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CMS announces plans to overhaul meaningful use, health data exchange

By David White

In March 2018, Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma announced a series of planned reforms designed to reduce regulatory burden, increase electronic health record (EHR) interoperability, and advance access to medical records for patients.

Administrator Verma announced CMS is planning on overhauling its meaningful use requirements, in response to years of provider complaints that the program is too burdensome and difficult to implement. CMS's stated goal is to reduce time and compliance costs associated with the program.

The agency's moves come just weeks after President Donald Trump signed a funding bill that includes measures to ease meaningful use requirements and expand telehealth access for Medicare beneficiaries. The meaningful use bill could make meeting EHR meaningful use requirements easier because those requirements no longer would become stricter over time.

The CMS administrator described the path to a digitized healthcare system wherein providers have easy access to patient lab test results, diagnoses, medical histories, and other types of health data as a "slog."

Verma noted that healthcare organizations nationwide have made progress related to EHR adoption, EHR use, and health data exchange; however, information blocking still poses a barrier to seamless interoperability.

"Providers also continue to find it difficult and burdensome to use EHRs," Verma noted. "In many ways, EHRs have merely replaced paper silos with electronic ones, while providers, and the patients they serve, still have difficulty obtaining health records. For the fortunate few who do ultimately obtain their records, the information is often incomplete, and not always digital or understandable."

"CMS will be announcing a complete overhaul of the Meaningful Use program for hospitals, and the Advancing Care Information performance category of the Quality Payment Program," Verma said in remarks published on the CMS website. "Our new direction will not only reduce time and costs but will also be laser focused on increased interoperability and giving patients access to their data across all of our programs."

Verma emphasized CMS plans to take a more aggressive stance toward preventing information blocking in the future. "It's not acceptable to limit patient records or to prevent them and their doctor from seeing their complete history outside of a particular healthcare system," Verma maintained.

In the announcement in a speech on March 6, Verma also unveiled two new initiatives. The first initiative, MyHealthEData, is intended to make it easier for patients to obtain and share their medical records.

The MyHealthEData initiative aims to ensure patients

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Budget Boosts Funds for Kidney Disease Research, Prevention

By ASN Staff

In March 2018, Congress passed, and President Donald Trump signed, a $1.3 trillion omnibus spending bill for fiscal year (FY) 2018 that included significant gains for the National Institutes of Health (NIH). Enacting at least a $2 billion budget increase for NIH in FY 2018 was a top advocacy priority for the American Society of Nephrology (ASN) and peer societies, which had repeatedly and persistently made the case for this investment for well over a year before the bill was signed into law on March 23. All told, NIH received a $3 billion increase, bringing its FY18 budget allocation to $37.1 billion—an 8.8% increase over the enacted fiscal 2017 level. The total U.S. Department of Health and Human Services (HHS) budget is $88 billion.

Within the $37 billion budget, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) will receive $1.97 billion, a boost of 5.4% over the FY17 spending level—in alignment with ASN legislative priorities. As of press time, the specific increases for the Division of Kidney, Urologic and Hematologic Diseases were still being finalized, and ASN will report on that number as

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Inside

CRRT

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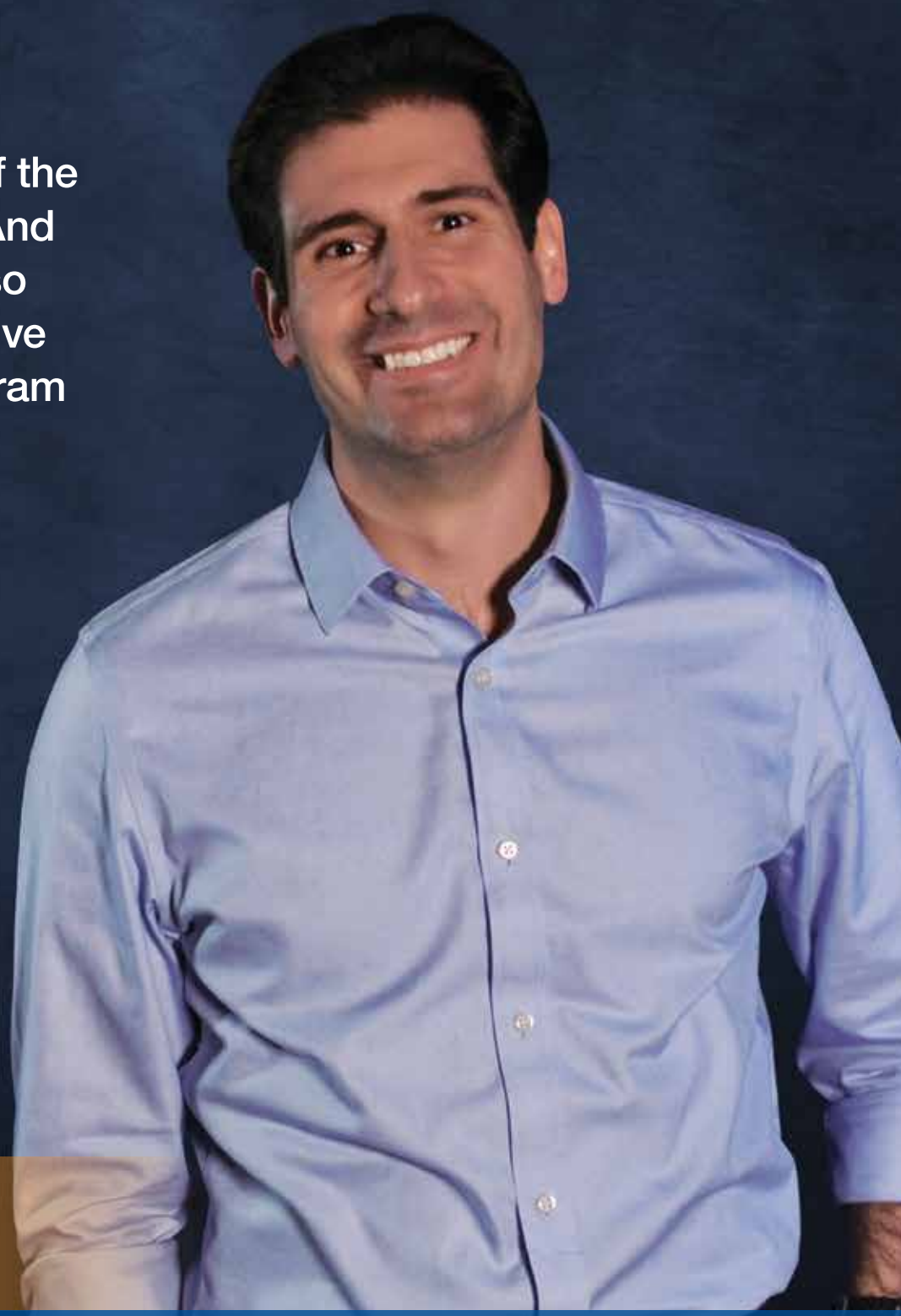
Juan Carlos Aycinena, MD



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Budget Boosts Funds

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soon as it is made publicly available. The bill includes $2.1 million for chronic kidney disease for the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention. The bill also prohibits the administration from capping administrative and facilities fees used to support research institutions—another deleterious proposal bandied around Congress in the last year that ASN opposed.

Increasing overall NIH funding by $2 billion in FY 2018, with a proportional increase for NIDDK, was the focus of requests made to members of Congress during both Kidney Health Advocacy Day 2017 and Kidney Community Advocacy Day 2017, when ASN brought together 21 kidney organizations to make the case for investing in greater funding for kidney research. Additionally, nearly 1000 ASN members responded to calls to and wrote their congressional delegation to urge their support for the $2 billion increase over the course of the past year. The FY 2018 increases for NIH are the result of coordinated advocacy efforts including ASN members nationwide, kidney patient and health professional groups uniting on Capitol Hill, and partnership with national research advocacy coalitions in Washington, DC.

The spending bill also includes language encouraging NIDDK to work with other NIH institutes to advance research for children and young adults with kidney diseases. The report urges support for the Cure Glomerulonephropathy (CureGN) initiative, which has enrolled over 1500 clinical research subjects working toward furthering the understanding of rare forms of kidney diseases. Furthermore, it requests that the National Institute of Minority Health and Health Disparities track the work being done to address the role disparities play in kidney diseases in children.

Language in the bill from the Veterans Affairs Military Construction Committee report requests that the U.S. Department of Veterans Affairs (VA) consider the "benefits provided by national contracts" for dialysis care and asks the VA to explore the Centers for Medicare & Medicaid Services' renal-focused efforts.

Why did Congress give NIH $1 billion more than the medical research community asked for (which was a $2 billion increase)? There are several possible reasons. First, Congress identified a need to urgently fund several specific needs that were not addressable through existing

NIH funds. Second, rather than reducing the budgets of existing Institute Centers or stinting on budget increases needed to keep pace with inflation, Congress allocated additional funding to address these specific new priorities beyond the $2 billion increase that advocates called for. Examples include $500 million for research into the opioid crisis and nearly $500 million to carry out the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative enacted in the 2015 21st Century Cures Act.

While the increased FY 2018 funding levels are welcome news, by law, spending bills should have been finalized before the beginning of October 1, 2017—the start of fiscal year 2018. Before Congress passed the spending bill to fund the government for the rest of FY 2018 on Friday, March 23, it had already enacted numerous smaller, stopgap spending bills to keep the government doors open. These hiccups in congressional procedure matter because it is difficult for regulatory agencies that fund kidney research—including NIDDK—to make plans for grant funding when it is unclear what, if any, funding will be in their future.

