ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Kidney News

July 2015 | Vol. 7, Number 7

Leveraging Electronic Health Records to Improve Care of Patients with CKD, Other Long-Term Conditions

By Tracy Hampton

While numerous research articles provide valuable insights on the potential of electronic health records (EHRs) to improve patient care, there continues to be a need to identify methods for more effectively designing and using EHRs, especially in the management of patients with chronic conditions. A new feature in the *Clinical Journal of the American Society of Nephrology (CJASN)* indicates that chronic kidney disease (CKD) may be an ideal model for identifying and evaluating such methods.

"CKD is common and its care is suboptimal, allowing significant room to show improvement as EHRs are optimized, and because CKD is defined by objective data, the disease is an ideal example of a condition that can be easily identified by information commonly found in EHRs," said co-author Uptal Patel, MD, of the Duke University School of Medicine. "CKD care also requires collaboration between diverse professionals across numerous health care settings, which could be facilitated by EHRs. Furthermore, CKD often heralds increased risk for hospitalizations, cardiovascular events, and all-cause mortality, so EHR-based improvements in CKD management may in turn improve care for these related conditions."

The potential of EHRs

Under the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, the US Department of Health and Human Services is spending billions of dollars to promote and expand the adoption of health information technology, with specific incentives designed to accelerate the adoption of EHR systems among providers.

EHRs can help clinicians monitor and care for patients with chronic conditions, increase the continuity of services patients receive, facilitate collaboration among providers, and support patient self-management. EHRs can also provide data for observational studies, help identify potential patients for research, and provide detailed information to national surveillance systems.

Several years ago, the US Centers for Disease Control and Prevention (CDC)

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Board Games: NBPAS, ABIM, and Maintenance of Certification

By Kurtis Pivert

The American Board of Internal Medicine (ABIM) maintenance of certification (MOC) program has generated controversy since its introduction in 2014. Physicians have expressed frustration with a process many find burdensome, costly, and irrelevant to their everyday practice.

Dissatisfaction with the new certification requirements led ABIM to suspend and revise parts of the initiative in February, but not before several leading physicians introduced an alternative to MOC. The National Board of Physicians and Surgeons (NBPAS) offers American Board of Medical Specialties (ABMS) board–certified physicians a choice for ongoing certification and lifelong learning. These developments have altered the landscape physicians must navigate to maintain their board certification and consequently their ability to practice.

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TINY CRYSTALS.
BIG PROBLEM.

Gout preys on more than just bones and joints— monosodium urate (MSU) crystals can deposit in the kidneys, spine, and soft tissues, including ligaments or tendons.[1,2] Even when patients are not flaring, these crystals can be associated with chronic inflammation, bone erosion, organ damage, and other systemic diseases.[2-6]

Keeping uric acid levels consistently <6 mg/dL—below the MSU saturation point—can dissolve existing crystals and prevent new crystal formation.[7-10]

Take a deeper look at TheRealGout.com

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References:

1. Paparo F, Zampogna G, Fabbro E, et al. Imaging of tophi with an extremity-dedicated MRI system. *Clin Exp Rheumatol.* 2011;29(3):519-526. **2.** Taylor JW, Grainger R. Clinical features of gout. In: Terkeltaub R, ed. *Gout and Other Crystal Arthropathies.* 1st ed. Philadelphia, PA: Elsevier Saunders; 2012:105-120. **3.** Dalbeth N, Stamp L. Hyperuricaemia and gout: time for a new staging system? *Ann Rheum Dis.* 2014;73(9):1598-1600. **4.** Schumacher HR Jr. The pathogenesis of gout. *Cleve Clin J Med.* 2008;75(suppl 5):S2-S4. **5.** Terkeltaub R, Edwards NL. Disease definition and overview of pathogenesis of hyperuricemia and gouty inflammation. In: Terkeltaub R, Edwards NL, eds. *Gout: Diagnosis and Management of Gouty Arthritis and Hyperuricemia.* 3rd ed. Durant, OK: Professional Communications, Inc; 2013:19-47. **6.** Terkeltaub R, Edwards NL. Clinical features and natural course. In: Terkeltaub R, Edwards NL, eds. *Gout: Diagnosis and Management of Gouty Arthritis and Hyperuricemia.* 3rd ed. Durant, OK: Professional Communications, Inc; 2013:69-84. **7.** Zhang W, Doherty M, Bardin T, et al. EULAR evidence based recommendations for gout. Part II: management. Report of a task force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). *Ann Rheum Dis.* 2006;65(10):1312-1324. **8.** Jordan KM, Cameron JS, Snaith M, et al. British Society for Rheumatology and British Health Professionals in Rheumatology guideline for the management of gout. *Rheumatology* (Oxford). 2007;46(8):1372-1374. **9.** Khanna D, Fitzgerald JD, Khanna PP, et al; 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. *Arthritis Care Res* (Hoboken). 2012;64(10):1431-1446. **10.** Sivera F, Andres M, Carmona L, et al. Multinational evidence-based recommendations for the diagnosis and management of gout: integrating systematic literature review and expert opinion of a broad panel of rheumatologists in the 3e initiative. *Ann Rheum Dis.* 2014;73(2):328-335.

Electronic Health Records

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noted the need for such a CKD surveillance system to help identify and track various aspects of CKD, and the agency pointed to the importance of having data sources such as EHRs and registries (Saran R et al. *Clin J Am Soc Nephrol* 2010; 5:152–161).

Early on, clinicians at the Cleveland Clinic developed a CKD registry at their institution and showed that it is reliable and valid in a large open health care system with an integrated EHR (Navaneethan SD et al. *Clin J Am Soc Nephrol* 2011; 6:40–49). The registry has allowed investigators to conduct an EHR-based clinical trial examining whether empowering patients with personal health records or patient navigators improves CKD care, along with identifying participants for other clinical trials and conducting health services research (Navaneethan SD et al. *Clin Nephrol* 2013; 79:175–183).

Also, the CDC has been collaborating with the University of California at San Francisco and the University of Michigan to implement a CKD surveillance system to track national trends in the number of cases, risk factors, and care practices that affect CKD prevention and control. In addition, the system is evaluating quality improvement efforts and monitoring kidney disease objectives for Healthy People 2020, which provides 14 objectives related to kidney disease (http://nccd.cdc.gov/CKD/default.aspx).

Optimizing EHRs to improve kidney disease care

Strategies to use existing EHRs to improve CKD and other chronic disease care are often developed in isolation, "which limits impact and forces individual health systems to recreate the wheel," Patel noted.

He and his colleagues, including lead author Paul Drawz, MD, MHS, MS, of the University of Minnesota, joined forces with the National Kidney Disease Education Program Health Information Technology Working Group to identify strategies for using EHRs to improve care for patients with CKD. In their *CJASN* article, they outline specific design features and goals for incorporating CKD-related data into EHRs—for example, the experts advocate for documenting CKD-related data (such as laboratory results and information related to risk factors and medical complications) into EHRs using standard code systems and units, and they recommend storing CKD-related data in formats that can be easily accessed by patients and clinicians. EHRs could also be used to develop CKD registries so that clinicians can manage panels of patients and coordinate care with other specialties.

"These strategies are absolutely on target for what's needed to create the CKD components of the Learning Health System, which is the notion of learning from structured EHR data shared from multiple health systems to identify at-risk populations and infer evidence-based approaches to improving quality and outcomes," said Brian Dixon, PhD, a faculty member at Indiana University's Fairbanks School of Public Health, who is not part of the working group but whose research focuses on the use of information systems to improve public health practice and clinical outcomes.

The concept of a continuous Learning Health System was first expressed by the Institute of Medicine and is now being adopted across the country and around the world (http://bit.ly/1cvuHrL). "Structuring data is an important precursor to making data available on CKD to enable surveillance, research, and quality improvement," Dixon said." The informatics work needed to improve CKD surveillance and research is not sexy but it is critical to achieving a high performing health system in the US."

