASN. "Besides impeding progress in patient care, the effect is hurting researchers who have had to scale back operations, cut jobs, and in some cases close laboratories and the businesses that support them."

"Cuts to medical research are coun-

terproductive and jeopardize our position as the global leader in research," ASN Research Advocacy Committee Chair John R. Sedor, MD, FASN, added. "You can help preserve America's preeminence in medical research and ensure the continued availability of the highest quality care for patients. Please join ASN's fall grassroots advocacy



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campaign and meet with your local congressional offices between now and January 15 to urge your U.S. representative and senators to protect NIH kidney research and patients' chance of a cure."

ASN provides an online resource page that includes all the information needed for scheduling and conducting successful six-minute meetings, including easy step-by-step instructions, a congressional phone directory, talking points, factsheets, a thank-you email to send after meetings, and a link to provide ASN feedback from visits. The webpage is available at http://www. asn-online.org/policy/grassroots2013. aspx.

### **Prct NIH Kidney Research and Patients' Chance of a Cure**

ASN needs your help. Funding cuts to the National Institutes of Health (NIH) are jeopardizing kidney research. Please join ASN's fall grassroots advocacy campaign and meet with your local congressional offices between now and January 15 to urge your U.S. representative and senators to protect patients' chance of a cure. ASN provides easy step-by-step instructions and all the tools you need for scheduling and conducting success-ful six-minute meetings at http://www.asn-online.org/policy/grassroots2013.aspx.



### Final ESRD Payment and Quality Rule Released

On Friday, November 22, 2013, the Centers for Medicare and Medicaid Services (CMS) released a rule finalizing changes to the Medicare End-Stage Renal Disease (ESRD) Program, including a 12% cut to dialysis payments, which will be phased in over 3 to 4 years. There will be no changes to current reimbursement levels in 2014 and 2015.

Congress mandated CMS to reduce dialysis payments due to decreases in drug utilization, and the agency first proposed the 12% cut in July 2013. ASN and other kidney community stakeholders raised concerns about potential deleterious effects on access to and quality of care for the most vulnerable patientsincluding those in rural and inner-city environments-that a cut of that magnitude could create. ASN advocated that CMS phase in any cut to dialysis payment over 4 years, allowing providers to ensure continued access to care and for CMS to monitor any adverse consequences.

CMS also increased payments for home dialysis training by 50%, advancing a longstanding ASN policy goal, and implemented many of ASN's recommendations for the ESRD Quality Incentive Program. Visit http://www. asn-online.org/policy or follow @AS-NAdvocacy for more information on the ESRD final rule.





#### Study description: An analysis of the outcomes in 40 patients from the database of the International Registry of Recurrent and Famil HUS/TTP with the complement factor H (CFH) mutation. The cumulative fraction of patients free of events (defined as the combination of the occurrence of chronic renal insufficiency or initiation of dialysis or death, whichever occurred first after the onset of HUS) we estimated by Kaplan-Meier analysis.<sup>6</sup>

- 33% to 40% of patients die or progress to end-stage renal disease with the first clinical manifestation<sup>2,6</sup>
- Plasma exchange/infusion (PE/PI) does not address chronic, uncontrolled complement activation, the underlying cause of TMA in aHUS<sup>2,5,7-13</sup>



## AKF Partners with ASN to Present Kidney Action Day Ahead of ASN Kidney Week 2013

Nearly 250 People Take Advantage of Free Kidney Disease Screening

By Kurtis Pivert

row the first time, ASN partnered with the American Kidney Fund (AKF) to kick off Kidney Week with a free kidney health screening and public awareness event. Kidney Action Day was held at downtown Atlanta's Underground and featured fitness, nutrition, and health education in addition to screenings and advice from volunteer health professionals from local institutions including Emory University School of Medicine.

#### Figure 1

A participant undergoes health screening at Kidney Action Day 2013 in Atlanta. Photo Credit: American Kidney Fund.



Quickly expanding since its 2010 launch in Chicago, Kidney Action Day has helped raise the profile of kidney disease while giving participants important knowledge to improve and preserve their kidney health.

"Kidney Action Day is our signature outreach event," said LaVarne Burton, AKF's president and CEO. "By arming people at risk for kidney disease with the tools they need to fight this devastating disease, AKF expanded our mission in a way that fights kidney disease on both fronts—helping people who have reached kidney failure and helping those who may be in a position to prevent kidney failure. Since an estimated 9 out of 10 people with early kidney disease don't even know they have it, screening and health education are a critical component of our efforts.

ASN Past-President Bruce A. Molitoris, MD, FASN, highlighted the event in his Kidney Week presidential address while emphasizing the importance of screening for kidney disease. "If detected early in its progression, kidney disease can be slowed," said Molitoris, "which is why regular screening and early intervention by a nephrologist is so important to stemming the epidemic of kidney disease in the United States."

During the 4-hour event, 248 people underwent screening for kidney disease risk factors and received valuable health advice on preventing and managing kidney disease, the 8th leading cause of death in the United States. After having their glucose and blood pressure levels checked, participants were offered the chance to speak with a health professional to discuss the results and offer advice for next steps (Fig. 1).