By delaying the finalization of FY 2018 spending, Congress also drastically decreased the time it has to work on a spending bill for FY 2019, leaving only 6 months for its completion. This delay further complicated FY 2019 funding; until this point it has been difficult for lawmakers to make predictions for budget needs and spending for FY 2019 as it was unclear what would take place in FY 2018.

Despite these challenges, ASN is again advocating for more NIH and NIDDK funding in FY 2019, as well as for congressional support of KidneyX, a public-private partnership to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. Announced at Kidney Week 2017 by HHS Chief Technology Officer Bruce Greenstein, KidneyX will focus on commercializing new therapies and serving as a catalyst for investment by the private market in ways that are not currently addressed by market forces or federal efforts.

Building upon previous success, ASN is promoting support for these requests from Congress through several initiatives. Highlights of these initiatives include participation in efforts by the Friends of NIDDK and the AdHoc Group for Medical Research to provide an increase for the NIH and NIDDK. In addition, ASN and the American Society of Pediatric Nephrology led a letter of community support for an increase to NIDDK. On March 28, advocates from ASN and the American Association of Kidney Patients were on Capitol Hill advocating for KidneyX and other legislative priorities. In the fall of 2018, ASN will convene a sixth Kidney Community Advocacy Day to bring attention to issues important to the kidney community. ■

CMS announces plans

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have control over their complete EHRs and are able to share their health data with any provider or healthcare organization they choose. The Trump administration asserts that the initiative will assist in developing a patient-centered healthcare system in which patients are part of the clinical decision-making process. "MyHealthEData will unleash data to trigger innovation, and advance research to cure diseases, and provide more evidence-based treatment guidelines that ultimately will drive down costs and improve health outcomes," Verma said.

"It is extremely rare for different provider systems to be able to share data," Verma said. "In most cases … it's in the financial interest of the provider systems to hold on to the data for their patients."

Verma also unveiled Medicare's Blue Button 2.0. The initiative is a web application that provides a secure way for Medicare beneficiaries to access and share their personal health data in a universal digital format. The application will allow patients to access and share their healthcare information, previous prescriptions, treatments, and procedures with a new doctor; such sharing can reduce duplication in testing and provide continuity of care.

More than 100 organizations, as of late March, including some of the most notable names in technological innovation, had signed on to use Medicare's Blue Button 2.0 to develop applications that will provide innovative new tools to help these patients manage their health.

In her remarks, Administrator Verma specifically called on all healthcare insurers to follow CMS's lead and give patients access to their claims data in a digital format.

"CMS serves more than 130 million beneficiaries through our programs, which means we are uniquely positioned to transform how important healthcare data is shared between patients and their doctors," she said. "Today, we are calling on private health plans to join us in sharing their data with patients because enabling patients to control their Medicare data so that they can quickly obtain and share it is critical to creating more patient empowerment."

In her announcement, Verma stated that at the current rate of healthcare-related spending, one in every five dollars spent in the US will go toward the healthcare industry by 2026.

Reducing duplicate tests and unnecessary medical services by facilitating the seamless flow of health information is key to cutting costs for both healthcare organizations and patients. Lack of patient health data access can lead to duplicate testing and unnecessary treatments, stunting progress toward a value-based care system and increasing costs for hospitals and health systems. Lack of EHR usability has also slowed the transition to a value-based care system.

As part of CMS' announced plan to reduce the regulatory burden for providers, CMS plans to redesign EHR clinical documentation requirements of Evaluation and Management (E/M) codes. "These are the codes that doctors use to bill Medicare for patient visits," Verma said. "And the billing requirements are outdated, so we will be updating and streamlining them so that doctors can spend less time using their EHRs, and more time with their patients."

Taken together, the Trump administration maintains these efforts to streamline federal regulation, promote health IT innovation, improve health data exchange, and enable patient-centered care will help advance the healthcare industry toward its goal of achieving a value-based care system.

In a March 19 *Fortune* magazine editorial, Joe Biden, 47th US Vice President and co-chair of the Biden Cancer Initiative, directly responds to these announcements.

"While I agree with the administration goals stated [here], these health data issues are not new and we must all get serious and specific about the details to take action in the near term," Biden writes in "To Save and Improve Lives Using Data, Details Matter."

"We have now had nearly a decade to examine the consequences of how the electronic health record systems have been deployed," he said. "The industry has had ample opportunity to voluntarily address the issues of interoperability and putting data in patients' hands, and they have not done so. Now is the time to do something about the data siloes they have created—to improve health and extend lives."

Biden recommended that health care providers be required to provide patients with their full medical record in electronic form within 24 hours of a request, and that those providers who do not comply should be held accountable by the U.S. Department of Health and Human Services for data-blocking as outlined in the 21st Century Cures Act. He also recommended that the Center for Medicare and Medicaid Innovation invest in a patient data system that brings data from disparate formats and care providers into a uniform patient data portal to help reduce confusion and duplication and eliminate unnecessary procedures.

Administrator Verma said CMS has implemented laws regarding information blocking—a practice in which pro-

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Fewer Adverse Renal Events with Balanced Crystalloids versus Saline

In both critically ill and non-critically ill adults, balanced crystalloids are associated with a lower risk of adverse renal events compared to saline, according to a pair of trials in *The New England Journal of Medicine*.

The "Saline Against Lactated Ringer's or Plasma-Lyte in the Emergency Department" (SALT-ED) study included 13,347 adult patients seen in the emergency department (ED) and subsequently hospitalized outside the ICU. Over 16 months, the ED crossed-over monthly from treatment using balanced crystalloids (lactated Ringer's solution or Plasma-Lyte A). Median volume of crystalloids administered in the ED was 1079 mL; about 88% of patients received their assigned solution.

The primary outcome of hospital-free days was not significantly different: median 25 days in both groups. Balanced crystalloids were associated with a significant reduction in major adverse kidney events within 30 days: 4.7% versus 5.6%, adjusted odds ratio 0.65. All-cause mortality, need for renal replacement therapy, and rate of persistent renal dysfunction were similar between groups.

In the "Isotonic Solutions and Major Adverse Renal Events Trial" (SMART), 15,802 adults in five ICUs were assigned to receive balanced crystalloids or saline. Balanced crystalloids were associated with a small but significant reduction in major adverse kidney events within 30 days: 14.3% versus 15.4%, OR 0.91. Thirty-day hospital mortality was also lower in the balanced-crystalloids group: 10.3% versus 11.1%. There was no significant difference in need for renal replacement therapy or persistent renal dysfunction.

The outcomes associated with the choice of isotonic crystalloid solutions are unclear, particularly outside of ICU settings. The SALT-ED trial shows no difference in hospital-free days with balanced crystalloids versus saline, but a lower incidence of major adverse kidney events with balanced crystalloids.

The SMART study shows that crystalloids are associated with a lower composite outcome rate, including death from any cause and major adverse kidney events. The researchers acknowledge some important limitations of their two pragmatic, single-center, open-label trials [Self WH, et al. Balanced crystalloids versus saline in noncritically ill adults. *N Engl J Med* 2018; 378:819–828; Semler MW, et al. Balanced crystalloids versus saline in critically ill adults. *N Engl J Med* 2018; 378:829–839].

Higher UACR Linked to Cardiovascular Risk in Diabetes

Urinary albumin excretion is independently associated with a range of adverse cardiovascular outcomes in patients with type 2 diabetes, reports a study in *JAMA Cardiology*.

The study included data on 15,760 patients from the SAVOR-TIMI 53 study: a randomized, placebo-controlled trial of the oral hypoglycemic drug saxagliptin in patients with type 2 diabetes at high cardiovascular risk. Two-thirds of patients were men. Baseline urinary albumin to creatinine ratio (UACR) was less than 10 mg/g in 36.8% of patients, 10 to 30 mg/g in 24.7%, 30 to 300 mg/g in 28.1%, and greater than 300 mg/g in 10.4%.

At a median 2.1 years' follow-up, rates of a primary composite outcome of cardiovascular death, myocardial infarction, and/or ischemic stroke increased progressively in each category of baseline UACR: 3.9%, 6.9%, 9.2%, and 28.1%, respectively. There were also stepwise increases for cardiovascular death, 1.4%, 2.6%, 4.1%, and 6.9%; and heart failure hospitalization, 1.5%, 2.5%, 4.0%, and 8.3%.

The UACR-related net reclassification improvement associated with these endpoints was 0.081, 0.129, and 0.056, respectively. Increases in cardiovascular risk associated with UACR values greater than 10 mg/g were observed at each stage of chronic kidney disease. The associations between UACR and cardiovascular outcomes remained significant on analysis including cardiac biomarkers, but were weakened.

Among those with type 2 diabetes, an elevated UACR is associated with reduced renal function and predicts an increased risk of renal failure and death. The new analysis shows that higher UACR is also associated with adverse cardiovascular outcomes at two years' follow-up.

Added to established cardiac biomarkers, the UACR provides little incremental information on cardiovascular outcomes. However, the researchers note that UACR is routinely measured to assess chronic kidney disease in patients with type 2 diabetes, whereas cardiac biomarkers are not typically available. [Scirica BM, et al. Cardiovascular outcomes according to urinary albumin and kidney disease in patients with type 2 diabetes at high cardiovascular risk. *JAMA Cardiol* 2018; 3:155–163].