With the implementation of the HITECH act, increasing numbers of hospitals and independent physician practices are implementing EHRs, said Sankar Navaneethan, MD, MPH, who helped establish the Cleveland Clinic's EHR-based CKD registry.

"In some states, there are ongoing initiatives to inter-link EHRs as this could reduce repetition of expensive investigations and improve communication between health care providers and health systems," he said. "Long-term studies examining whether such improved communication improves outcomes in kidney disease and other chronic conditions are warranted."

Because the possibility of improving CKD-related care with EHRs will require collaborations among primary care providers, nephrologists, and experts in public health, outcomes research, and bioinformatics, the National Institute of Diabetes and Digestive and Kidney Diseases will convene stakeholders in CKD health information technology, population health management, and research in the fall of 2015 to begin to identify pragmatic methods for seizing opportunities and overcoming challenges in using EHRs to manage CKD populations.

Study co-authors include Patrick Archdeacon, MD, Clement McDonald, MD, Neil Powe, MD, MPH, MBA, Kimberly Smith, MD, MS, Jenna Norton, MPH, Desmond E. Williams, MD, PhD, and Andrew Narva, MD.

Disclosures: The authors reported no financial disclosures.

The article, entitled "CKD as a Model for Improving Chronic Disease Care through Electronic Health Records," will appear online at http://cjasn.asnjournals.org/

PE Drawz, et al. CKD as a Model for Improving Chronic Disease Care through Electronic Health Records. *Clin J Am Soc Neph* CJN.00940115; published ahead of print June 25, 2015, doi:10.2215/CJN.00940115.

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KidneyNews

ASN Kidney News is published by the American Society of Nephrology
1510 H Street NW, Suite 800, Washington, DC 20005. Phone: 202-640-4660

www.asn-online.org

Postmaster: Please send address changes to *ASN Kidney News*, c/o Customer Service, American Society of Nephrology 1510 H Street NW, Suite 800, Washington, DC 20005.

Publications mail agreement No. 40624074. Return undeliverable Canadian addresses to PO Box 503, RPO West Beaver Creek, Richmond Hill ON L4B 4R6

ASN Kidney News (ISSN print 1943-8044 and online 1943-8052) is an official publication of the American Society of Nephrology, 1510 H Street NW #800, Washington DC 20005, and is published monthly. Periodicals postage paid at Washington, DC and at additional mailing offices. Subscription rates: $12 per year. To order, please email bhenkel@asn-online.org. Subscription prices subject to change. Annual ASN membership dues include $12 for *ASN Kidney News* subscription.

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SANOFI RENAL

Lifelong Learning in the 21st Century

By Adrienne Lea

For people who choose to become physicians, continually improving their knowledge is a hallmark of their profession and essential to improving patient care.

Like almost all working adults, doctors learn most, and most effectively, through informal (incidental) learning opportunities: knowledge gained on the job (1). Unlike most other working adults, physicians must regularly, and formally, demonstrate their knowledge to retain their ability to practice, admit patients, receive payor reimbursements, and hold academic positions.

The physician's focus on learning

Physicians have long focused on the value of improving their knowledge to improve treatment. The 13th-century Oath of Maimonides noted "Today he can discover his errors of yesterday and tomorrow he can obtain a new light on what he thinks himself sure of today"—an approach echoed by Sir William Osler: "…you will draw from your errors the very lessons which may enable you to avoid their repetition."

In 1935, the Philadelphia County Medical Society formed the Anesthesia Mortality Committee, a precursor to the now-familiar Morbidity and Mortality (M&M) Conference, "to facilitate discussion and to share knowledge about fatalities secondary to anesthesia, and other interesting anesthetic situations" (2). M&M conferences still constitute a potentially valuable teaching tool, although they vary considerably in structure and effectiveness.

The Accreditation Council for Continuing Medical Education (ACCME), established in 1981, was designed to develop a national system for providing continuing education to physicians in the United States. In 1982, the ACCME issued its first set of accreditation requirements, the Seven Essentials, and it now accredits 2000 organizations that offer 138,000 learning opportunities to 24 million health care professionals worldwide.

For many years, continuing medical education focused on didactic learning. However, didactic learning fails to incorporate some of the methods that have proved most effective in improving physician knowledge and, ultimately, patient care. In addition, many of these single-meeting lectures triggered skepticism among physicians regarding vested interests involved in disseminating what might—or might not—be advances in treatment. In 2004, the ACCME implemented stronger limitations on commercial interests, but presenting bias-free material in a complex and ever-changing industry like medicine will remain a perpetual challenge.

In recent years, accreditors have shifted somewhat to competency-based professional education, but how does one effectively gauge a physician's competency? As described in the article beginning on page 1 of this issue, current debate centers on how to accurately and fairly evaluate a physician's knowledge and performance over the course of a career.

The commitment to evolving care

The debate over physician recertification sometimes overshadows the reality that most physicians possess innate curiosity and a strong commitment to contributing to the evolution of patient care.

Physicians, like other adults, learn best when they are self-directed and can plan and evaluate their own learning; moreover, their learning increases based on the need to know (3). Interactive education that involves physicians in its planning and execution, and engages them as active learners, is more likely to influence changes in physicians' practice and performance that will exert a significant and positive effect on improving practice.

Recently some medical centers have developed new approaches to the M&M conference. The New Mexico Veterans Administration Health Center recently developed a "revised morbidity and mortality format" that involves interdisciplinary teams (4). The Agency for Healthcare Research and Quality now offers access to online M&M rounds at http://webmm.ahrq.gov/.

Technology may provide avenues to address two common complaints: that many recertification requirements do not reflect knowledge relevant to a physician's practice, and that they drain valuable time from a doctor's practice and personal life. The applied use of the electronic health record (EHR) may be potentially transformative: "The EHR should be explored as an aggregation point for professional development, a space in which physicians can continuously transfer questions and observations from practice and obtain answers to mature their expertise" (5). Similarly, the strategic use of data gleaned from registries and other emerging technologies may provide a wealth of patient data that is credible and useful to physicians in improving their treatment of patients.

The challenge to educators, accrediting organizations, and professional societies like the American Society of Nephrology is to evolve the provision and use of educational tools and assessment in ways that most support and advance physicians' desire to develop and improve patient care.

Adrienne Lea is a healthcare consultant.

References

1. Dobbs K. Simple moments of learning. *Training* 2000; 35:52–58.
2. Orlander JD, Barber TW, Fincke BG. The morbidity and mortality conference: the delicate nature of learning from error. *Acad Med* 2002; 77:1001–1006.
3. Knowles MS. *The Modern Practice of Adult Education*, New York, Cambridge, The Adult Education Company, 1980.
4. Gerstein WH, et al. Interdisciplinary quality improvement conference: using a revised morbidity and mortality format to focus on systems-based patient safety issues in a VA hospital: design and outcomes. *Am J Med Qual* 2014 Oct 20. doi 1062860614555430.
5. Moja L, Kwag KH. Point of care information services: a platform for self-directed continuing medical education for front line decision makers. *Postgrad Med J* 2015; 91:83–91.

Board Games

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No MOC and NBPAS

Designed to improve upon continuing medical education (CME), MOC was adopted by ABMS and their member boards in 2000. The program focuses on six core competencies—medical knowledge, patient care, professionalism, interpersonal communication, and personal and system improvement. In addition to the 10-year recertification exam requirement, ABIM's implementation added patient survey and patient safety modules, and public reporting of physician participation in MOC activities.

"Many physicians are upset about the recent changes to the MOC process, which we believe are onerous, time consuming, time wasting, and expensive," NBPAS President Paul Teirstein, MD, told *ASN Kidney News*. "The main reason why doctors care about certification is because hospitals, and some payers, require it for them to practice."