Among those volunteering to screen and counsel participants were pre-med, medical, and nursing students from schools across Atlanta. In light of declining interest in pursuing nephrology careers, the opportunity to interact with people and help improve their health could give students a different perspective of the specialty.

"A lot of times medical students only think of nephrology as acid-base and equations, but there is a lot more to nephrology and we hope with Kidney Action Day and Kidney MAPS we can show them community outreach and also teach them about clinical nephrology at the same time," said Jason Cobb, MD, of the Emory University School of Medicine. A new ASN initiative, Kidney MAPS (Kidney Mentoring and Assessment Program for Students) is modeled after the Kidney Disease Awareness and Screening Program (KDSAP) created by Li-Li Hsiao, MD, PhD, at Harvard. Kidney MAPS is a student-led outreach program that identifies people at risk for chronic kidney disease (CKD) in medically underserved communities.

#### Filling an unmet need

Kidney Action Day fills an unmet need for those individuals who may be at increased risk for CKD but who may also have limited or no access to health care. "Kidney Action Day is an opportunity for people in at-risk communities to learn about their risk and walk away with information about how to live a healthier lifestyle," said AKF's Burton. "We hold Kidney Action Days in cities where rates of kidney disease are above the national average. Often, there is a direct relationship between the high rates of kidney disease and the percentage of uninsured in the population, along with many other factors such as the presence of food deserts."

At Kidney Action Day in Atlanta, Cobb noted a number of participants were screened and identified with having abnormal GFR, abnormal blood pressure, and glucose readings. "Those participants were identified and educated to follow up with clinicians at local safety-net clinics and hospitals. Some of them were not even aware of the options for them without insurance," Cobb said.

"Beyond providing a valuable health service, Kidney Action Day allows ASN to give back to the Atlanta community, which plays an important role in Kidney Week's success," Molitoris said.

The event was hosted by Rep. John Lewis (D-GA), a member of the Congressional Kidney Caucus. "All of this is made possible with support from our sponsors. In 2013, Kidney Action Day was nationally sponsored by American Renal Associates," Burton added.

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## Molecular Insights into How a Western Diet May Promote Hypertension

By Kurtis Pivert

ew research on the sodium-chloride cotransporter (NCC) and its mechanisms provides a clearer understanding of how a typical Western diet—high in sodium and low in potassium could promote hypertension. In a study presented at Kidney Week 2013, Andrew Terker, an MD/PhD student at the Oregon Health & Science University, and coworkers found this diet profile may play a role in the development of hypertension in an NCC-dependent manner. Although the results need to be confirmed in human studies, this insight could further inform research about dietary sodium's role in hypertension, an area of continuing controversy.

"The mechanics of NCC are understood, but modifications of activity are still in progress, such as was shown in this nice study," said Matthew Weir, MD, of the University of Maryland School of Medicine, who was not affiliated with the study.

Terker and colleagues used three different animal models to determine NCC's effects on the mechanics of blood pressure homeostasis in the kidney. The first modeled primary aldosteronism and researchers observed an increase in total and phosphorylated NCC. Potassium wasting was observed in NCC knockout mice, but not in wild-type controls. A pseudohypoaldosteronism type I simulation found that in addition to the expected hyperkalemia, total and phosphorylated NCC levels dropped dramatically.

In the final series of experiments, high-salt diets were administered, in combination with either a normal amount of potassium or no potassium added, to both wild-type and NCC knockout mice. Terker found the Western diet (high in sodium and low in potassium) caused a large increase in total and phosphorylated NCC, as well as increases in the enzyme WNK4 (an important molecular switch expressed in the distal nephron) and SPAK. Most important, the diet decreased urinary sodium in wild-type mice but not in NCC knockout mice.

The results are biologically plausible and concordant with previous clinical work showing that higher sodium and lower potassium in the diet results in higher blood pressure, said Weir. "Clinically, higher potassium in the diet helps lower blood pressure on a high sodium diet," he added.

"Our work indicates that NCC primarily functions to regulate potassium, perhaps at the cost of blood pressure increases," said Terker. "For patients, this means that increasing dietary potassium may prevent sodium retention by inhibiting NCC, even on a high salt diet."

Terker said the next steps in their research are to



determine the molecular mechanism mediating the effect of potassium on NCC function and to test if this effect is observed in humans.

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## Atenolol Demonstrates Superior Safety Profile in Comparative Effectiveness Trial

#### By Kurtis Pivert

Results of a late-breaking clinical trial presented at Kidney Week 2013 show that atenololbased antihypertensive therapy may be superior to lisinopril-based therapy in preventing cardiovascular morbidity and all-cause hospitalizations among maintenance dialysis patients. The trial was terminated early in September by the data safety monitoring committee when it became clear that lisinopril was associated with an increased risk for cardiovascular events.

"The results suggest that atenolol-based antihypertensive therapy among hypertensive hemodialysis patients with left ventricular hypertrophy may reduce cardiovascular events," said lead author Rajiv Agarwal, MD, MBBS, FASN, of the Indiana University School of Medicine and the VA Medical Center in Indianapolis.