In CKD Patients with AF, Anticoagulation Increases Risks

In older adults with chronic kidney disease (CKD), new anticoagulant therapy for atrial fibrillation (AF) is associated with increased risks of ischemic stroke and hemorrhage, reports a study in the *British Medical Journal*.

From a UK general practice database, the researchers identified 6977 CKD patients newly diagnosed with AF. Of these, 2434 were started on anticoagulation within 60 days. Propensity scores were used to create matched pairs of patients, exposed or not exposed to anticoagulant therapy. Mean age was about 82 years. At a median follow-up of 506 days, rates of ischemic stroke, cerebral or gastrointestinal bleeding, and death from any cause were compared between groups.

The crude rate of ischemic stroke was 4.6 per 100 person-years after starting anticoagulants, compared to 1.5 for matched patients not taking anticoagulants. Rates of hemorrhage were 1.2 versus 0.4 per 100 person-years, respectively. Both adverse outcomes were significantly increased in the anticoagulant group: hazard ratio 2.60 for ischemic stroke and 2.42 for hemorrhage. All-cause mortality was paradoxically lower for patients starting anticoagulants: hazard ratio 0.82.

About one-third of patients with CKD also have AF. Decisions about anticoagulant therapy are complicated by the fact that stroke and bleeding risk both increase progressively as kidney function declines.

The results show increased rates of ischemic stroke and cerebral or gastrointestinal hemorrhage in older CKD patients who start anticoagulants after being diagnosed with AF. The reasons for the unexpected reduction in mortality are unclear. "These paradoxical findings emphasise the urgent need for adequately powered randomised controlled trials to provide clarity on correct clinical management," the researchers conclude [Kumar S, et al. Ischaemic stroke, haemorrhage, and mortality in older patients with chronic kidney disease newly started on anticoagulation for atrial fibrillation: a population based study from UK primary care. *BMJ* 2018; 360:k342].

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Marijuana Users Aren't at Increased Kidney Disease Risk

Current or past use of marijuana does not appear to affect the risk of developing kidney disease or decreased renal function, reports a study in *The American Journal of Medicine*.

The cross-sectional study included data from 13,995 respondents, aged 15 to 59, to the National Health and Nutrition Examination Survey from 2007 to 2014. Self-reported marijuana use, recent or past, was analyzed for association with renal outcomes: serum creatinine concentration, estimated glomerular filtration rate, and chronic kidney disease (stage 2 or higher).

In the nationally representative survey, 46.3% of respondents said they had never used marijuana, 39.3% were past users, and 14.4% were current users. Current marijuana users were more likely to be male, younger, and current alcohol and tobacco users. Unadjusted data suggested higher mean serum creatinine and lower mean eGFR in past and current marijuana users.

However, on adjusted analysis, none of the three renal outcomes was associated with marijuana use. Serum creatinine and eGFR showed an increasing trend in past and current marijuana users versus never-users, but these were not statistically significant. Sensitivity analysis limited to respondents free of cardiovascular disease also found no significant associations.

As more states legalize medical and recreational marijuana, use of this drug in the population is likely to increase. As for other acute and chronic health effects, little is known about how marijuana affects renal function.

This study—the largest of its kind—finds no clinically significant effect of past or current marijuana use on serum creatinine, eGFR, microalbuminuria, or stage 2 or higher CKD. While characterizing the results as "somewhat reassuring," the authors note that their study provides no information on the renal safety of marijuana in heavy users, older adults, or patients with pre-existing CKD [Lu C, et al. Marijuana use and renal function among US adults. *Am J Med* 2018; 131:408–414] .

Biologic Therapies for RA Reduce Kidney Risks

In patients with rheumatoid arthritis, treatment with biologic agents is associated with a lower risk of declining renal function and chronic kidney disease (CKD), reports a study in *Kidney International*.

Using a Department of Veterans Affairs database, the researchers identified 20,757 veterans diagnosed with RA between 2004 and 2006, with follow-up to 2013. All included patients had initially normal kidney function: estimated glomerular filtration rate (eGFR) 60 mL/min/1.73 m^2 or higher. Treatment with biologic agents was examined for association with incident CKD, defined as eGFR less than 60 mL/min/1.73 m^2, with at least a 25% decrease; and change in renal function, classified as <–3, –3, <0 (reference), and ≥0 mL/min/1.73 m^2. Treatment and control groups were propensity-matched, based on their likelihood of initiating biologic treatment.

Overall, 22% of patients received biologic agents: most commonly etanercept, followed by adalimumab and infliximab. Patients receiving biologic therapy were younger and less likely to be male and African American. They also had higher eGFR, higher income, and less comorbidity.

Biologic therapy was associated with a lower incidence of CKD: hazard ratio 0.95 for a cutoff of under 60 mL/min/1.73 m^2 and 0.71 for under 45 mL/min/1.73 m^2. Patients receiving biologics were also less likely to have progressive eGFR decline: multinomial odds ratio 0.67 for an eGFR slope <–3 mL/min/1.73 m^2 and 0.76 for ≥0 mL/min/1.73 m^2 (relative to –3 to <0). The yearly rate of eGFR decline slowed from –1.0 mL/min/1.73 m^2 before to –0.4 mL/min/1.73 m^2 after biologics were started.

Patients with RA are at elevated risk of kidney disease, likely via chronic inflammation and/or exposure to nephrotoxic drugs. Newer biologic agents used to reduce systemic inflammation in RA have been shown to have beneficial effects in lowering cardiovascular risk.

This study suggests that biologic therapy reduces the risk of CKD and progressive decline in renal function in a nationwide cohort of veterans with RA. The associations are independent of known risk factors for CKD. [Sumida K, et al. Treatment of rheumatoid arthritis with biologic agents lowers the risk of incident chronic kidney disease. *Kidney Int* 2018. DOI: 10.1016/j.kint.2017.11.025].

Many Living-Donor Kidney Recipients Start Dialysis before Transplant

One-third of living-donor kidney transplant recipients are started on dialysis before transplantation—even while their donor's evaluation is proceeding, reports a study in *Transplantation*.

The retrospective study included 478 patients who ultimately received a living-donor kidney transplant, and who were not on dialysis when their donor was being evaluated for at least 3 months. The transplants were performed at five centers in Ontario between 2004 and 2014. The proportion of patients initiating dialysis before transplantation was analyzed, along with factors associated with this outcome.

Thirty-five percent of patients initiated dialysis a median of 9.7 months after their donor started evaluation. Median time on dialysis before transplantation was 8.8 months. The costs of dialysis in this group were $8.1 million (in Canadian dollars). Twenty-six percent of patients initiated dialysis urgently in the hospital.

Median time from the start of donor evaluation to transplant was 22.4 months for patients who started dialysis before transplantation, compared to 10.6 months for pre-emptive transplant recipients. Initiating dialysis before transplantation was more common when the donor was female, nonwhite, lived in a lower-income neighborhood, and had later referral to the transplant center. Rates of potential unrealized pre-emptive transplants varied between centers.

Pre-emptive kidney transplantation avoids the risks of initiating dialysis and leads to better patient experiences and outcomes. However, even after a living donor is identified, there are many challenges to pre-emptive transplantation, including a lengthy donor evaluation process.

In this series from Ontario, 35% of eventual living-donor kidney recipients initiated dialysis before transplantation, even though their donor's evaluation was well underway. "Future studies should consider whether some of these events can be prevented by addressing inappropriate delays to improve patient outcomes and reduce healthcare costs," the investigators conclude [Habbous S, et al. Initiating maintenance dialysis prior to living kidney donor transplantation when a donor candidate evaluation is well underway. *Transplantation* 2018; DOI: 10.1097/TP.0000000000002159].

Glycated Albumin Predicts Mortality in Dialysis Patients with Diabetes

In diabetic patients on hemodialysis, glycated albumin (GA) might provide a valuable alternative for predicting mortality, according to a study in *Nephrology Dialysis Transplantation*.

The study included a cohort of 84,282 diabetic patients on maintenance hemodialysis in Japan, identified from the Japanese Society for Dialysis Therapy Renal Data Registry. Mean age was 67 years and mean time on dialysis 6.4 years; about 70% of patients were male. Measurements of both GA and glycated hemoglobin (HbA1c) were available for 22,441 patients. One-year follow-up data were used to assess the two measures as predictors of mortality, with adjustment for potential confounders.

Overall 1-year mortality was 8.4%. Mortality was lowest for patients with a GA level between 15.6% and 18.2% (1st to 3rd decile) and those with HbA1c of 5.8% to 6.3%. The associations with GA were independent of serum albumin level or cardiovascular disease history. Glycated albumin had a linear or J-shaped association with mortality, while HbA1c had a U-shaped curve.

Adjusted hazard ratios for mortality were significantly higher at GA levels less than 12.5% and 22.9% or above. The trends were flatter in older patients, those with higher hemoglobin, and those with a history of cardiovascular disease. There was evidence that models incorporating GA might have better predictive value than adding HbA1c.

Glycated hemoglobin may be limited as a predictor of mortality in patients with diabetes on hemodialysis. Glycated albumin—reflecting glycemic control over approximately the previous 2 weeks—has been proposed as a glycemic marker in dialysis patients.