Teirstein, a leading interventional cardiologist, started an online petition—http://nomoc.org/—which became a rallying point, garnering more than 19,000 signatories. Sensing the demand for an alternative, he joined with other leaders in academic medicine to create NBPAS, a not-for-profit organization providing ongoing physician certification. "Why should the ABMS have a monopoly on continuing certification?" he asked. "There have to be different ways and people have different needs."

NBPAS ensures physicians are staying current with medical advances, have valid licensure, and have no outstanding issues, such as loss of hospital privileges. Instead of patient surveys and other MOC practice quality improvement activities, physicians have to complete 50 hours of CME every 24 months, as evidence of lifelong learning, to receive a 2-year NBPAS certification.

Both sides of the MOC divide point to evidence in the literature to support their positions—pro (ABMS [1] and ABIM [2]) and con (Teirstein [3, 4])—on MOC and the adequacy of CME for lifelong learning. Teirstein cites meta-analyses that show little correlation between actual MOC activities and improved patient outcomes, and points to potential conflicts of interest in ABMS's research. "We've looked carefully at the entire certification process and are trying to come up with a more reasonable and meaningful method of ensuring lifelong learning," he said.

A serious point of contention is the 10-year recertification exam, which Teirstein believes is meaningless. "It makes you study for things you don't know, and the reason you don't know them is that you don't need to know them."

Other MOC activities, such as the medical knowledge modules, may not be clinically relevant to an individual's practice. Still others, such as modules for patient safety, are redundant for physicians practicing in hospitals or other institutional settings.

"CME has tightened up quite a bit in the last decade," said Teirstein. Still, he believes there's room for improvement to ensure physician engagement and comprehension.

The American Medical Association (AMA) and other physician organizations have expressed concern about MOC's cost ($1940 for a 10-year ABIM certification in internal medicine, $2560 for any specialty) and have called on ABMS to ensure MOC "doesn't lead to unintentional economic hardships." Teirstein noted that NBPAS isn't focused on making money. "None of the doctors are getting paid and we're trying to charge very reasonable fees ($169 for a 2-year certification for all specialties)."

The path to acceptance

Yet acceptance of the new credentialing organization will take time. "This is a multi-month process," said Teirstein, "that requires physician champions at every hospital to push this through."

Because most hospitals require ABMS board certification, recognition of NBPAS certification necessitates changing the bylaws. Credentialing or medical executive committees must approve the change, before final approval from the board of trustees. Since committees usually only meet once a month, it can take several months to gain approval. Teirstein added it was still ongoing at his own institution.

At press time, NBPAS was set to announce eight hospitals had approved NBPAS certification for admitting privileges. "I expect to see a lot more hospitals approve it over the next couple of months and I think it will snowball from there," he added. However, it may take longer for payers to come on board. Blue Cross Blue Shield of Michigan recently announced it "does not intend to recognize NBPAS as a qualified board that meets our current standards for network participation."

"We got it wrong, and we're sorry."

A year after launching MOC, ABIM President and CEO Richard Baron, MD, announced major changes to the program, noting "ABIM clearly got it wrong," in a February 3, 2015, statement. These included suspending the Practice Assessment, Patient Voice, and Patient Safety requirements for at least 2 years; changing language reporting a diplomate's MOC status; updating the internal medicine MOC exam; and maintaining enrollment fees at or below the 2014 levels for 3 years.

ABIM recently released the new internal medicine exam blueprint to be administered fall 2015 (http://www.abim.org/pdf/blueprint/im_moc.pdf). Developed with community input, the blueprint provides granular details on exam content designed to be more relevant for internists. In addition, ABIM announced plans to provide improved feedback on exam performance to physicians.

As controversy around its MOC implementation grew, ABIM became a target of public scrutiny. A series of *Newsweek* articles by Kurt Eichenwald (5) raised questions about the organization's finances and alleged ABIM held a monopoly on certification. While nothing has been substantiated, some of ABIM's statements during this period have provoked discussion.

In his March 11, 2015, response to the *Newsweek* article, ABIM Board Chair David H. Johnson, MD, said physicians had "… a choice among certifying boards that certify physicians in internal medicine and its subspecialties." However, until NBPAS' formation in January, nephrologists had only two choices for maintaining specialty certification—ABIM and its osteopathic analogue the American Osteopathic Board of Internal Medicine (the American Board of Physician Specialties certifies internal medicine only).

In the wake of MOC, the AMA recently called for ABMS to develop "fiduciary standards" for member boards, and for full transparency for MOC costs.

ASN and lifelong learning

Throughout the MOC process, ASN has listened to members' concerns and conveyed them directly to the ABIM leadership. Over a series of meetings with ABIM, ASN also discussed issues surrounding ABIM governance, the new ABIM Nephrology Board, and potential effects related to conflicts of interest and commitment.

"ASN is taking a leadership role in addressing issues related to MOC," said ASN President Jonathan Himmelfarb, MD, FASN. "This includes making sure our members have access to information about alternatives to the ABIM process—including information about NBPAS—as well as opportunities for lifelong learning and the necessary tools to make MOC as painless as is possible."

"We strongly support the importance of ongoing physician education to ensure best patient care, and to support professional development," Himmelfarb told *Kidney News*. "ASN remains committed to helping our members navigate these complex issues."

The road ahead

Despite ABIM's decision to suspend some MOC activities, the program remains in effect, although it does not affect maintenance of licensure (MOL). The Federation of State Medical Boards (FSMB) has stated MOC is not required for MOL, and has emphasized the independence of each system. The Interstate Medical Licensure Compact, an FSMB initiative passed in seven states to date, also makes no reference to MOC because no state requires MOC as a condition of licensure.

The controversy surrounding MOC has been focused on standards to ensure physicians remain current with the latest medical advances. However, the implications of lifelong learning are wide reaching—involving every nexus in health care and affecting public trust in physicians and their ability to provide optimal patient care—which is why MOC remains a top priority for ASN and other physician organizations.

"We're at a tipping point now," said Teirstein. "We're looking to organizations such as ASN to help propel the movement to take back some control over the onerous requirements physicians have had to comply with."

ASN will host a Board Certification Forum special session on Friday, November 6, at 10:30 am PST at ASN Kidney Week 2015 in San Diego, CA. Teirstein will address the forum, which will be chaired by ASN leadership and give ASN members another opportunity to voice their concerns and opinions about the controversies in board certification and recertification.

Listen to the *ASN Kidney News* Podcast with Dr. Teirstein and ASN Executive Director Tod Ibrahim at https://www.asn-online.org/media/podcast.aspx. For more information, view ASN's comparison of certifying bodies (https://www.asn-online.org/education/moc/Certifying_Boards.pdf), and visit the ASN (https://www.asn-online.org/education/moc/), NBPAS (https://nbpas.org/), and ABIM (http://www.abim.org/) websites.

References

1. Irons MB, Nora LM. Maintenance of certification 2.0 — strong start, continued evolution. *N Engl J Med* 2015; 372:104–106.
2. Baron RJ. Professional self-regulation in a changing world: Old problems need new approaches. *JAMA* 2015; 313:1807–1808.
3. Teirstein PS, Topol EJ. The role of maintenance of certification programs in governance and professionalism. *JAMA* 2015; 313:1809–1810.
4. Teirstein PS. Boarded to death—why maintenance of certification is bad for doctors and patients. *N Engl J Med* 2015; 372:106–108.
5. Eichenwald K. The ugly civil war in American medicine. *Newsweek*. March 10, 2015. http://www.newsweek.com/2015/03/27/ugly-civil-war-american-medicine-312662.html

ERA-EDTA

Vitamin D Supplements Not Advised in First Year Post–Kidney Transplant

By Daniel M. Keller

Kidney transplant recipients with vitamin D deficiency who received vitamin D supplementation fared no better in the short term post-transplant than those who did not receive vitamin D. Supplementation may even have had adverse effects on the transplanted organs, a study shows.