The HDPAL (Hypertension in Hemodialysis Patients Treated with Atenolol or Lisinopril) trial was designed to evaluate the comparative efficacy and safety of antihypertensive therapy using either an angiotensin-converting enzyme (ACE) inhibitor or a beta blocker. Agarwal conducted a randomized, open-label, parallel-group, single-center trial of 200 maintenance hemodialysis patients who were diagnosed with echocardiographic left-ventricular hypertrophy and hypertension. One hundred patients each were randomized to receive either lisinopril or atenolol 3 times weekly after dialysis, with a primary outcome of change in left ventricular mass index.

Both antihypertensives were effective in controlling blood pressure and left ventricular mass index with no statistically significant difference observed. However, there were significantly more serious cardiovascular events in the lisinopril group (40 events in 26 subjects) than the atenolol group (18 events in 14 subjects). Patients receiving lisinopril also had significantly higher rates of combined serious adverse events (myocardial infarction, stroke, hospitalization for heart failure or cardiovascular death), hospitalizations for heart failure, and all-cause hospitalizations

"Most physicians who take care of dialysis patients and have used atenolol are aware that it can lower blood pressure effectively and more so than ACE inhibitors, so the results are not entirely surprising. But we were certainly surprised by the magnitude of the difference," said Agarwal.

"Nothing really surprises me about dialysis patients anymore," said Frank Brosius, MD, of the University of Michigan Health System, and who was not associated with the study. "They have so many different responses than the general population that we really cannot extrapolate from studies of other populations, even from studies of chronic kidney disease patients. That's why these sorts of clinical trials are so important to help make sure we give our maintenance dialysis patients optimal care." Although these results need to be confirmed in other larger multicenter studies, they strongly suggest that interdialytic hypertension might be best managed with a beta blocker instead of ACE inhibitors," Brosius said. "This is a bit surprising given the cardiovascular protective effects of ACE inhibitors in other populations, but again cardiovascular disease in dialysis patients is clearly different."

Brosius pointed out that administering the antihypertensive just after dialysis is probably a different management practice than that used in most dialysis units. "There was not a comparison of the same/similar treatments given daily at home which is probably more common practice. Nonetheless the postdialysis treatment has multiple advantages," he said.

"A small study such as ours comparing two inexpensive and commonly used drugs in a randomized trial design suggests that we should stop extrapolating from studies from CKD or in the general population and start performing randomized trials," Agarwal said. "Observational studies can only go so far, but for real answers we need randomized trials."

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## New Saliva Test for AKI Could Impact Kidney Health in the Developing World

By Kurtis Pivert

dipstick that uses the saliva of an individual with suspected acute kidney injury (AKI) can quickly and accurately detect and diagnose AKI, without the need for laboratory facilities. The novel test strip, described in research presented at ASN Kidney Week (1), could help preserve the kidney health of millions of individuals in developing countries and help first responders in natural disaster zones make a fast diagnosis to help save kidney function and lives.

The test uses a pH marker to indicate the amount of urea in the saliva. To verify the dipstick's accuracy, Vivian Calice da Silva, MD, of Brazil's Pró-Rim Foundation and her colleagues conducted a study in 44 patients with suspected AKI. They first had to demonstrate the test could discriminate low levels from high levels of saliva urea nitrogen and that these levels correlated closely with the blood urea nitrogen normally used to diagnose AKI. They used saliva and blood urea nitrogen levels to classify AKI stages utilizing the Acute Kidney Injury Network (AKIN) criteria.

"We found a good correlation between blood and saliva urea nitrogen," said Calice da Silva. The laboratory analysis of the blood samples and the results from saliva samples were positively correlated at all AKIN stages and for all causes of AKI. Importantly, the test significantly discriminated the more severe AKIN Stage 3 from earlier stages of renal injury.

The impact of this new diagnostic method to quickly assess kidney health could be felt greatest in the developing world, said Jorge Cerda, MD, FASN, of the Albany Medical College in Albany, NY. "This study shows how a simple test can have enormous projections," he said. "In many places in the developing world people do not have access to lab facilities, and those health professionals that are available may not be able to diagnose the problem. But if this test could quickly identify the presence of renal dysfunction without complicated tests, this could be a valuable component of an initial screening model."

In developing countries AKI is thought to be less of a problem than in developed countries, but that's not true, said Cerda (2). "Probably the incidence is the same, only it's profoundly underrecognized," he said. "From a population standpoint, what is unknown doesn't get treated and doesn't become a policy priority. If you can determine the true incidence of AKI, you can appropriately allocate the limited public health funds available."

Many developing nations cannot afford an end stage renal disease (ESRD) program, but small interventions—like this test or offering clean water—offer a large bang for the buck and can help avoid the ESRD complications, Cerda said. "We can make a tremendous difference."

"The saliva urea nitrogen dipstick could help in primary care in areas with limited medical infrastructure, or in emergent settings where quick decisions are crucial for the patient's benefit," said Calice da Silva, "particularly since the incidence of volume-responsive AKI caused by diarrheal diseases, malaria, or gynecological/obstetric complications is substantially higher than in developed countries. It could be a useful tool to diagnose AKI early, allow immediate therapeutic approaches such as fluid resuscitation and/or hemodialysis, resulting in improved outcomes."