This study shows a linear or J-shaped association between GA and 1-year mortality, in a large group of diabetic hemodialysis patients in Japan. While emphasizing the need for further research, the investigators conclude, "[O]ur analyses suggest the potential superiority of GA over HbA1c in predicting mortality." They also discuss the implications for understanding the phenomenon of "burnt-out diabetes" [Hoshino J, et al. Glycated albumin versus hemoglobin A1c and mortality in diabetic hemodialysis patients: a cohort study. *Nephrol Dial Transplant* 2018; DOI: 10.1093/ndt/gfy014].

CMS announces plans

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viders prevent patients from getting their data. Under some CMS programs, hospitals and clinicians must show they have not engaged in information blocking activities.

The administrator also highlighted other CMS plans to empower patients with data:

- CMS is requiring providers to update their systems to ensure data sharing.
- CMS intends to require that a patient's data follow them after they are discharged from the hospital.
- CMS is working to streamline documentation and billing requirements for providers to allow doctors to spend more time with their patients.
- CMS is working to reduce the incidence of unnecessary and duplicative testing that occurs as a result of providers not sharing data.

As these reforms progress, the American Society of Nephrology will provide input to CMS and report back here on CMS' progress.

The Death of Contrast-Induced Nephropathy Is Premature

By Michael R. Rudnick, MD, and Amanda Leonberg-Yoo, MD

The occurrence of acute kidney injury (AKI) resulting from the intravascular administration of contrast media (CM), commonly referred to as contrast-induced nephropathy (CIN), has become firmly entrenched.

CIN has been described with both intra-arterial and intravenous (IV) administration of CM. Most clinical studies of CIN occur in a population receiving CM during coronary angiography, even though most intravascular CM exposures occur via IV administration during contrast-enhanced computed tomography (CECT).

Within the past decade, an increasing number of studies have called into question the true incidence and even the existence of CIN after IV CM administration. This has led some physicians to opine that CIN after IV CM administration has been overstated, may not even occur, and is not of a sufficient magnitude to be clinically significant (1). Physicians should be concerned about the implications of these opinions, given the associations of AKI with short-term and long-term mortality and the development of chronic kidney disease (CKD) (2, 3). Thus, in order to "first do no harm," it is important to critically examine the literature reports that have been purported to negate the risk of CIN from IV CM administration.

The initial studies of CIN after CECT were limited by the absence of control groups of patients who underwent unenhanced computed tomography (CT). The inclusion of a control group is necessary to determine whether factors other than CM may be responsible for the observed AKI in a given study. The next generation of studies included a control group and demonstrated similar rates of AKI after CECT and unenhanced CT, with conclusions that the entity of CIN after IV CM either had been overstated or does not exist (1). These studies have several limitations, including small sample sizes (especially of high-risk patients) and evidence of selection bias. Selection bias could steer patients with predisposition to AKI other than CM exposure to receive unenhanced CT imaging, whereas AKI in the CECT group could still be attributable to CM exposure, thus biasing the risk of CIN toward the null in these studies (1). Thus, the similar incidence of AKI could be attributable to factors other than CM that may have influenced inclusion in the control group. In an effort to diminish the impact of selection bias, contemporary studies were performed with the use of propensity score methods. Propensity scores adjust for risk factors that may influence receipt of the exposure variable (CECT in this case) in an attempt to make retrospective observational analyses more similar to prospective randomized trials.

It is instructive to review two large propensity score–adjusted studies on IV CIN. McDonald et al. (4) performed a retrospective propensity score–adjusted analysis of 12,508 patients to evaluate the risk of AKI in a cohort exposed to CECT or unenhanced CT. Patients in both groups were stratified by baseline estimated GFR (eGFR) and were matched 1:1 by propensity score. The incidences of AKI between CECT and unenhanced CT were similar for each eGFR cohort (≥90 mL/min: 1.2%–1.3%; 60–89 mL/min: 2.1% versus 2.0%; 30–59 mL/min: 5.8% versus 6.2%; and <30 mL/min: 14% versus 14%, respectively), with no statistically significant increased odds of AKI. Davenport et al. (5) also performed a propensity score–adjusted cohort analysis of 17,652 patients who underwent CECT or unenhanced CT with risk stratification by eGFR. The incidence of AKI was similar between higher eGFR cohorts in CECT versus those in unenhanced CT (eGFR >60 mL/min: 5.4% versus 5.5%; 45–59 mL/min: 10.5% and 10.8%, respectively). In patients with eGFR 30 to 44 mL/min, the incidence of AKI was slightly higher among those with CECT exposure than in those with unenhanced CECT (16.7% versus 14.2%, odds ratio 1.40; 95% confidence interval 0.997–1.970). In patients with eGFR <30 mL/min, however, there was an increased incidence of AKI among those with CECT exposure compared with unenhanced CT (36.4% versus 19.4%, respectively). These studies show similar incidence rates of AKI between CM exposed and unexposed patients with normal or mildly impaired renal function. However, in the Davenport study, the odds of AKI were increased in patients with severe and possibly moderate renal impairment who were exposed to CM. The disparate results between these two studies are likely due to differences in baseline cohort characteristics, differences in propensity score models, and the relatively small number of the highest-risk patients.

These and other propensity score–adjusted studies examining IV CIN have significant limitations. Although propensity score adjustment may reduce selection bias, it is not equivalent to the balance of risk factors achieved in prospective randomized controlled trials. The retrospective basis of propensity score adjustment leaves open the possibility that there are confounders not included in the propensity score models that were considered by clinicians in deciding which patients received CECT or unenhanced CT.

Currently available propensity studies demonstrating equivalence of AKI between groups exposed and not exposed to CM are also limited by the numbers of patients studied who are *truly at increased risk*. Despite the robust number of patients studied, the majority have normal or mildly impaired renal function. In the studies by McDonald et al. (4) and Davenport et al. (5), the proportion of patients with eGFR >60 mL/min were 45% and 79%, respectively. It should not be surprising to any nephrologist that the AKI rates for these two groups were similar, given that it is well established that CM is rarely nephrotoxic in patients with normal or mildly impaired renal function. Conversely, the number of patients in these studies with more severe pre-existing CKD, and thus at higher risk of CIN, was comparatively small, with only 11% of individuals in the study by McDonald et al. (4), and 0.6% of those in the study by Davenport et al. (5), having an eGFR <30 mL/min. Other limitations include failure to adjust for other confounding covariates, including prophylactic strategies, concomitant use of nephrotoxic medications, and volume of CM administered; the inclusion of patients with AKI before CT was performed; and misclassification of comorbidities by International Classification of Diseases 9th edition codes. Furthermore, these studies were composed primarily of inpatients, who are inherently more at risk for AKI from multiple causes; were not adjusted for the clinical indications for the CTs; and did not include assessments for long-term mortality or development of CKD.

In addition to the limitations of the current observational literature, there are other important reasons why physicians should not adopt a cavalier position on the nephrotoxicity of IV CM. Multiple experimental studies have demonstrated CM nephrotoxicity (6). The limitations of these experimental studies notwithstanding, the collective evidence of these studies raises a serious concern about CM nephrotoxicity in humans. Furthermore, AKI in general and from CM specifically has been associated with an increased risk of CKD and long-term mortality, and these associations are supported by experimental studies proving plausible biologic mechanisms for these adverse outcomes (2, 3).

So how should physicians interpret the risk of AKI from IV CM administration in light of recent studies? It is clear that there is a negligible risk for AKI from IV CM in patients with normal (eGFR ≥60 mL/min) or mildly impaired (eGFR 45–59 mL/min) renal function. It is also clear that patients with eGFR <30 mL/min are at greatest risk for CIN and should continue to be classified as such, despite mixed findings of propensity-matched studies. This leaves open the question of how to risk classify patients with eGFR between 30 and 45 mL/min. Although propensity-adjusted studies suggest this group is not at increased risk, there remain lingering concerns over the

methods behind these observational studies. We suggest that risk classification for CM nephrotoxicity should not be based solely on eGFR, especially for patients with eGFR of 30 to 45 mL/min. Physicians evaluating the nephrotoxic risk of CM should take into consideration each patient's unique risk factors for AKI and the benefit gained from a CECT. Resolution of the question of the potential risk of IV CM nephrotoxicity in patients historically considered to be at moderate to high risk will require additional clinical research. Prospective randomized trials will not be possible for ethical reasons. However, observational studies should be conducted in a variety of clinical settings, primarily in patients with eGFR <45 mL/min, with adequate power using methods that adjust for patient differences.

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Contrast-Induced Nephropathy: Is the Concern Exaggerated?

By Teresa K. Chen, MD, MHS, and Derek M. Fine, MD

Intravascular iodinated contrast has historically been considered a risk factor for acute kidney injury (AKI), particularly among individuals with underlying chronic kidney disease (1). Recent studies, however, have suggested that incidence of contrast-induced nephropathy (CIN) may not be as frequent as previously thought (2,3). In this commentary, we argue that contrast material can often be safely used without increased risk of AKI, even among individuals with underlying kidney disease.

Although the definition can vary from study to study (4), CIN is usually characterized by a 0.5 mg/dL rise in serum creatinine from baseline 24 to 72 hours following exposure (1, 3–5). In the clinical setting, CIN is usually a diagnosis of exclusion, as other causes of kidney injury may also manifest during this timeframe. Most studies on CIN, however, do not adjudicate records to confirm diagnosis. Thus, while the occurrence of contrast-associated AKI has been reported to be approximately 8–14% in the context of chronic kidney disease, this is likely an overestimation (3,5,6).