Almost 90 percent of patients who receive renal allografts show a lack of vitamin D because of treatments with corticosteroids for immunosuppression as well as advice to avoid sun exposure because of an increased risk of cancer from immunosuppression. However, there has not been consensus about what to do for these patients.

Researchers led by Ursula Thiem, MD, of the Division of Nephrology and Dialysis at the Medical University of Vienna, Austria, conducted VITA-D, a large, randomized, placebo-controlled, double-blind trial among adult kidney transplant recipients whose calcidiol levels were less than 50 nmol/L (equivalent to 20 ng/mL). Patients (n = 203) were randomly assigned in a 1:1 ratio to receive either 6800 IU oral vitamin D3 daily or placebo for 1 year.

Outcome measures were renal function as assessed by serum creatinine, as well as the incidence of rejection episodes and infections at 1 year posttransplant. Rejection episodes and infections were weighted by severity to produce a monthly combined event rate. Analyses of only those patients who were compliant and completed the study were performed at 6 (n = 135) and 12 months (n = 123).

Thiem presented the study at the annual meeting of the European Renal Association—European Dialysis and Transplant Association conference in London in May.

Worse kidney function with vitamin D3 supplementation

At 12 months, patients who had received vitamin D3 supplements had worse allograft function than patients who had received placebo. A per protocol analysis showed that the serum creatinine level for the group taking the vitamin supplements was 1.545 mg/dL compared to 1.415 mg/dL for patients on placebo (p = 0.0157). Analysis at 6 months showed an even more dramatic difference: 1.61 mg/dL with supplementation vs. 1.43 mg/dL without (p = 0.0052). There were no differences between the groups in terms of the incidence of acute rejection episodes or infections.

The authors concluded that kidney transplant recipients' renal function was not improved in the short term by treatment of their vitamin D deficiency, and vitamin D supplementation may have even had negative effects on allograft function.

Senior author Kyra Borchhardt, MD, of the Medical University of Vienna and the Dialysis Institute Klagenfurt in Austria commented that the vitamin D3 dosing regimen in the study achieved adequate 25-hydroxyvitamin D levels in the majority of patients at 6 and 12 months. Nonetheless, any expected benefits on allograft function were not seen. The researchers had hypothesized that fewer rejection episodes and infections could improve allograft function, but "there was no difference in the incidence of infections and acute allograft rejections between vitamin D3-treated patients and control patients," she said.

She noted that the patients in the group receiving vitamin D3 supplements had received organs from significantly older donors, which could predispose them to worse outcomes. But once this and other possible confounding factors were controlled for, the negative treatment effect of vitamin D3 was still apparent at 6 and 12 months.

Although Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend vitamin D supplementation after kidney transplant, Borchhardt notes that KDIGO emphasizes that the recommendation is based on low-quality evidence because of a lack of randomized, controlled trials. In light of the VITA-D study results, "we believe that vitamin D therapy in the first year after kidney transplantation should be considered carefully and closely monitored for hypercalcemia." she said.

So far, the VITA-D investigators have not performed any subgroup analyses of their data, so the possibility remains that certain subgroups of patients could benefit by taking vitamin D post-transplant, Borchhardt said.

Pediatric Nephrology Workforce: Comprehensive Survey

A nationwide survey raises concerns of a potential shortage of pediatric nephrologists, according to a special report in the *American Journal of Kidney Diseases*.

Commissioned by the American Academy of Pediatrics, the 2013 e-mail survey yielded 504 responses from pediatric nephrologists trained or practicing in the US. Just over half of the respondents were men, but women accounted for more than 60 percent of more recent graduates. Two-thirds of respondents were US graduates, and nearly 80 percent were board certified in pediatric nephrology.

The 384 respondents based in the US worked long hours, averaging 56.5 hours per week for men and 53 for women. Nearly all participated in patient care; most also taught, did administrative work, and performed clinical research. About three-fourths worked in academic settings, and half worked in programs that teach pediatric nephrology fellows. Respondents reported a median of 16 weeks on call per year; about 30 percent had no partner or only one partner.

About one-third of US respondents said they planned to reduce or stop their pediatric nephrology practice within the next 5 years, and about half said that they planned to retire at least partially. Two-thirds of the US respondents said they competed for patients with other pediatric nephrologists in their area. Nearly half of the US division directors considered their division staffing to be inadequate. Many divisions lacked the full team of interdisciplinary professionals recommended for care of pediatric kidney disease.

The report highlights the characteristics and challenges facing the pediatric nephrology workforce. The authors discuss the implications for efforts to recruit qualified trainees, with attention to issues including work-life balance, compensation, and mentorship [Primack WA, et al. The US pediatric nephrology workforce: a report commissioned by the American Academy of Pediatrics. *Am J Kidney Dis* 2015; doi:10.1053/j.ajkd.2015.03.022].

Kidney Markers May Help Predict Cardiovascular Outcomes

Key measures of chronic kidney disease (CKD) can improve prediction of cardiovascular outcomes, suggests a meta-analysis in *Lancet Diabetes and Endocrinology*.

The analysis included individual-level data on more than 637,000 individuals with no history of cardiovascular disease, drawn from 24 cohorts included in the Chronic Kidney Disease Prognosis Consortium. The median follow-up times ranged from 4 to 19 years. The study focused on the cardiovascular predictive value achieved by adding creatinine-based estimated GFR (eGFR), albuminuria, or both to traditional risk factors. Albuminuria was assessed by either albumin-to-creatinine ratio (ACR) or dipstick proteinuria. The 5-year outcomes of interest were cardiovascular mortality and fatal or nonfatal coronary heart disease, stroke, and heart failure.

In general populations, adding eGFR and ACR to traditional risk factors significantly improved discrimination. The greatest improvements were seen for cardiovascular mortality, with C statistic differences of 0.0139 for ACR and 0.0065 for eGFR; and heart failure, with differences of 0.0196 and 0.0109, respectively. Dipstick proteinuria had less predictive value than did ACR.

Adding eGFR and ACR to predictive models offered the best discrimination improvement in patients with diabetes or hypertension. However, ACR still had significant predictive value for cardiovascular death or heart failure in patients with neither of those conditions. For patients with CKD, the combination of eGFR and ACR had better risk discrimination than did traditional risk factors.

There are conflicting data as to whether key measures of kidney health are relevant to cardiovascular risk prediction. This meta-analysis suggests that eGFR and ACR have significant cardiovascular predictive value and should be considered when these measures are already available or if there is special interest in assessing the risk of cardiovascular death or heart failure [Matsushita K, et al. Estimated glomerular filtration rate and albuminuria for prediction of cardiovascular outcomes: a collaborative meta-analysis of individual participant data. *Lancet Diabetes Endocrinol* 2015; doi:10.1016/S2213-8587(15)00040-6].

ERA-EDTA

Supportive Therapy Can Be as Good as Immunosuppression in IgA Nephropathy

By Daniel M. Keller

Optimal supportive therapy (SUP) can obviate the need for immunosuppression in treating progressive IgA nephropathy (IgAN), a new study shows. Among patients with biopsy-proven IgAN, SUP drove 30 percent of them into a low-risk category, slowing their loss of renal function and overcoming the benefits of immunosuppression.

For the prospective Supportive Versus Immunosuppressive Therapy for Progressive IgA Nephropathy (STOP-IgAN) trial, eligible adult patients at 32 nephrology centers underwent a 6-month run-in phase of SUP using antihypertensive, antiproteinuric (ACE inhibitor or angiotensin-receptor blocker), and statin medications as well as dietary counseling. Patients with persistent proteinuria >0.75 g/day at the end of the run-in were randomly assigned in an open-label manner to SUP or to SUP plus immunosuppressive therapy for 3 years.