The test could also be used in natural disaster zones when a quick diagnosis and urgent treatment are necessary to protect kidney health. "It could be specifically useful for triage of patients in large-scale disaster emergency settings, but also for primary caregivers first-responding to acute morbid events, Calice da Silva said. "In such settings it could make a difference resulting in improved outcomes and facilitate decisions such as dialysis initiation or transportation to (often far distant) medical facilities."

The strip has yet to be approved by the FDA;

its manufacturer (IBT Biomed) anticipates the cost per strip when available to be approximately \$1.

#### New paths for a correlation

The close correlation of saliva to blood urea was not unexpected. "In the early days of dialysis, it was well-known that patient's breath smelled like urine because the bacteria in the mouth had broken down the urea into ammonia," said Cerda. "The novelty of this study is that they correlated the lower levels of urea with the blood urea nitrogen, making it a useful marker in the early stage of renal dysfunction."

This correlation could be used to advance other areas of research, Calice da Silva added. "If the link between saliva and blood urea nitrogen is confirmed in future work, it could benefit research into the epidemiology of chronic kidney disease and AKI in developing countries (due to the noninvasive nature of the test), post-transplantation settings, patients at risk for kidney failure (for example those with congestive heart failure treated with antihypertensives, or patients with diabetes), or when radio contrast media is used in outpatient settings to prevent contrast nephropathy," she said.

Calice da Silva noted the next step in their research is to repeat this research with a follow-up of 7 days to see if the strip is able to show change over time, according to the treatment applied.

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### **Mediterranean Diet May Help Preserve Kidney Function**

#### By Kurtis Pivert

Mediterranean diet may be beneficial for not only heart health, but kidney health as well. This is the conclusion of a new long-term study presented at Kidney Week 2013 that found individuals following a regimen similar to a Mediterranean diet reduced their risk for developing chronic kidney disease (CKD) and for rapid decline in kidney function. Although the diet's heart health benefits have received public attention, it has been unknown if this diet confers any nephroprotective effects. Because of the close connection between cardiovascular and kidney disease, Minesh Khatri, MD, and his coworkers from Columbia University theorized a Mediterranean diet may have a positive effect on preserving renal function.

They examined the multiethnic Northern Manhattan Study cohort, a prospective, long-term, multiethnic cohort of 3298 residents of Upper Manhattan. Each participant underwent a baseline screening and was followed up annually by phone. Khatri isolated a subset of 900 individuals who underwent subsequent laboratory testing approximately 7 years later. Adherence to a diet similar to a Mediterranean diet (higher in vegetables, fruit, unrefined whole grains, and lower in meat and dairy products than a traditional Western diet) was scored using the 9-point MeDi system.

In contrast to the DASH (Dietary Approaches to Stop Hypertension) diet—which limits sodium intake to less than 2300 mg (or in some case 1500 mg) per day—the Mediterranean diet has more of an emphasis on the so-called "heart-healthy" monounsaturated fats (such as those found in olive oil and nuts) as well as a moderate intake of wine, said Khatri.

Their analysis looked at two outcomes: a primary outcome of incident stage III CKD, and a secondary outcome of rapid kidney function decline. The observational, longitudinal study of 900 mostly older participants in New York demonstrated that participants who were consuming a Mediterranean diet at a level above the median for this cohort had a 50 percent reduced risk for incident CKD, and a 42 percent reduced risk of rapid kidney function decline (greater than 2.5 mL/min/1.73 m<sup>2</sup>/year) over the course of the 7-year follow-up period.

"There were no interactions between the Mediterranean diet and age, race-ethnicity, BMI, or hypertension," Khatri said. "However, increased vegetable intake may have been driving the benefit as that individually was one component of the Mediterranean diet that was significantly associated with reduced risk of incident CKD."

The study results appear to be consistent with a number of recently published studies on diet and kidney disease, said Lauren Graf, MS, RD, a renal dietician at Montefiore Medical Center who was not affiliated with the study.

"A Mediterranean diet is higher in vegetables, fruit, and unrefined whole grains, and lower in meat and dairy products compared to a traditional Western diet," Graf said. "The benefits of a Mediterranean diet over a standard American diet are multifactorial. The lower animal protein content of the Mediterranean diet puts less stress on the kidneys and reduces the acid load on the body. The diet is also higher in fiber and antioxidants, which has been shown to reduce inflammation and mortality. One study found these benefits to be even more profound in patients with CKD than in those without."

Since observational studies like this have limited ability to detect causality, the next research step would be to have a controlled clinical trial where subjects are randomized to receiving a Mediterranean diet versus a controlled diet," Khatri said. "In the future, observational studies should focus on the effect of a Mediterranean diet in subjects with advanced CKD. Our study was in a cohort of people with relatively well-preserved kidney function. Larger, longitudinal studies in other populations would also add useful information. Ultimately, however, randomized control trials are needed to definitively prove whether a Mediterranean diet significantly impacts kidney function."

Asked whether physicians should recommend the diet for their patients, Khatri said clinicians and patients should understand that this is an observational study.

"We cannot draw firm conclusions that the Mediterranean diet is beneficial for either kidney disease prevention or progression," he said. "Further research is needed before we can universally recommend this approach for kidney disease patients. However, there is substantial data that the Mediterranean diet may be beneficial for prevention of heart disease (2). Given the close relationship between salt intake and hypertension, I would probably modify the Mediterranean diet to limit sodium intake to less than 2.3 g per day, which is part of the DASH diet. I think among people with preexisting advanced kidney disease, factors such

as serum potassium and phosphate levels would need to be considered, and the diet should be individualized with input from a nutritionist."