Moreover, patients who undergo imaging tests requiring contrast enhancement often have comorbidities that place them at increased risk for developing AKI. In a retrospective study of over 12,000 propensity score–matched patients who underwent either contrast-enhanced or unenhanced CT scans, McDonald and colleagues reported that incidence of AKI was independent of contrast material exposure (3). In another large study that also utilized propensity score matching, Hinson and colleagues found similar rates of AKI, regardless of baseline kidney function, among 17,934 patients who presented to a large urban emergency department and underwent contrast-enhanced CT (n=7201), unenhanced CT (n=5499), or no CT (n=5234) (2). The use of propensity score matching in these two studies minimized the likelihood of selection bias (2,3). It is interesting that risk factors associated with an increased risk of AKI included older age, administration of nephrotoxins, hypoalbuminemia, history of congestive heart failure, and underlying chronic kidney disease (2).

Certainly, one cannot account for all potential confounders in a retrospective study. Nonetheless, even if residual confounding were to exist, both studies suggest a low risk of contrast-associated AKI (2,3), particularly in the context of intravenous fluid administration (2). It is important to note that the number of patients with advanced chronic kidney disease (defined as a baseline estimated glomerular filtration rate [eGFR] <30 mL/min/1.73 m^2) was limited, although even in this group there appeared to be no increase in risk for AKI with contrast-enhanced scans (2,3). The small number exposed, however, suggests that contrast is likely avoided in individuals with most compromised kidney function due to concern for kidney injury.

Even if patients develop AKI following the administration of contrast material, few have persistent renal impairment. In a recent 2 x 2 factorial trial in which 5177 patients undergoing angiography were randomized to receive intravenous bicarbonate versus intravenous sodium chloride and oral acetylcysteine versus oral placebo, 8–9% developed CIN (6). At 90 days, however, only ~1% required dialysis, ~1% had persistent kidney impairment, and ~2% had died. Of note, this trial restricted enrollment to individuals with moderate to severe chronic kidney disease (baseline eGFR of 15 to 44.9 mL/min/1.73 m^2 or eGFR of 45 to 59.9 mL/min/1.73 m^2 with concurrent diabetes mellitus) (6).

Unfortunately, no angiography study can be done without contrast to serve as a control in order to fully delineate the effects of contrast. Also, one might argue that the lack of effect of interventions is in part due to the lack of significant toxicity of contrast in the context of fluid administration. Even in the most frequently used CIN risk prediction model (1), volume of contrast exposure contributes far less to the risk score compared to other clinical factors such as chronic kidney disease, presence of hypotension, congestive heart failure, or diabetes mellitus. Thus, it remains unclear whether kidney injury that occurs following contrast administration is due to the contrast itself or independent of the contrast.

Historical studies reporting an association of contrast material with AKI were done in the context of high-osmolar and ionic forms of iodinated contrast, likely larger infusion volumes, and in the absence of adequate hydration. Findings in these recent studies, with a trend toward the judicious use of safer agents in well-hydrated patients, suggest that the concern for CIN may be significantly less than we have previously anticipated. As such, we conclude that in cases where the administration of contrast is deemed to be likely helpful, we should rethink our risk-benefit analysis when considering risk of CIN.

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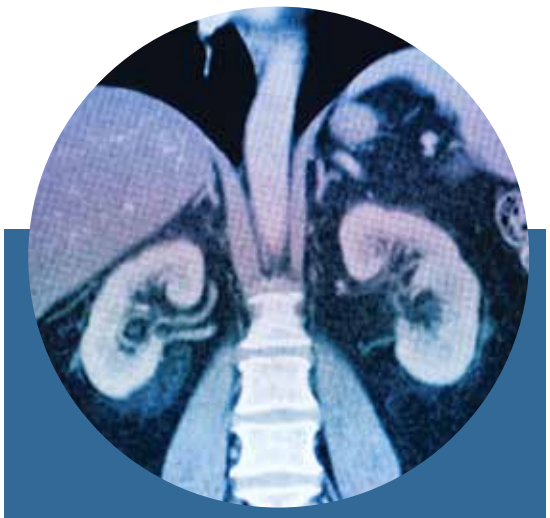

Even in the most frequently used contrast-induced nephropathy risk prediction model (1), volume of contrast exposure contributes far less to the risk score compared to other clinical factors . . . "

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Effective Patient Engagement Strategies to Develop Therapies and Advance Patient Safety

By Kevin Fowler

Last year, I attended a medical conference focused on developing medications for kidney diseases. Unlike previous meetings, this conference was centered on developing upstream interventions, a welcome and very positive development for people with kidney diseases.

A nephrologist stated during a presentation at the conference that dialysis and kidney transplantation are barriers to innovation because they provide a "safe landing" for patients. When I heard this statement, I turned my attention away from the speaker to the audience to gauge the audience members' nonverbal response. Much to my disbelief, the audience appeared to accept this statement as fact. Internally, I had a much different response.

Growing up, I saw my mom and her two sisters sustain their lives by receiving dialysis but with a diminished quality of life. I saw the constant fatigue and other quality-of-life challenges imposed by dialysis.

Beyond my personal experiences, it is important to look at the data. For dialysis patients, the 5-year survival rate is less than 50%, and there are still no fluid management guidelines. Although kidney transplantation is a superior treatment option compared with dialysis, half of kidney transplants fail within a decade, and some significant quality-of-life issues are associated with kidney transplantation (1). I can say without hesitation that dialysis and kidney transplantation are not a "safe landing" for kidney disease patients.

Shortly after this meeting, I was invited to be a part of the speaker faculty at Kidney Week 2017. My presentation, "Effective Patient Engagement Strategies to Develop Therapies and Advance Patient Safety," had three learning objectives: to understand the barriers and patient perspectives on kidney disease clinical trials as an impetus for future research, to identify solutions to patient participation in kidney disease clinical trials and offer recommendations, and to create a vision for patient participation in clinical trials.

Understanding barriers and patient perspectives on kidney disease clinical trials: impetus for future research

Although the U.S. Medicare ERSD program was developed with the best of intentions by policymakers and patient advocates, it has created structural barriers to the development of new therapies for kidney diseases. The enduring legacy of the Medicare ESRD program has been unrestricted access to dialysis. However, the rest of the healthcare system in the United States has fallen short of building on this incomparable entitlement program.

Currently, there are no reimbursement incentives that would encourage early detection of chronic kidney disease (CKD). Not surprisingly, fewer than 10% of patients with stage 3 CKD are aware of their kidney function (2). Moreover, there are no incentives to encourage coordination of patient care and early referral to a nephrologist. As a result, 40% of CKD patients "crash" in hospital emergency departments and are transitioned immediately to dialysis (3).

Given that the remedy to structural barriers resides with healthcare policies, it is important to focus on the role of culture in the kidney disease community (4). Until her death in February 2017, Celeste Castillo Lee was an ardent and strong patient advocate for kidney disease patients. She envisioned the role of patients as partners within the kidney disease community. She was very aware of the need to elevate the expectations of all stakeholders, most notably patients. Yet not only have patients accepted a system of care that rewards downstream interventions, but they have accepted a system that has offered minimal innovation in the downstream interventions.

Kidney disease patients and clinical trials

At the suggestion of nephrologist Barbara Gillespie, MD, I conducted a survey of kidney disease patients with two primary objectives:

- To determine why patients participated in kidney disease clinical trials.
- To learn why patients did not participate in clinical trials.

The demographic breakdown of those surveyed was as follows:

- 192 patients: 58% female; 42% male.
- White, 78%; black, 14%; Hispanic, 5%; Asian, 3%.
- CKD, 41%; dialysis, 28%; kidney transplantation, 31%.

The survey had one major limitation. The racial composition of the audience did not reflect the US population with kidney diseases.

As no surprise, 70% of the respondents had not participated in a clinical trial. When queried further on their lack of trial participation, these were the responses (Tables 1 and 2):

- Over two-thirds of patients did not participate in a trial because their doctors never discussed the subject.
- Almost three-fourths of patients said a physician's discussing a clinical trial with them would influence their trial participation.

Table 1. Reasons patients do not participate in clinical trials

Survey question: If you have not participated in a clinical trial, what was the reason?

ANSWER CHOICES	RESPONSES	
My doctor and care team never discussed a trial with me	68.57%	96
I was never offered compensation to participate in the trial	6.43%	9
I did not understand how I, my family, and other patients would benefit from the trial	6.43%	9
I can't afford to take time off work to be in the trial	4.29%	6
I was afraind of the risks of the trial	5.00%	7
Other (please specify)	24.29%	34
Total Respondents: 140		

The patients who did participate in clinical trials appeared to be internally motivated:

- Almost two-thirds of the respondents participated in a trial because they wanted to help fellow patients.
- Less than 10% of respondents stated compensation as a motivating factor.
- The number one stated reason for trial participation was the respondent's communication with their physician.

The survey responses show there is an opportunity to engage patients further in clinical trial participation (Table 2):

- 36% of patients reported that their trial results were shared with them.
- Only 17% of patients were recognized for their participation.
- The majority of patients, 60%, expressed a desire to be recognized for trial participation.