At the 52nd annual meeting of the European Renal Association—European Dialysis and Transplant Association conference in London in May 2015, Jürgen Floege, MD, Director of the Division of Nephrology at RWTH Aachen University in Germany, reported that of 309 patients who completed the run-in phase, 94 (30%) achieved a reduction of proteinuria to <0.75 g/day on SUP. These patients were therefore "low-risk" for progression and did not enter the randomized treatment phase.

After accounting for patients who dropped out or refused randomization, 80 patients were assigned to SUP and 82 to SUP plus immunosuppression with corticosteroids alone or in combination therapy.

Equivalent proportions progressed regardless of immunosuppression

At 3 years there was no significant difference in the proportion of patients in each arm of the randomized phase of the trial whose disease progressed, defined as loss in estimated glomerular filtration rate (eGFR) of at least 15 mL/min compared to baseline. In the SUP-alone group, 24 patients (30%) had such an eGFR loss vs. 28 patients (34%) in the SUP plus immunosuppression group (p = 0.602).

A minority of patients in each arm of the randomized phase of the trial reached full clinical remission at 3 years, defined as proteinuria <0.2 g/day and an eGFR loss of <5 mL/min, although the group receiving immunosuppression did significantly better. Only 4 patients (5%) in the SUP arm were in remission versus 14 patients (17%) who achieved full clinical remission in the SUP plus immunosuppression arm (p = 0.011).

"There seems to be a benefit of immunosuppresssion for some IgAN patients as indicated by the higher number of patients achieving full clinical remission," Floege concluded. "However, this benefit is not accompanied by any detectable effect on functional loss," as measured by eGFR decline. He noted that immunosuppressive treatment was accompanied by more serious adverse effects, including infections, diabetes, and weight gain.

The value of immunosuppression on top of SUP in the treatment of IgAN is controversial. Recent reports of the European Validation Study of the Oxford Classification of IgAN (VALIGA) trial indicated that immunosuppression was associated with significant reductions in proteinuria and in renal functional decline and with increased renal survival. The benefits were seen regardless of initial eGFR and with greater benefit at higher levels of proteinuria.

However, Floege noted that VALIGA was based on a retrospective analysis, "and it would not be the first time that a prospective, randomized study has refuted what was previously indicated by observational studies," adding that STOP-IgAN is the largest randomized clinical trial that has addressed the question of immunosuppressive therapy in IgAN. A key difference between STOP-IgAN and previous trials also may be that STOP-IgAN achieved "very strict blood pressure control" during the run-in phase and throughout the ensuing 3 years of the trial, he said.

Floege said an implication of STOP-IgAN for clinical practice is that "intensified, supportive therapy" with maximized antihypertensive and antiproteinuric medication "should always be provided initially." If the desired outcomes are not achieved, then immunosuppression may be considered for patients with proteinuria up to 1.5 g/day. However, his results indicated that higher levels of proteinuria do not seem to benefit from immunosuppression, and these patients should therefore be spared the side effects of such treatment without an adequate prospect of success.

Delayed Graft Function Varies Between Transplantation Centers

Transplantation centers vary widely in their rates of delayed graft function (DGF) after deceased-donor kidney transplantation, reports a study in *Transplantation*.

The study used data on more than 82,000 patients receiving deceased-donor kidney transplants at centers in the US between 2003 and 2012, drawn from the Scientific Registry of Transplant Recipients. The association between center characteristics and DGF was assessed, with adjustment for identified patient risk factors.

Delayed graft function, defined as the need for dialysis during the first week after transplantation, occurred in 27.0 percent of patients. Across the 177 transplantation centers, DGF incidence ranged from 2.3 to 63.3 percent, with an interquartile range of 18.7 to 33.8 percent.

Center-level factors associated with a lower likelihood of DGF included the proportion of pre-emptive transplantations, odds ratio (OR) 0.83 per 5 percent increment; and percentage of kidneys with cold ischemia time of 30 hours or longer, OR 0.95 per 5 percent increment. Factors associated with more DGF were the center's proportion of donation of cardiac death, OR 1.12 per 5 percent increment; and imported kidneys, OR 1.06 per 5 percent increment.

In a combined patient-level and center-level logistic model, 41.8 percent of centers had a DGF incidence in line with the national median. The predicted incidence was above the median for 28.2 percent of centers and below the median for 29.9 percent.

Although patient-level factors associated with DGF are well established, little is known about differences in DGF between transplantation centers. This study found significant variations in DGF between centers, even after adjustment for patient-level and center-level factors.

The authors note that their findings may reflect the subjective nature of the decision to begin dialysis in patients during the first week after transplantation [Orandi BJ, et al. Center-level variation in the development of delayed graft function after deceased donor kidney transplantation. *Transplantation* 2015; 99:997–1002].

APOL1 Genotype Affects Outcomes of Transplantation from African American Donors

The presence of *APOL1* gene variants in African American kidney donors influences the risk of allograft failure after kidney transplantation, reports a study in *American Journal of Transplantation*.

The researchers performed genotyping for apolipoprotein L1 gene G1 and G2 variants in DNA samples from African American deceased donors of kidneys recovered, transplanted, or both in Alabama and North Carolina. The association of APOL1 genotype findings with kidney transplantation outcomes at 55 centers was assessed. The findings were adjusted for recipient age, sex, and race/ethnicity; HLA matching; cold ischemia time; panel reactive antibody levels; and donor type.

Analysis of 221 kidneys recovered in Alabama showed a trend toward shorter allograft survival in patients receiving kidneys with two *APOL1* risk variants. For the total of 675 transplanted kidneys, allograft failure risk was significantly increased with *APOL1* genotype, hazard ratio 2.26; and African American donor race/ethnicity, hazard ratio 1.60. For 99 kidneys with two APOL1 risk variants, allograft survival decreased from 89.3 percent at 1 year to 73.0 percent at 5 years to 54.5 percent at 10 years.

A previous single-center study reported lower renal allograft survival associated with *APOL1* risk variants in African American deceased kidney donors. The new findings in a large, multicenter sample of African American donors show an increased risk of allograft failure after transplantation of kidneys with two *APOL1* nephropathy variants. "These findings warrant consideration of rapidly genotyping deceased African American kidney donors for *APOL1* risk variants at organ recovery and incorporation of results into allocation and informed-consent processes," the researchers write. [Freedman BI, et al. Apolipoprotein L1 gene variants in deceased organ donors are associated with renal allograft failure. *Am J Transplant* 2015; 15:1615–1622].

Findings

Options for BP Control in Diabetic Kidney Disease

No BP-lowering medication strategy leads to increased survival in diabetic patients with kidney disease, concludes a network meta-analysis in *The Lancet*.

A systematic literature search was performed to identify randomized trials comparing the outcomes of treatment with oral BP-lowering drugs in adults with diabetes and kidney disease. A random-effects network meta-analysis included 157 studies comprising more than 43,000 patients—most with type 2 diabetes and chronic kidney disease. All-cause mortality and ESRD were the main outcomes of interest; secondary safety and cardiovascular outcomes were evaluated as well.

The analysis identified no drug treatment that reduced all-cause mortality, compared with placebo. However, strategies using an angiotensin-receptor blocker (ARB) were associated with a significant reduction in ESRD compared with placebo. The odds ratios for this outcome were 0.77 with ARB monotherapy and 0.62 with ARB plus an angiotensin-converting enzyme inhibitor. The results for the primary outcomes were "generally robust" in sensitivity analyses.

No treatment strategy was associated with an increased risk of hyperkalemia or acute kidney injury. However, the combination of ARB and angiotensin-converting enzyme (ACE) inhibitor was associated with borderline increases, making it the lowest-ranked treatment for both safety outcomes.

There is continued debate over the relative safety and efficacy of different BP-lowering drugs, mainly because of the lack of head-to-head comparisons. Although ARBs and ACE inhibitors are assumed to be clinically equivalent, their concurrent use is not recommended.