Graf also cautions people do not always understand what the Mediterranean diet is and what aspects of the diet are beneficial. "One misconception is that people often think the health benefits of a Mediterranean diet are mainly from olive oil," she said. "The real benefits of the diet come from higher intake of vegetables, fruit, nuts, beans, and other high fiber foods and also from minimal intake of red meat and processed foods."

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## Mindfulness Meditation Can Reduce Hypertension in Patients with Kidney Disease

By Kurtis Pivert

editation could be a valuable, low-cost, nonpharmacologic intervention for reducing blood pressure and adrenaline levels in patients with chronic kidney disease (CKD) according to research presented at Kidney Week 2013. Because CKD patients have a higher risk for cardiovascular disease, in part due to increased sympathetic nervous system activity, Jeanie Park, MD, of Emory University School of Medicine and her colleagues (1) investigated the technique to determine if it could help control hypertension and reduce this risk. Although examined in other therapeutic settings (2, 3), mindfulness meditation, "a stress-reduction technique involving focused awareness on internal and external sensory stimuli in the present moment without judgment or cognitive elaboration," has never been studied in this population.

Park conducted a randomized crossover study of 15 male VA patients with stage III CKD and hypertension. Each underwent either mindfulness meditation or education on managing hypertension (control) while undergoing continuous microneurography (for sympathetic nerve activity), electrocardiography, and blood pressure monitoring. A subset of six patients underwent an additional study comparing deep breathing alone to mindfulness meditation and control.

A significant decrease in systolic and mean arterial pressure and sympathetic nerve activity was observed in patients undergoing mindfulness meditation compared to control. Dramatically lower levels of nerve activity were also shown in the subset of patients when meditating compared to controlled breathing alone.

"Because mindfulness meditation acutely lowered muscle sympathetic nerve activity and blood pressure in hypertensive patients with CKD, it may have beneficial effects on blood pressure and autonomic function in patients with kidney disease," said Park. She added that although their findings demonstrated that blood pressure and sympathetic activity were significantly improved acutely during one session of mindfulness meditation, there are no studies investigating the long-term effects or sustained effects on hemodynamics and autonomic function.

"Although mindfulness meditation has previously been shown to lower blood pressure among patients with hypertension, I was surprised by the difference in impact on sympathetic nerve activity between mindfulness meditation and deep breathing alone, which has also been shown to decrease blood pressure and reduce stress," said Delphine Tuot, MD, of the University of California, San Francisco, who was not affiliated with the study.

Tuot highlighted that hypertension in patients with CKD is multifactorial, with hypervolemia, activation of the renin angiotensin system, and overactivity of the sympathetic nervous system all playing a role. "It is thought that impaired kidney function may lead to chemical changes in the blood, which in turn communicate to the central nervous system to increase sympathetic outflow. If sustained, this can lead to higher arterial blood pressures, faster heart rates, irregular heart rhythms, and structural changes in the heart muscle," said Tuot. All are independent risk factors for cardiovascular disease, but in patients with kidney disease they can act synergistically to increase cardiovascular risk even more, she added.

Park noted that there are not enough data to definitively conclude that mindfulness meditation lowers blood pressure and sympathetic activity in patients with CKD. "However, this intervention is safe, and without side effects, and may have beneficial physiologic and psychologic effects; thus, it may be a reasonable complementary therapy to offer to interested patients." "Future research will determine if mindfulness meditation has long-term beneficial effects on blood pressure, adrenaline levels, and mortality in patients with kidney disease," said Park. She and her coworkers were currently investigating the potential benefits of an intradialytic mindfulness-based stress reduction program on physiologic and psychologic end points in patients with end stage renal disease.

"This low-cost, low harm intervention is clearly a promising adjunct for our patients. However, it's important to know how to teach and lead patients through such an exercise and how to select patients who are good candidates for mindfulness meditation," said Tuot. "In light of the short-lived impact of mindfulness meditation on blood pressure and sympathetic activity, I would be surprised if mindfulness meditation can reduce the number of antihypertensive medications that nephrologists must prescribe patients. However, with these results and prior studies demonstrating that mindfulness meditation can lead to sustained stress reduction, it's exciting to see that mindfulness meditation might be another weapon in our arsenal to combat high blood pressure in patients with CKD."

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## - NHLBI Work Spans Heart, Kidney Care

Gary H. Gibbons, MD, is director of the National Heart, Lung, and Blood Institute (NHLBI), the third largest institute at the NIH, with an annual budget of more than \$3 billion. Before joining the NHLBI, Gibbons served as founding director of the Cardiovascular Research Institute, chairperson of the Department of Physiology, and professor of physiology and medicine at the Morehouse School of Medicine in Atlanta.



#### KN:

You have led NHLBI for a year. Tell us about the institute and your vision for the future direction of NHLBI.

#### **Gibbons:**

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, blood, and sleep diseases and disorders and enhance the health of all individuals so that they can live longer and more fulfilling lives.