Table 2. Influences that could affect clinical trial participation

Survey question: If you have not participated in a clinical trial, what would influence you to enroll in a study? Select all that apply.

ANSWER CHOICES	RESPONSES	
Have my physician explain the benefits of the trial to me and my family	72.73%	104
Have another kidney disease patient explain to me the benefits of trial participation	25.87%	37
Compensation for trial participation	31.47%	45
Have my patient organization explain to me the benefits of trial participation	26.57%	38
Other (please specify)	18.18%	26
Total Respondents: 143		

Identifying solutions to patient participation in kidney disease clinical trials: recommendations

Patient-centered policy is the solution to dismantling the structural barriers to CKD patient care. The introduction of H.R. 3867 in September 2017 is the first step in amending Title XVIII of the Social Security Act, which established regulations for the Medicare program. H.R. 3867 would create a demonstration pilot that would focus on early detection of CKD and combine it with coordination of care and engaging patients in their clinical care decisions (5). It is believed that this pilot would improve clinical outcomes while lowering healthcare costs. At long last, there is light on the horizon.

I recommend three ways to change the culture of the kidney disease community, thereby elevating the community's expectations:

Patient engagement: understanding patient attitudes and beliefs about clinical trials

Based on my pharmaceutical and consulting experience, I see many assumptions made about people with kidney diseases and their participation in clinical trials.

To balance the assumptions with evidence, I would like to see the following:

- Baseline understanding of kidney disease patients' viewpoints about clinical trials.
- Identification of the biggest gaps in understanding patients' perspectives.
- Based on gap analysis, identification of research priorities to improve understanding.

Nephrology communication skills training

Recognizing a deficit in skills training for nephrology fellows, Robert Cohen, MD, initiated a quality improvement program to aid nephrology fellows when they have conversations with their patients, including discussions about ending dialysis and preparing for the end of life. Dr. Cohen conducted a 1-day workshop resulting in the improvement of the fellows' communication skills (6).

I would like to see this training expanded across the spectrum of CKD to include conversations about clinical trials. Given that the Centers for Medicare & Medicaid Services Quality Improvement Program will evaluate nephrologists' communication skills, this investment would serve several interests.

Changing the conversation

When my mom started hemodialysis in August 1981, the risk of treatment was never fully explained to her or to our family. For example, we were never told that half of hemodialysis patients are not alive at 5 years. At that time, we faced an uncertain future with no options.

Since that time, options have expanded for patients. They include peritoneal dialysis, pre-emptive transplantation, extended criteria organs, and clinical trials that provide upstream interventions for certain kidney diseases. There need to be risk-to-benefit conversations about the various options and full explanations of the risks associated with dialysis. This must change now.

Creating a vision for patient participation in clinical trials

We are in the very early stages of a transformative time in nephrology patient care, in which an environment is being established to create upstream treatments for kidney diseases. I am very excited about the future, based on three developments.

Kidney Health Initiative, Patient Family Partnership Council

One of the legacies of kidney disease advocate Celeste Castillo Lee is the creation of the Patient Family Partnership Council, whose charge is to provide strategic guidance to the Kidney Health Initiative (KHI) about how to activate and include patients, their families, and their care partners in KHI activities, including but not limited to these activities:

- Advise KHI members regarding patient involvement in their project proposals.
- Outline opportunities for patients to serve once a project has been endorsed.
- Identify patients to serve on project work groups.
- Collaborate on developing patient-centered project(s) to submit for KHI endorsement (7).

The senior leadership of the American Society of Nephrology has demonstrated a willingness not only to listen to patients like myself but also to act on patient feedback. One recent example is the formation of a work group to overcome barriers in upstream innovation.

Kidney Precision Medicine Project

The National Institutes of Health (NIH) investment in the Kidney Precision Medicine Project signals a strategic shift toward upstream innovation and interventions. This project aims to ethically obtain and evaluate human kidney biopsy specimens from participants with acute kidney injury or CKD, create a kidney tissue atlas, define disease subgroups, and identify critical cells, pathways, and targets for novel therapies. This project will pave the way for pharmaceutical investment in novel therapies.

Treatments on the horizon

There are various candidates in phase II and phase III trials for several rare and autoimmune diseases, including Alport syndrome, focal segmental glomerulosclerosis, IgA nephropathy, lupus nephritis, and autosomal dominant polycystic kidney disease.

All of these potential treatments represent upstream innovation and hope for thousands of patients and families.

At the 2016 KHI stakeholder meeting, Eric Dishman, director of the NIH All of US Research Program, drew on his Intel professional career and his patient perspective to make suggestions to KHI stakeholders: Once a vision is clear and visible to a stakeholder community, it becomes easier for a group of stakeholders to invest their dollars and their emotions.

The kidney disease community is now in a transition phase. Now is the time to gather all the stakeholders, including patients, into defining the future state of the kidney disease ecosystem. ■

Kevin Fowler is a recipient of a preemptive kidney transplant and founder of The Voice of the Patient, Inc., and Vice-Chair, Patient Family Partnership Council, Kidney Health Initiative. Follow Kevin on twitter at @gratefull08052004 or contact him at kevinjohnfowler@gmail.com.

"We are in the very early stages of a transformative time in nephrology patient care, in which an environment is being established to create upstream treatments for kidney diseases."

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Industry Spotlight

Pharma News

The National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) has published draft guidelines for a new renal cell carcinoma treatment. The guidelines support the use of EUSA Pharma's (Hemel Hempstead, England) Fotivda (tivozanib) as a first-line treatment option for advanced renal cell carcinoma. NICE provides national evidence-based guidance and quality standards to practitioners in the National Health Service.

In clinical trials, patients treated with Fotivda experienced longer progression-free survival—11.9 versus 9.1 months—in the overall population compared with those taking Bayer's Nexavar (sorafenib). The drug also reduced side effects: 14% of patients on Fotivda compared with 43% of patients on Nexavar needed a dose reduction due to adverse events, noted EUSA Pharma. The company said it plans to pursue FDA approval.

In other news, AstraZeneca said it expects an FDA decision about its drug ZS-9, a candidate to treat hyperkalemia, during the first half of 2018.

The company noted that problems uncovered at a manufacturing facility in Texas that resulted in the FDA's suspending the drug's approval process have been ameliorated.

Third, Bizjournals.com reported that a drug that may help the immune system's chances of slowing progression of several different cancers has placed Nektar Therapeutics in the path of a potential $3.6 billion deal with Bristol-Myers Squibb (BMS) (New York, NY). Nektar's value to BMS is the potential for its investigational drug NKTR-214 to be used in combination with other BMS drugs to stimulate the immune system and fight renal and other cancers. NKTR-214 is believed to stimulate the immune system into producing a protein called PD-1.

Nektar (San Francisco, CA) is being eyed for a trial with Opdivo and also a three-drug combination trial with Opdivo and Yervoy, which bind to PD-1. Early results from a collaboration the companies started in fall 2016 showed that NKTR-214 and Opdivo together could generate a response in more than half of patients, including those with cancers in which PD-1 is not expressed.

Studies in renal cell carcinoma and melanoma are expected to begin in mid-2018, reports ClinicalLeader.com.

And Danish in vitro diagnostics firm BioPorto announced in February 2018 a deal with Roche for the global distribution of a neutrophil gelatinase-associated lipocalin (NGAL) test for use on the Cobas c 501 and Cobas c 502 clinical analyzers, according to GenomeWeb.

NGAL is a diagnostic biomarker that alerts clinicians to acute kidney injury within a few hours. BioPorto's NGAL test has the European CE mark of approval.

The company is conducting research to generate data ahead of potential approval by the US Food and Drug Administration, potentially later this year.

Legal News Round-up

Dialysis companies have found themselves settling lawsuits recently. Fresenius Medical Care North America (FMCNA) disclosed breaches of protected electronic health information and settled with a federal agency, while American Renal Associates (ARA), without admitting wrongdoing, settled with shareholders.

In early February 2018, FMCNA, a major dialysis provider, settled with the Department of Health and Human Services Office of Civil Rights (OCR).

The settlement involved patient privacy breaches that occurred in 2012, including computers stolen during a break-in, a hard drive on a desktop taken out of service and removed from a facility without a report to the corporate risk manager, a laptop and passwords stolen from a car at an employee's home, a USB drive stolen from a facility parking lot, and computers stolen from a facility.

Besides paying $3.5 million to OCR, the company, whose parent company FMC is based in Bad Homburg, Germany, must implement more effective policies to protect patients through device and media controls, encryption, and secure facility access.

"The number of breaches, involving a variety of locations and vulnerabilities, highlights why there is no substitute for an enterprise-wide risk analysis for a covered entity," OCR Director Roger Severino said.

In the shareholder lawsuit, ARA settled to pay shareholders who alleged they lost money because the company failed to disclose a "scheme before the company went public in April 2016," the *Salem (MA)* News wrote. The stock price fell substantially when news of an investigation into ARA practices was reported.

ARA, based in Beverly, MA, which operates in 25 states through approximately 217 dialysis clinics, settled for $4 million to shareholders, but still faces a lawsuit from insurer United Healthcare.

ARA was alleged to have made commercial insurance plans attractive by agreeing to pay co-pays or deductible amounts, the *Salem News* noted. Premiums were to be paid out of funds for lower-income patients provided by the American Kidney Fund.