Within its limitations, the network meta-analysis suggests that no BP-lowering treatment reduces mortality in diabetic patients with kidney disease. The use of ARBs and ACE inhibitors, alone or in combination, appears most effective against ESRD. The authors emphasize the need for close follow-up for treatment-related acute kidney injury and hyperkalemia in patients receiving these drugs [Palmer SC, et al. Comparative efficacy and safety of blood pressure-lowering agents in adults with diabetes and kidney disease: a network meta-analysis. *Lancet* 2015; 385:2047–2056].

Strict BP Control May Reduce Mortality from ESRD

Although strict BP control doesn't slow progression from chronic kidney disease (CKD) to ESRD, it is associated with a lower risk of death after ESRD develops, reports a study in *Kidney International*.

The study presents extended follow-up of patients enrolled in the Modification of Diet in Renal Disease (MDRD) trial. In that study, 840 patients with CKD were assigned to strict or usual BP control; the mean arterial pressure targets were less than 92 mm Hg versus 107 mm Hg, respectively. The occurrence of ESRD and death were determined by linkage to the U.S. Renal Data System and National Death Index.

At a median follow-up time of 19.3 years, ESRD developed in 627 patients, with no significant difference between the two BP strategies. A median of 10 years after the occurrence of ESRD, there were 142 deaths in the strict control group versus 182 in the usual control group: 4.4 versus 6.1 deaths per 100 person-years, respectively.

With strict control, the unadjusted hazard ratio for death after the onset of ESRD was 0.72. On analysis regardless of ESRD status, strict BP control was also associated with a lower risk of death. Patients in the usual care group were more likely to have coronary artery disease and congestive heart failure at the time of ESRD diagnosis.

Few studies have examined how BP control and other CKD treatments affect clinical outcomes after ESRD develops. The new study suggests that patients receiving strict control have a lower long-term risk of death after incident ESRD. Further studies are needed to confirm this finding and its relationship to cardiovascular health status at ESRD onset [Ku E, et al. Association between strict blood pressure control during chronic kidney disease and lower mortality after onset of end-stage renal disease. *Kidney Int* 2015; 87:1055–1060].

"Kicking CAUTI" Lowers Antibiotic Use for Asymptomatic Bacteriuria

An "antimicrobial stewardship" program can reduce antibiotic overuse in patients with asymptomatic bacteriuria (ASB) related to urinary catheters, according to a study in *JAMA Internal Medicine*.

The researchers developed the "Kicking CAUTI" intervention as a new approach targeting inappropriate treatment of ASB. The program focused on the reduction of urine culture ordering, with elements that included a case-based audit and streamlined diagnostic algorithm. Preintervention and postintervention comparisons were carried out at two Veterans Affairs health care systems, including patients with urinary catheters on acute medical and long-term care units. The main outcomes were urine cultures ordered and antibiotic prescriptions for patients with ASB—defined as positive urine culture with no signs or symptoms.

During the intervention period, urine culture ordering decreased from 41.2 to 23.3 per 1000 bed-days: incidence rate ratio (IRR) 0.57. During a subsequent maintenance period, there was a further reduction to 12.0 per 1000 bed-days: IRR 0.29. The rate of ASB overtreatment decreased from 1.6 to 0.6 per 1000 bed-days, IRR 0.35, and then to 0.4 per 1000 bed-days, IRR 0.23.

Comparison of sites showed no change in either outcome. The intervention effect on ASB overtreatment was significant on long-term care wards.

The challenges of differentiating ASB from catheter-associated urinary tract infection can lead to overtreatment of asymptomatic patients with positive cultures. The guidelines-based Kicking CAUTI intervention led to sustainable improvements in antimicrobial overuse for ASB without reducing appropriate treatment. Long-term care may be "an emerging domain for antimicrobial stewardship," the researchers write [Trautner BW, et al. Effectiveness of an antimicrobial stewardship approach for urinary catheter associated asymptomatic bacteriuria. *JAMA Intern Med* 2015; doi:10.1001/jamainternmed.2015.1878].

Diagnostic Errors Are Key Source of Inappropriate Antibiotic Use

Inaccurate diagnosis is an important contributor to inappropriate antimicrobial prescribing for hospitalized patients, according to a report in *Infection Control and Hospital Epidemiology*.

The retrospective analysis included a random sample of 500 patients receiving systemic antimicrobial drug treatment during a stay at a Veterans Affairs hospital. In blinded fashion, a panel of infectious disease physicians rated the accuracy of the initial diagnosis and the appropriateness of treatment.

The initial diagnosis was rated correct in 58 percent of cases, incorrect in 31 percent, and of indeterminate accuracy in 4 percent. In the remaining 6 percent of cases, the "diagnosis" was actually a sign or symptom rather than a disease or syndrome. Cystitis, pyelonephritis, and urosepsis were the diagnoses with the lowest rate of agreement between providers and reviewers—just 27 percent. The agreement rate for pneumonia was 48 percent.

Antimicrobial treatment was considered appropriate for 62 percent of cases when the diagnosis was correct but only 5 percent when the diagnosis was incorrect, indeterminate, or a sign or symptom. On analysis of 309 instances of inappropriate treatment, an incorrect antimicrobial was chosen for 73 percent of patients with a correct diagnosis. In cases of diagnostic error, antimicrobial treatment was not indicated in 84 percent of cases.

The study builds on previous results showing that inappropriate antimicrobial prescribing for hospitalized patients is often related to diagnostic error. Factors that may contribute to inaccurate diagnosis and inappropriate antibiotic use include reliance on intuitive processes, fatigue, previous diagnoses from other providers, and lack of experience [Filice GA, et al. Diagnostic errors that lead to inappropriate antimicrobial use. *Infect Control Hosp Epidemiol* 2015; doi:10.1017/ice.2015.113].

Home Hemodialysis:

Thoughts from a Practicing Nephrologist

By Andrew King

"It is much more important to know what sort of a patient has a disease than what sort of disease the patient has."

— Sir William Osler

What do our patients with ESRD want? They want to stay alive, to feel well, to be autonomous and to continue to be valued by their family and community. To achieve these goals, dialysis in the home, whether by peritoneal dialysis (PD) or by home hemodialysis, remains the best option for many. Why then does the percentage of home patients remain stubbornly low, and where does home hemodialysis fit in?

Although the answer to this question is multifaceted, the community of nephrologists must first look in the mirror and accept the brunt of responsibility. The choice of dialysis modality requires the managing nephrologist to be proactive, creative, and to firmly believe in the patient's ability and right to make his own informed choice. Being proactive means believing that dialysis options provided by trained personnel (not the time-constrained nephrologist) are an essential part of management, even for those patients who land in the hospital with ESRD and invariably find themselves in-center with a central venous catheter.

We must advise, but not dictate, what is right for any individual. Being proactive also means forcing yourself to become competent and comfortable with PD and home hemodialysis, despite any prior deficiencies in training. It means demanding that your dialysis provider create a competent home program and if they do not, that you send the patient elsewhere. It means not relinquishing decisions regarding what is best for your patient and the community to large dialysis organizations, intermediaries, and the Centers for Medicare & Medicaid Services (CMS). As practicing nephrologists, we must act in the best interests of our patients.

This proactive and creative spirit needs to extend to making home hemodialysis an option for our patients. Although successful home hemodialysis dates back to the beginning of renal replacement therapy, rapid technological advances have made this a more viable option. Confusion and hesitancy by practicing nephrologists is understandable, but this needs to be a challenge that we undertake—and eventually overcome.