My vision for the NHLBI is guided by several key enduring principles:

- Value and support investigator-initiated fundamental discovery science.
- Maintain a balanced, cross-disciplinary portfolio (basic, translational, clinical, population science).
- Support implementation science that empowers patients and enables partners to improve the health of the nation.
- Train and nurture a diverse biomedical workforce.
- Value the health of all communities; elucidate and eliminate health inequities in the U.S. and around the globe.

#### KN:

How do you balance basic, clinical, and translational research opportunities? Do you see the mission of NHLBI changing with the expanded focus by NIH recently on translational research?

#### Gibbons:

The NHLBI has a proud legacy of funding a balanced portfolio that includes the full spectrum of basic, clinical, translational, and population science. We are pursuing a leadership agenda that rethinks prior approaches and incorporates the lessons from a "holistic," systems approach in order to address the complexities of diseases such as sickle cell disease, hypertension, heart failure, and asthma.

Science is an iterative, interactive process. In my Director's Corner "Behind the Bench" conversations with NHLBI grantees, these renowned experts offer provocative viewpoints on how these four arenas are increasingly seen as interdependent parts of their research. Many of them talk about the benefits of being a clinician-scientist and how the patients, i.e., clinical science, often guide the research questions that they ask and seek to answer. These conversations are instructive and reinforce our "balanced portfolio" philosophy here at NHLBI.

We are always seeking new opportunities to innovate and have an even greater impact on human health, which often means further engagement in the translational research space. One recent example is the launch of the NIH Centers for Accelerated Innovations (NCAIs). The NHLBI currently is the only NIH IC (institute or center) funding these centers, which are a great example of the intersection between basic and translational science. Our hope is that through the NCAIs, we can better leverage our existing R&D investments and ensure that the basic research we're supporting through Small Business grants results in breakthroughs that can become commercially viable products to improve patient care and advance public health.

#### KN:

High blood pressure and cardiovascular disease place patients at increased risk for conditions such as kidney disease. The reverse is also true. What is NHLBI doing to address this issue?

#### **Gibbons:**

Research into causes of hypertension and ways to control blood pressure are top priority areas for the NHLBI.

We fund a number of clinical trials related to the link between high blood pressure and cardiovascular disease and kidney disease. One example of a trial we're currently funding along with NIDDK is the Systolic Blood Pressure Intervention Trial (SPRINT), a randomized controlled trial that is testing whether a systolic blood pressure (SBP) level of less than 120 mm Hg (intensive arm) is better than a SBP level of less than 140 mm Hg (standard arm). The trial is looking at whether the lower SBP will further reduce the risk of cardiovascular disease (CVD), kidney disease, stroke, or dementia.

Another great example is the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), which was the largest antihypertensive treatment trial ever conducted. The main study and subsequent studies using ALLHAT data have looked at a number of issues including blood pressure, diabetes, heart failure, chronic kidney disease, atrial fibrillation, and metabolic syndrome. The NHLBI is supporting the continuing analysis of the ALLHAT data by the scientific community. There are also highly productive Renal Working Groups within a number of our studies-including ALLHAT, the Cardiovascular Health Study (CHS), Multi-Ethnic Study of Atherosclerosis (MESA), Atherosclerosis Risk in Communities Study (ARIC), and the Jackson Heart Study-that are looking at the relationships among cardiovascular disease, hypertension, and chronic kidney disease.

Our work to address issues related to CVD and high blood pressure reaches beyond research and into health education campaigns that seek to help individuals live healthier lifestyles. Examples include We Can! (Ways to Enhance Children's Activity & Nutrition), The Heart Truth (focused on raising awareness of heart disease in women), and the DASH eating plan (Dietary Approaches to Stop Hypertension).

#### KN:

How does NHLBI collaborate with other NIH institutes and federal agencies on kidney-related studies?

#### **Gibbons:**

The NHLBI co-funds a number of studies with other NIH institutes and federal agencies that have kidney disease as a component of the study, such as the SPRINT trial mentioned earlier. We're always looking for new opportunities to co-fund important studies. Increasingly, investigators are realizing that you can't isolate biological systems and that medical research requires a true multidisciplinary, systems biology approach. We are increasingly seeing this research cross traditional boundaries.

Another example is a study published in the September New England Journal of Medicine from the Chronic Kidney Disease Prognosis Consortium (CKD-PC). The study looked at cystatin C and its ability to characterize risk related to renal dysfunction, cardiovascular disease, and end stage renal failure. Five NHLBI-supported studies, including RE-GARDS, ARIC, CHS, the Framingham Heart Study, and MESA, provided patient data for that report.

#### KN:

Have the 2013 budget cuts affected NHLBI, and what happens if Congress does not stop the additional cuts planned for 2014-2021?

#### **Gibbons:**

The sequester is having an impact on investments in biomedical research across all NIH institutes and centers, including the National Heart, Lung, and Blood Institute. The NHLBI is engaging scientific experts to take a strategic look at its portfolio, from basic science to clinical trials to observational epidemiology, as part of its efforts to maximize scientific output within the current budget climate.