The insurer claims that ARA failed to tell patients that the coverage through the premium assistance program only covered dialysis and would not cover transplant care, for example. United Healthcare also said ARA's earmarked donations to the kidney fund to pay premiums violated anti-kickback laws, the *New York Times* reported in 2016.

Lupus Nephritis Educational Website Launched

Among the approximately 500,000 people in the United States affected by lupus nephritis each year, most are women. The disease appears in people with systemic lupus erythematosus (SLE).

Aurinia (Victoria, British Columbia) recently launched an educational campaign about lupus nephritis, called ALL IN, to increase support and awareness of the disease. The company's first offering is a website for patients and families, www.allinforlupusnephritis.com, which provides a community support page, information about lupus nephritis and its management, and other resources. To date, no therapy specifically for lupus nephritis has been approved by the US Food and Drug Administration (FDA).

Aurinia is in phase 3 clinical trials with an immunosuppressant therapy called Voclosporin, an investigational drug that is a novel calcineurin inhibitor. The trial includes clinical data for over 2400 patients, across indications including lupus nephritis, nephrotic syndrome, and dry eye syndrome.

The current standard of care is to use mycophenolate mofetil or low-dose intravenous cyclophosphamide plus glucocorticoids as the initial treatment for patients with class III–IV disease.

Voclosporin has the potential to improve near- and long-term outcomes in lupus nephritis when added to mycophenolate mofetil, the company notes on its website. The drug provides a latching section on its molecule that forms a complex with cyclophilin A that then binds to and inhibits calcineurin. The binding affinities of Voclosporin and cyclosporine A for cyclophilin are comparable; however, upon binding, the ethynyl side chain of Voclosporin induces structural changes in calcineurin that may result in increased immunosuppressive activity compared to cyclosporine A, Aurinia reports on its website.

New Technologies Detect Kidney Irregularities

Two companies are offering products that use artificial intelligence (AI) to help improve kidney conditions.

AI start-up Medial EarlySign (Kfar Malal, Israel) has shown how the combination of AI and electronic health record (EHR) data can facilitate early detection and treatment of kidney problems and can help slow or even help prevent progression to end stage renal disease. AI refers to the concept of machines being able to carry out tasks in a manner considered to be "smart, while Machine Learning is an application of AI based on the idea that we should give machines access to data and let them learn for themselves," notes Forbes magazine contributor Bernard Marr.

Medial EarlySign's machine learning–based model analyzes information available in EHRs to predict which patients may be at high risk of experiencing renal dysfunction in the coming year. The technology assesses a combination of laboratory test results, demographics, medications, diagnostic codes, and other factors to predict the risk of renal dysfunction within the next year.

By isolating less than 5% of the 400,000 patients with diabetes selected among the company's database of 15 million patients, the algorithm was able to identify 45% of patients who would progress to significant kidney damage within a year, prior to their becoming symptomatic. This represents 25% more patients than would have been identified by commonly used clinical tools and judgment, the company says.

The AI firm DeepMind (London, UK) has been expanding into healthcare. The Google-owned company's app, Streams, is being used in the Royal Free, a London teaching hospital. One of Streams' first uses is to rapidly alert clinicians to potential cases of acute kidney injury (AKI) in patients, reports ZDNet.The company noted that the Streams app is not strictly AI. "The more time we spent with the clinicians at the Royal Free, the more it became obvious that … their core challenge was in how you actually implement an algorithm to change the way care is delivered in practice," not necessarily the most perfected algorithm.

Streams allows AKI to be detected in several hours, rather than a day or two, ZDNet wrote. A low hemoglobin and elevated urea might point to blood loss, while an elevated white cell count might result from an infection.

DeepMind hopes that in the future the Streams app could be used to study the performance of clinical teams—recording how long it takes to respond to an AKI alert, for example—and patient outcomes related to certain clinical activities.

Practice Pointers

Dangers of overtreating "mild" hyponatremia?

From the ASN Communities WEEKLY REWIND on *Kidney News* Online

By Roger Rodby, MD, FACP, FASN

"Are patients with chronic asymptomatic hyponatremia (hypoNa) with serum sodium of 125 meq/L and higher at risk for osmotic demyelination syndrome (ODS) with rapid correction of their serum sodium?" This question was recently posed in an ASN Communities discussion thread.

The question was asked because the poster's Pharmacy and Therapeutics Committee at a local hospital had noticed that following the use of tolvaptan for hypoNa, 3 of 45 patients had an increase in plasma sodium concentration (PNa) of 6–12 meq/L and 3 had an increase >12 meq/L, within a 24-hour period. The average PNa pre-tolvaptan was 127. The committee wanted to know if those patients needed a maneuver to re-lower their post-tolvaptan Na to avoid risking ODS.

Query and Hypothesis

Is the risk of ODS the same at all levels of starting PNa levels? And if not, perhaps we do not need to re-lower the PNa if starting in the mid-120s?

Discussion

The discussion focused on several points:

1. The relative change in serum osmolality (and therefore shifting of brain water) is not the same with a 12 meq/L PNa change when you consider, for example, starting at a PNa of 110 vs. 125. Thus, you would not expect the risk of ODS to be the same in those two patients. This is confirmed by the fact that most cases of ODS have been reported at lower starting PNa levels. Other ODS risk factors should be considered such as cirrhosis, alcoholism, hypoK, hypophosphatemia, and malnutrition.
2. The discussants found one case of ODS following tolvaptan, but the PNa went from 126 to 167 over 3 days before tolvaptan was stopped: https://www.ncbi.nlm.nih.gov/pubmed/24511399. However, this was felt to be a mismanagement issue more than due to tolvaptan itself.
3. Even though ODS is rare following the treatment of "mild" hypoNa, cases of ODS have been reported with acute hypernatremia https://www.ncbi.nlm.nih.gov/pubmed/29277507 and hyperglycemia https://www.ncbi.nlm.nih.gov/pubmed/19565358 in which the starting PNa was relatively normal.
4. There was no consensus about whether or not you need to re-lower the PNa following an overly rapid correction in mild hypoNa. Data simply do not exist to guide us. However, the point was made that acute changes in brain water are always risky and that perhaps you should try to avoid these rapid changes when using tolvaptan for SIADH (syndrome of inappropriate antidiuretic hormone secretion). In that regard, there are two recent papers that report this phenomenon when using a starting dose of 15–30 mg: http://www.ajkd.org/article/S0272-6386(18)30004-0/fulltext and http://journals.sagepub.com/doi/full/10.5301/jon.5000025 . Both papers suggested using a starting dose of 7.5 mg.

Conclusion

ODS may be rare when using tolvaptan for mild hypoNa, and it is unknown if the PNa needs to be lowered in cases where the PNa increase exceeds standard recommendations. Using lower starting doses of tolvaptan may make this discussion moot. ■

Roger Rodby, MD, FASN, is Professor of Medicine at Rush University Medical Center and a Community Leader for the Patient Care Q&A ASN Community.

Fellows Corner

Renal Biopsies in the Elderly: Challenges and Caveats

By Manasi Bapat

Manasi Bapat

The first chapter of the American Society of Nephrology's Geriatric Nephrology Core Curriculum reminds us that "the degree of humanity in our healthcare world will be made evident in the way we treat (or do not treat) our minorities, our underprivileged, our poor, our mentally infirm, those who have no voice to speak for themselves, and finally, the aged" (1).

The elderly population is among the fastest growing in the United States and accounts for a large percentage of those with chronic kidney disease (CKD). Kidney senescence causes gradual structural loss and functional decline during aging. In addition, the natural progression of cardiovascular disease; other systemic diseases, such as malignancies; and the elderly's exposure to potential nephrotoxic drugs place these patients at particular risk for new or worsening kidney disease.

I recently cared for a frail 74-year-old woman in my nephrology clinic who had worsening CKD and a new diagnosis of smoldering multiple myeloma. Because she was otherwise asymptomatic, the decision regarding initiation of chemotherapy was dependent on whether she had renal manifestations of myeloma-related kidney disease. When the patient asked me if she really needed a renal biopsy, it made me want to dive deeper into the question "Renal biopsy in the elderly and very elderly: Useful or not?" that Bomback et al. (2) have addressed.

In the majority of the elderly population, a renal biopsy alone cannot differentiate between chronic age-related changes and disease-specific changes. Certain conditions, however, may require histologic details to form a clear-cut diagnosis and frame a management plan. A thorough evaluation of risk factors is mandatory to guide the decision to biopsy.

Many elderly patients are on anticoagulation and antiplatelet agents, and special attention is needed to determine which agents need to be held in order to perform biopsies safely. Kohli et al. (3) analyzed the rate of complications in 210 patients with native renal biopsies, 26 of which were done in elderly patients. The incidence of gross hematuria was higher in the elderly than in younger individuals (15% versus 3%), but the rate of severe complications (blood transfusions and perinephric hematomas) was similar between the two subgroups (3). Evidence suggests that the rate and type of complications in the elderly are not significantly different from those of the general population, and age alone should not be a contraindication for performing a renal biopsy (Table 1) (4).