Making sense of the emerging literature is difficult, especially related to the wide range of dialysis prescriptions being assessed (number of treatments, nocturnal vs. short daily home dialysis, etc.), the small sample sizes, and the nuances of dialysis dose related to available machines (e.g., NxStage). Many of us were never exposed to home hemodialysis patients during training and are unfamiliar with current technology. These challenges can be overcome, just as happened in the early days of PD or in-center hemodialysis. The key to success in home hemodialysis (and PD) is a well run home program, the scarcity of which is likely the greatest impediment for most nephrologists. What is more difficult is the threat of CMS intermediaries effectively squashing this modality in its infancy by making it economically non-viable. The recent communications from Noridian (https://med.noridianmedicare.com/web/jeb/policies/coverage-articles/hemodialysis-frequency) and other intermediaries regarding reimbursement of additional treatments had a chilling effect on those who deliver this modality.

Will home hemodialysis fulfill the need to increase value in the care of ESRD? That is, will it increase quality of care while being cost-effective? The jury is out on this question as it is for many of our interventions.

The Frequency of Dialysis Network data supports the possible quality benefits of additional treatments (1), but how does that endorsement apply to the NxStage machine, where clearance rates are lower? Recent data suggest that hospitalization rates for Medicare patients on home hemodialysis are equivalent to those for in-center hemodialysis, calling into question the promise of reduced total cost of care (2). Admissions for septicemia were higher for home hemodialysis, whereas those for heart failure were lower. Patient selection is likely a large modifier of the value equation for home hemodialysis. Review of the past 8 years of our experience suggests that the home hemodialysis population we serve is not reflective of the general dialysis population; it is divided into healthy individuals wanting to continue busy work schedules and extremely sick patients who have failed in-center (e.g., owing to persistent hypotension, congestive heart failure, or inability to travel to the dialysis unit).

The question of value related to home hemodialysis will require larger clinical trials and more in-depth analysis of current practices. As with all areas of medicine, the answer to this question is a moving target related to rapid technological advances and greater understanding of what is needed to support the patient at home. The improvement of survival over the past decade for PD has exceeded that for in-center hemodialysis perhaps in part owing to better home dialysis programs (3). Similar advances are likely to occur for home hemodialysis.

Addressing the questions of quality and cost-effectiveness in a rigorous fashion is our obligation. It is also the obligation of CMS and its intermediaries to not put undue economic barriers on innovation. For those on the ground, including physicians, facility personnel, and patients, there is little doubt that home hemodialysis has a role to play in the management of ESRD. What most patients want is to live, not just to stay alive. To achieve this goal, we as nephrologists must be creative and proactive.

1. The FHN Trial Group. In-center hemodialysis six times per week versus three times per week. *N Engl J Med 2010*; 363: 2287–2300. http://www.nejm.org/doi/full/10.1056/NEJMoa1001593

2. Weinhandl, ED, et al. Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. *Am J Kidney Dis*; 2015, 65:98. http://www.ajkd.org/article/S0272-6386%2814%2900973-1/abstract

3. Schaubel, DE, et al. Effect of renal center characteristic on mortality and technique failure on peritoneal dialysis. *Kidney Int* 2001; 60:1517. http://www.nature.com/ki/journal/v60/n4/abs/4492573a.html

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Why Are International Medical Graduates Not Choosing Nephrology?

By Fahad Saeed and Jean L. Holley

Recently, a substantial decline in interest in the field of nephrology has occurred, not only among medical graduates in the US (USMGs) but also among international medical graduates (IMGs) (1). Factors such as lifestyle, income potential, job opportunities, and others have been discussed (2), but little is known about the declining interest of IMGs. This article is a personal narrative of the first author on why he chose nephrology as a career. The article will also communicate the gist of our conversations and email communications with our IMG colleagues about these questions:

- Why did they not choose nephrology?
- Why have they not chosen nephrology as their subspecialty?
- Why are they not practicing nephrology despite having completed formal fellowship training?
- Why would they not advise other people to choose this field?

I am an IMG currently working as a faculty member in the department of nephrology and hypertension at the Cleveland Clinic. During my years of training and appointment as a faculty member, I have been a mentor to many talented IMGs, both formally and informally. I did not develop my interest in nephrology during my medical school training but found it to be quite interesting during my residency.

One of the main reasons I became interested in nephrology was that I had the good fortune to work with a great role model and mentor who was also a nephrologist at my residency training institute, a community-based hospital with an academic affiliation. She led case conferences, and presented the subject matter in a very interesting way. The complexities of renal physiology, the delicacies of acid-base and electrolyte disorders, and the challenges of glomerulonephritis management, when presented in a logical and understandable way, eventually led to my decision to choose nephrology as a career. My residency program also offered me the opportunity of a formal mentee–mentor relationship that not only helped me in developing a research project during my residency but also inculcated a lifelong habit of intellectual curiosity. In my case, one single mentored research project led to several other research projects and a persisting interest in clinical research even after I had matched with a nephrology training program.

My personal story highlights the important fact that even in a semiacademic institution, role modeling and research opportunities can inspire residents to choose a particular field and even pursue an academic career in that field.

In our observation, declining interest in nephrology is not restricted to the US but affects other countries as well. This is documented by the recent match results for nephrology fellowship positions (3).

Nephrology concepts at times can be hard to understand and, if not taught in an approachable and interesting way, can lead to disinterest in this fascinating specialty. Recent efforts by the American Society of Nephrology through the renal educators' listserv, sessions on nephrology education at the annual meeting, and travel grants and learning sessions for medical students and residents at Kidney Week attest to the realization that teaching clinical nephrology is important to our specialty. Additional research examining the trends of formal medical school teaching in nephrology may be helpful. More collaborative efforts between nephrology societies across the globe to formulate a standard nephrology curriculum and medical student teaching strategies may also be useful. A nephrology lecture series by renowned educators across the world could be organized and may attract more talented medical students to nephrology.

Many IMGs have the privilege of serving and training in internal medicine programs in community-based teaching hospitals, where they may or may not be exposed to well-rounded faculty members who can serve as role models and attract them to the field of nephrology. Many of the attendees in such programs are in private or group nephrology practices and are not necessarily committed to teaching. Perhaps formal teaching workshops for such community physicians who also hold teaching appointments at community hospitals could be arranged. Nephrology societies could organize such programs along the lines of regional nephrology reviews and provide continuing medical education credits. Exceptional nephrology teachers could be recruited as faculty for these programs and could share their tips for making clinical nephrology attractive to residents as a career choice.

Visa issues, future job prospects, and nephrology

Visa issues and future job prospects were not the primary focus of the first author in selecting a subspecialty for additional training. But not everyone makes decisions based solely on passion and interest in a field. For some IMGs, visa issues can make or break the deal in choosing a career (2).

Two types of visas are available for those wishing to do residency and fellowship training in the United States: the H1-B visa and the J-1 visa. Ordinarily, an H1-B visa can be extended for a total of 6 years. An H1-B visa holder can spare the sixth year to file for a green card, which is usually employer-based, and the IMG physician is still able to work under that visa. A total visa duration of 6 years makes it challenging for some IMGs to pursue additional training years in research, although it is theoretically possible if an employer sponsors a green card application during the IMG's second or third year of fellowship. However, academic institutions typically do not hire a faculty member 1 or 2 years in advance. This situation may result in fewer candidates choosing research careers, despite the desire of many talented IMG physicians in training. It is also important to note that H1-B visa sponsorship legally requires programs to pay for the sponsorship fee, an unattractive option for some programs.

A J-1 visa held by an IMG candidate can be extended for a total of 7 years. However, this visa option is tied to a requirement that the IMG practice for 3 years in an underserved area or return to his or her home country for 2 years to change immigration status and then be eligible for long-term residency in the United States. This whole process can take several years, depending on the country of origin. From the research training standpoint, if a J-1 visa holder does an extra research training year, the chances of pursuing a research academic career are small because the waiver requirement of 3 years of practice in an underserved area of the United States or 2 years in the home country would still need to be completed. If only a clinical fellowship is completed, finding a decent job in an underserved area at times may be difficult. There is some concern that a future employer may take advantage of the nephrologist with a J-1 visa because of the legal requirement of practicing in an underserved area and relatively fewer decent job opportunities (2). Training programs have no financial obligation to pay for visa fees for J-1 visa holders.