That said, the NHLBI prioritizes investments in investigator-initiated R01 awards, new/early stage investigators, and trainees. In May 2012, I was pleased to announce an increase in the R01 awards payline for fiscal year 2013 from the 6th percentile to the 11th percentile. In September, I also announced an increase in the paylines for the pre- and postdoctoral National Research Service Award (NRSA) grants and fellowships (F31, F32, and F33) from the 30th percentile to the 38th percentile and the NHLBI's decision to participate in NIH's R56 mechanism, known as the "High-Priority, Short-Term Project Award."

If additional cuts happen, the NHLBI will continue to prioritize the investments I've mentioned above. The fiscal challenges may force us to be more imaginative; however, it doesn't change the fact that there are unprecedented scientific opportunities out there today thanks to the incredible advances in the tools and technologies available to researchers.

#### KN:

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

#### **Gibbons:**

One of the most important investments the NHLBI can make is to support and encourage the next generation. We are committed to ensuring that we help sustain a vibrant, innovative, and diverse biomedical workforce despite the current fiscal challenges. That's one of the reasons that we've prioritized training grants, K-awards, and investigator-initiated grants, despite budget reductions. This is an issue about which I'm extremely passionate. I look forward to ideas coming from the people at the front lines—such as your members-about how we can do an even better job at nurturing career development.

Our work to address issues related to CVD and high blood pressure reaches beyond research and into health education campaigns that seek to help individuals live healthier lifestyles.

#### KN:

Studies have shown that, compared to Caucasians, African Americans are at higher risk of developing hypertension, cardiovascular disease, and kidney disease. What is the institute doing to address health disparities?

#### **Gibbons:**

The NHLBI is funding hundreds of studies that look at health disparities, including studies such as ARIC, ALLHAT, the Jackson Heart Study, MESA, SPRINT, the Coronary Artery Risk Development in Young Adults (CARDIA) Study, and the Hispanic Community Health Study/Study of Latinos (HCHS-SOL).

We also hope to fund several grants that were submitted in response to the "Cardiovascular Risk Reduction in Underserved Rural Communities" RFA.

Beyond the CVD space, we've recently funded studies that look at health disparity issues such as genetic variants associated with asthma severity in African Americans, obstructive sleep apnea and comorbidities in the Hispanic community, and the underdiagnosis of chronic obstructive pulmonary disease in the African American community.

In addition, through the NHLBI's Excellence in Hemoglobinopathies Research Award program, a study recently began that is looking at why adults with sickle cell disease (which has a higher prevalence in the African American and Latino communities) are at an increased risk for renal disease and more rapid progression to dialysis. In addition to renal disease, as people with sickle cell disease live longer, they are now facing heart disease, lung disease, and stroke.

The institute continues to view sickle cell disease as a high priority and is well poised to match this complex condition with a comprehensive, integrative systems approach that extends beyond the research lab to the primary care and community environments of persons living with the disease.

On a more global level, we co-fund the NIH's Centers for Population Health and Health Disparities, which promote transdisciplinary research in the area of health inequities to improve health outcomes and quality of life for populations with a disproportionate burden of chronic disease.

#### KN:

What do you consider the greatest research opportunities for NHLBI over the next decade?

#### Gibbons:

I mentioned earlier the unprecedented scientific opportunities that currently exist thanks to advances in science that simply were not there just a decade ago. The explosion of -omics and imaging technology and the advances in stem cell technologies, bioinformatics, and big data all present huge opportunities for today's young investigators who are best poised to leverage these technologies. It is genuinely an exciting time to be in this field, even with the fiscal challenges.

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Inside

### **Journal View**

## Are Lower Blood Pressure Targets Beneficial in Chronic Kidney Disease?

Intensive blood pressure reduction slows the progression of chronic kidney disease (CKD), but only in patients with proteinuria, suggests a meta-analysis in the *Canadian Medical Association Journal*.

A systematic review identified 11 randomized trials in which CKD patients were assigned to different blood pressure reduction targets. A meta-analysis included data on more than 9000 patients; blood pressure targets in the intervention groups varied widely. Outcomes of interest were a composite of doubling of serum creatinine level and a 50 percent decline in GFR, and the progression of ESRD.

Intensive blood pressure reduction was associated with a lower rate of both renal outcomes: hazard ratio 0.82 for the composite outcome and 0.79 for ESRD. However, there was a significant modifying effect of proteinuria. The reduction in kidney failure was significant only in patients with proteinuria at baseline: hazard ratio 0.73.

The effect on renal outcomes also appeared stronger in studies with lower markers of trial quality. The rates of cardiovascular events, all-cause mortality, and severe adverse events were similar between the intervention and usual care groups.

The current CKD guidelines recommend a blood pressure target of less than 130/80 mm Hg, but the strength of evidence behind this recommendation has been questioned. The new metaanalysis finds a reduced risk of kidney failure events with intensive blood pressure lowering, but mainly in patients with baseline proteinuria. Further study would be needed to show a similar protective effect in CKD patients without proteinuria [Lv J, et al. Effects of intensive blood pressure lowering on the progression of chronic kidney disease: a systematic review and meta-analysis. CMAJ 2013; 185:949–957].

#### **Cystatin C–Based eGFR Improves Risk Prediction**

Estimates of GFR (eGFR) based on cystatin C—alone or combined with creatinine—improve the prediction of adverse clinical outcomes related to kidney function, according to a meta-analysis in the *New England Journal of Medicine*.