In the current literature, biopsies in patients aged 65 years and older make up anywhere between 3% and 20% of total kidney biopsies done. However, 40% to 70% of biopsies in the elderly reveal lesions that would benefit from therapeutic interventions. Studies show that the two most common indications for biopsy in elderly populations are acute kidney injury and nephrotic syndrome of rapid onset. The two most common histologic findings in biopsies from these patients reveal membranous nephropathy (MN) and pauci-immune crescentic glomerulonephritis (4–6). Acute interstitial nephritis (AIN) is also exceedingly prevalent in the elderly. In one retrospective study from France, AIN was the most frequent histologic report. Histologic diagnosis in elderly patients may lead to targeted, successful treatment in 40% to 67% of patients or perhaps more important, advise against potentially harmful approaches (5–7).

Advanced age often raises concerns that renal lesions will be progressive. These patients usually have findings of fibrosis and sclerosis as a sequela of longstanding hypertension, atherosclerosis, and cardiovascular disease. There is also a question about risk versus benefit of the treatment strategies available (e.g., immunosuppressive and chemotherapeutic agents) as well as the likelihood of favorable response to therapy.

Because of the greater degree of progressive lesions and concomitant disease in elderly and very elderly patients, outcomes in these age groups have been worse than those in younger populations. Despite this, the literature still supports the use of conventional therapies in these age groups, including the use of immunosuppressive agents and cytotoxic therapies, with a general principle of using the lowest doses and the shortest durations to achieve the best results with the least toxicity (2). The decision to treat should be individualized on the basis of age, patient preference, long-term goals of care, and comorbid conditions.

Extensive research in epigenetics and DNA methylation experiments is currently underway to gain insight into mechanisms of disease and to develop useful biomarkers or prognostic indicators in disease courses. Epigenetic modifications in antineutrophil cytoplasmic antibody vasculitis are being investigated for potential insights into its pathogenesis and prediction of outcomes. There is an explosion of studies to discover novel biomarkers that may have a role in the detection of AKI and glomerular disorders (Gd-1gA1 for IgA nephropathy and suPAR for focal segmental glomerulosclerosis). Phospholipase A2 receptor is now increasingly being used as a marker for identifying primary membranous nephropathy since its discovery in 2009. These biomarkers could potentially allow noninvasive ways for clinicians to guide treatment decisions and even forgo renal biopsies in the elderly. Despite these exciting developments, renal biopsy remains the gold standard for the diagnosis of many kidney diseases.

Thankfully, my elderly patient ended up having an uneventful renal biopsy, which revealed chronic changes secondary to hypertension without any cast nephropathy or amyloidosis. She has managed to stay away from chemotherapy to date.

Manasi Bapat is a renal fellow at Mount Sinai Hospital in New York.

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Table 1
Post-biopsy complications

	Elderly (*n*=26)	Young (*n*=184)
Gross hematuria	4*	7
Perinephric hematoma	0	1
Need for blood transfusion/ hemodynamic compromise	0	4
intervention (bladder lavage due to clot obstruction)	0	1

* $P < 0.01$

Why Will Geriatric Nephrology Be an Important Area of Focus in Kidney Care in the Near Future?

By Jawed Areeba

With fertility in decline and life expectancy on the rise around the world, there are many unanswered questions that warrant answers in healthcare. Currently, living to age 70 or 80 years old is no longer considered a rarity in the developed world. However, longer lifespans have led to new challenges. How many years can older people expect to live in good health? Which chronic illnesses will affect these aging individuals? How will the rising cost of healthcare be accounted for? The world is facing these and many more questions as the population continues to age. Nephrologists need to direct their efforts and attention to the fastest-growing subset of patients with chronic kidney disease (CKD), which overwhelmingly includes those more than 65 years of age.

Challenges for the nephrologist in the face of an aging patient population

It is predicted that, from 2025 to 2050, the older population will almost double to 1.6 billion globally, whereas the total population will grow by merely 34%. Within the United States, the oldest populations, those at extremely old ages of 90 to 100 years or older, are growing faster than their younger counterparts, despite representing a small portion of the total population. From 1980 to 2010, U.S. Census data showed that the population of those 90 years old and older almost tripled and that those 100 years old and older increased by 65.8% compared with a doubling of the population ages 65 to 89 years old (1).

These numbers imply that nephrologists will now also be dealing with what seems to be a predominantly geriatric condition (i.e., CKD), a finding reinforced by National Health and Nutrition Examination Survey (NHANES) data that show the highest prevalence of CKD to be in the population subset more than 70 years of age (2). However, there are various criticisms of this dataset, including the methods used for estimated GFR assessment and its applicability to the older population along with conflicting opinions regarding age-related estimated GFR decline versus true increases in CKD prevalence related to the rising epidemic of obesity and diabetes (3), which remains the most common cause of CKD in the elderly population. Regardless of the arguments, as per the most recent U.S. Renal Data System report, ESRD prevalence was highest for the 65- to 74-year-old cohort. Although those 75 years old and older had the highest end stage renal disease (ESRD) incidence rate, lower prevalence was presumably because of higher mortality among these oldest ESRD patients (4).

When it comes to addressing the needs of the geriatric CKD population, there are several parameters that are unique and require special attention. These range from sifting through competing diagnoses and management options in the setting of multiple comorbidities to dealing with profound symptom burdens affecting quality of life, as well as helping patients with the much-feared decision of conservative versus aggressive renal care toward the end of life. This milieu of conflicting assessments and competing comorbid conditions requires the nephrologist to envision a holistic and geriatric-focused plan of care, where decisions regarding treatment of CKD and ESRD have grave socioeconomic, functional, psychological, and ethical implications.

The role of the nephrologist in the geriatric assessment

Despite having limited specific geriatric training, the nephrologist is expected to perform a wide range of services for the elderly, because they assume primary care responsibilities for the dialysis patient and for many of those with CKD.

The geriatric assessment is focused on maintaining the functionality of older individuals and requires a multidisciplinary approach with which the nephrologist is familiar. The components of a comprehensive geriatric assessment include those listed in Table 1 (5).

More recently, studies have shown that dialysis in the very elderly may not offer longevity (6) and, in fact, could contribute to a poorer functional status and declining quality of life, requiring nephrologists to be equipped with better tools to use when having these daunting conversations, which will help align the plan of care with the patient's goals and values. Current frameworks that have been developed to guide nephrologists include the Nephrotalk communication skills model, guidelines by the Renal Physicians Association, and educational resources developed by the Coalition for Supportive Care of Kidney Patients (7, 8).

The change in payment models and the rising cost of healthcare also necessitate nephrologists' responsibility for value-based decisions for their complex older patients. Nephrologists need to find solutions to financially unsustainable models, whereby dialysis patients make up the majority of Medicare spending toward end of life and fall at the bottom of hospice utilization, despite significant expected mortality (9).

Which areas of geriatric nephrology need additional focus?

There are many unanswered questions about the management of elderly patients with CKD. Of utmost concern are the issues in nephrology specifically affected by age and the effect of age on diagnosis and therapy in important ways. Broadly speaking, these unanswered questions can be divided into 1) knowledge gaps regarding issues of pathogenesis, diagnosis, and therapy in the geriatric patient with kidney disease, and 2) specific and unique aspects of care that confront the nephrologist of geriatric patients.

Nephrologists struggle with the variability in pathogenesis of the aging kidney and assessment of CKD in the older population because, unfortunately, most studies exclude this population subset. There is a lack of risk assessment tools to identify which patients will progress to ESRD and why some patients are protected from sharp declines in kidney function, which remain puzzling for most of us. Does the management of comorbid conditions, such as diabetes and hypertension, remain the same in the elderly?

In summary, to optimize the experience of the geriatric CKD patient, one needs more than the average set of nephrology skills. Adequate training in issues specific to geriatric nephrology coupled with a multidisciplinary approach, value-based decision making, and incorporation of palliative care skills into the care of these patients are key for providing comprehensive care to our older patients.

Table 1. Comprehensive geriatric assessment for the nephrologist

- Functional assessment, including ability to perform activities of daily living to identify patients who may be in need of additional resources
- Cognitive assessment using the Montreal Cognitive Assessment tool thought to be more sensitive for patients with CKD; this helps evaluate patients for decision-making capacity
- Recognizing polypharmacy in the elderly, the revised Beer Criteria can be used as a reference for interactions and side effects
- Managing mental and emotional health, including identifying and treating depression
- Assessing for mobility and risk of falls
- Nutrition parameters
- Sensory screening, including regular ophthalmologic and audiology examinations
- Advance care planning

Abbreviation: CKD = chronic kidney disease.

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Kidney Health Initiative Project Explores Cardiovascular Clinical Trials for People with Kidney Diseases

Kidney disease is common in people with cardiovascular disease (1, 2), and managing cardiovascular disease in people with kidney diseases is an important clinical problem. However, the evidence to support optimal management is hampered by the continual exclusion of people with kidney diseases from cardiovascular trials (1–4). In order to understand this problem and determine potential solutions, a Kidney Health Initiative (KHI) project aims to identify the barriers to involving people with kidney diseases—with a focus on those with advanced chronic kidney disease (stage 4) and end stage renal disease—in cardiovascular trials and strategies to overcome these challenges.

Achieving these aims requires input from a variety of stakeholders, including patients, academia, industry, academic and contract research organizations, and regulators. This is being accomplished through diverse representation on the workgroup, online surveys designed to elicit perspectives on barriers and solutions, and a workshop that will review the challenges and identify actionable strategies to address them. The results of the project will be detailed in a future white paper targeted for completion in late 2018.

Please visit the KHI website for more details about the project or to complete the online survey: https://www.asn-online.org/khi/project.aspx?ID=63.

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