The meta-analysis included data from 11 general population studies, with nearly 91,000 participants, and five cohort studies including nearly 3000 patients with chronic kidney disease. All reports provided information on standardized serum creatinine and cystatin C measurements. The eGFRs based on cystatin C, creatinine, or both were evaluated for associations with mortality, death of cardiovascular disease, or ESRD.

In the general population studies, the prevalence of eGFR less than 60 mL/  $min/1.73 m^2$  was higher with estimates based on cystatin C than in those based on creatinine: 13.7 percent versus 9.7 percent. For all three outcomes, risk was decreased when eGFR was reclassified to a higher value based on cystatin C, and

it was increased when eGFR was reclassified to a lower value based on creatinine. Cystatin-based eGFR was associated

with a net reclassification improvement of 0.23 for death and 0.10 for ESRD. This was so with estimates based on either cystatin C alone or cystatin C plus creatinine. With both methods, mortality was significantly increased below a threshold eGFR value of about 85 mL/ min/1.73 m<sup>2</sup>.

Using cystatin C to calculate eGFR increases the accuracy of kidney function estimates. The new results suggest that cystatin C-based estimates strengthen the association between eGFR and adverse outcomes, especially all-cause mortality, but also cardiovascular mortality and ESRD. The study "provides evidence that the use of cystatin C improves the role of eGFR in risk categorization" [Shlipak MG, et al. Cystatin C versus creatinine in determining risk based on kidney function. *N Engl J Med* 2013; 369:932–943].

#### **Cholecalciferol Lowers Albuminuria in Chronic Kidney Disease**

In patients with chronic kidney disease (CKD), a daily oral cholecalciferol supplement reduces albuminuria—with the potential to delay the progressive decline in kidney function, reports a trial in *Nephrology Dialysis Transplantation*.

The prospective study included 101 CKD patients with albuminuria who were not receiving dialysis. Fifty of these patients had low 25(OH) vitamin D along with a high parathyroid level; this group received vitamin D supplementation with cholecalciferol, 666 IU/day. The remaining 51 patients were free of hyperparathyroidism and did not receive cholecalciferol, regardless of their vitamin D status. Changes in albuminuria were compared for the cholecalciferol and control groups.

The mean 25(OH)D level increased by 53 percent in the cholecalciferol group. After 6 months, the patients receiving cholecalciferol had a significant decrease in the urinary albumin-to-creatinine ratio (ACR): from 284 to 167 mg/g, compared with no change

in untreated control individuals.

The drop in ACR was significantly correlated with the increase in 25(OH)D but was unrelated to other factors that could affect proteinuria. Cholecalciferol treatment was also associated with a decrease of 13.8 percent in mean parathyroid hormone level, with small increases in phosphate and calcium-phosphate product.

Previous reports had suggested that activation of the vitamin D receptor might have antiproteinuric effects. The new intervention study finds that six months of cholecalciferol treatment is associated with decreased albuminuria in CKD patients. The potential long-term effects on disease progression in this patient population await future trials [Molina P, et al. The effect of cholecalciferol for lowering albuminuria in chronic kidney disease: a prospective controlled study. *Nephrol Dial Transplant* 2013 [Epub ahead of print] doi: 10.1093/ndt/gft360.

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## **Industry Spotlight**

#### **Rockwell Medical's Latest Hope**

Biopharmaceutical company Rockwell Medical in Wixom, MI, reported its third quarter results for calendar year 2013. With a modest increase in sales of 3.2 percent over the same quarter in 2012, the company also had a gross profit of \$1.6 million, the same amount as in the company's 2012 third quarter.

Rockwell's latest treatment offering in the realm of ESRD and chronic kidney disease secured its trade name of Triferic in September. Triferic is a new type of iron drug for dialysis patients that is demonstrating in phase 3 clinical trials that it can safely and effectively deliver sufficient iron to bone marrow, maintain hemoglobin, and not increase iron stores (ferritin). The drug also can reduce the amount of erythropoietin-stimulating agent a dialysis patient needs—a property that has business analysts interested. Triferic is in the later stages of approval by the U.S. Food and Drug Administration,

"Rockwell's research shows that Triferic reduces the need for expensive erythropoiesisstimulating agent, or ESA. . . by 35%," the financial site Motley Fool reported. "The impact of this on dialysis providers is enormous." The report said that dialysis providers spend about \$2 billion each year on erythropoiesis-stimulating agents, and a 35 percent reduction in that number would be about \$700 million in yearly cost savings. The article also noted that because DaVita and Fresensius, the two largest global providers, have about 71 percent of the industry market, it would be fairly easy to enter the United States market with a new dialysis treatment. The two dialysis powerhouses participated in Rockwell's phase 3 trials.

Forbes magazine also covered Triferic's

abilities and concluded that the drug would assist patients because of its more natural effects in the body. The drug gradually delivers iron directly to the bone marrow in a more physiologic way and "helps to maintain hemoglobin levels without the rapid changes in iron levels that occur with intravenous administration," wrote Robert Glatter, in the Pharma pages of *Forbes*. "Most importantly, by improving the effectiveness of iron delivery, Triferic may help to prevent iron induced liver damage, which is quite important for patients with pre-existing liver disease."

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