Hospitalist medicine and nephrology

The declining interest in nephrology perhaps parallels the rise in hospitalist medicine. Hospital medicine offers several potential advantages to IMGs, such as more geographic options, a better job market, and relaxed timelines for filing green card applications. The more favorable work schedules of hospitalist jobs are equally attractive to both USMGs and IMGs. The prospects of income in this field may be similar or slightly better, or they may be worse.

Some IMGs who train in nephrology choose a hospitalist job because of better opportunities in terms of geographic location and income. Typically, hospitalist employers may sponsor a green card ahead of time for a more qualified physician who has received advanced training in a subspecialty field and has taken care of patients with very complicated conditions. Many IMGs have heard the statement from recruiters that "nephrologists make excellent hospitalists." Our IMG colleagues who have chosen to become hospitalists invariably base this decision on lifestyle, geographic preference, and easy-to-find green card jobs in a better location and—more importantly—in a timely fashion. Frequently, they aspire to return to nephrology, either full time or part time. Their hope is to make connections with local nephrology groups that will help them find a job and resolve immigration issues. However, depending on the time required for processing a green card, the available job opportunities in their preferred area, and the duration of a partnership track, IMGs may return to nephrology after several years or, in some cases, choose to continue a career in hospital medicine.

Although there are no easy solutions to these issues, a change in legislation regarding visa options to prevent a workforce crisis in nephrology may be of value. Changes to visa requirements may also attract more IMGs to fellowship training in nephrology. Collaboration by the international nephrology societies may be of value in preventing the global future workforce shortage we face. And attracting IMGs to nephrology may best begin in their medical schools and extend to residency training programs in community hospitals here in the United States, where enthusiastic, committed nephrologists can be seen as excellent teachers and role models.

References

1. ASN NRMP SMS Nephrology Match for Appointment Year 2015. https://www.asn-online.org/education/training/workforce/ASN_NRMP_SMS_2015_Analysis.pdf.
2. Salsberg E, Masselink L, Wu X. *Findings from The 2014 Survey of Nephrology Fellows*. Washington, DC: American Society of Nephrology; 2015.
3. Field M. Addressing the global shortage of nephrologists. *Nat Clin Pract Nephrol* 2008; 4:583.

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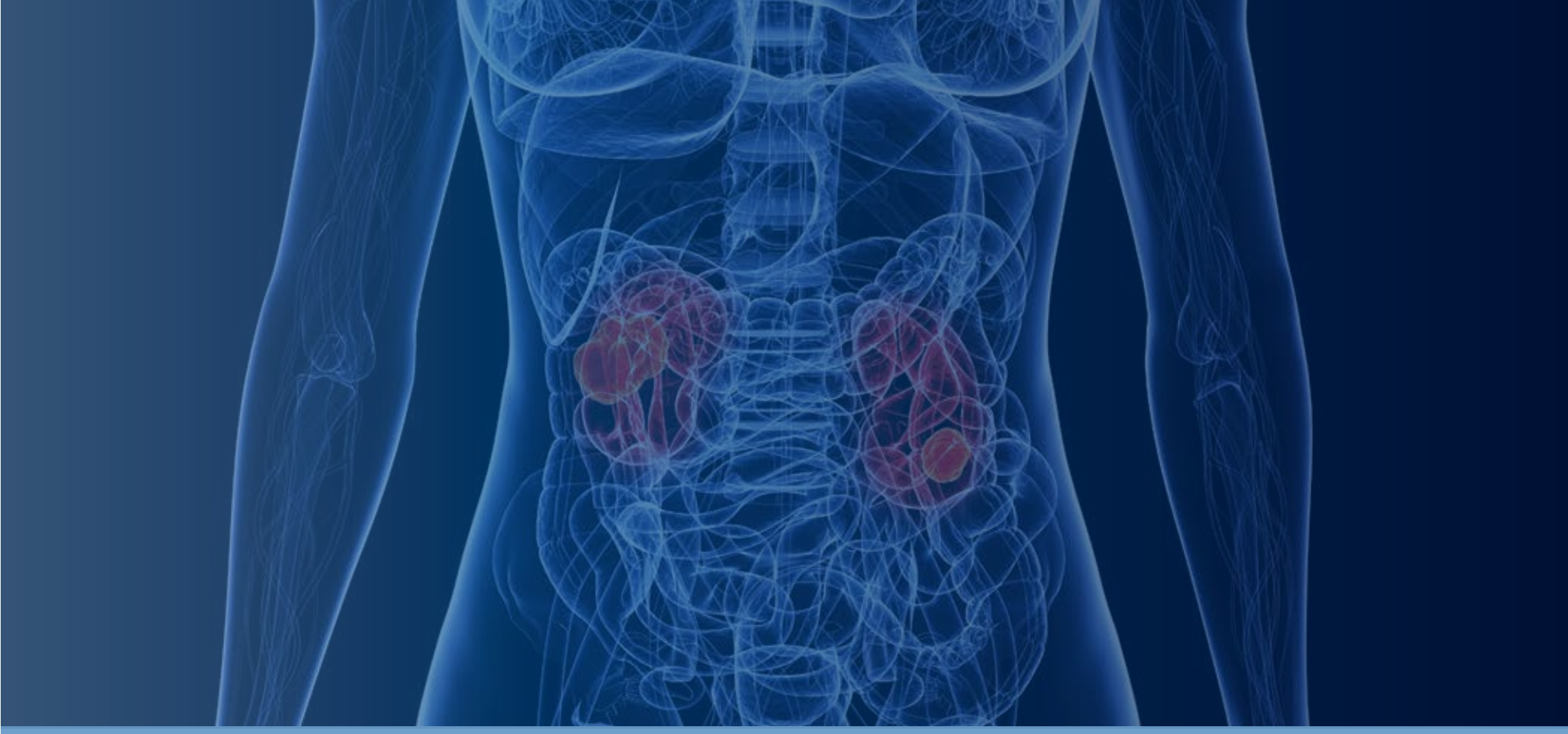

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ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Policy Update

CMS Releases Proposed Changes to Bundled Payment and Quality Measures

By Rachel Meyer and Mark Lukaszewski

A new proposed rule from the Centers for Medicare & Medicaid Services (CMS) lays out changes to how Medicare will reimburse providers for dialysis care, as well as how it will assess the quality of dialysis care. Released on Friday, June 26, and open for comment from stakeholders through Tuesday, August 25, the proposal includes several anticipated adjustments to the bundled payment and modest tweaks to the Quality Incentive Program (QIP).

Highlights of the proposed rule related to the Prospective Payment System (PPS) bundle included a reduction to the base rate, overhauls to the low-volume and case-mix adjustments to the base rate, and clarification on how new products might be added to the bundle. Many of the changes to the payment system were anticipated, as Congress had mandated that CMS reassess several PPS elements.

The ASN Quality Metrics Task Force (see box) is analyzing the proposed rule and will provide comments to CMS on behalf of the society.

Prospective Payment System proposed changes

CMS proposed changing the base bundled payment rate from $239.43 to $230.20 (a reduction of $9.23 per treatment), yet total payments to all dialysis facilities are projected to increase 0.3%. While the rule calls for a modest cut to monthly bundled payment rates, changes to low-volume, case-mix, and other adjustors may offset that reduction. Overall, CMS projects that the adjustments to the Medicare ESRD Program will be budget neutral.

Originally, CMS had established six patient conditions for which it would adjust the bundled payment. In this rule, the agency proposes to reduce that to just four conditions (with larger payment multipliers).

The rule also proposes to provide low-volume payment adjustors only to facilities at least 5 miles from the next closest facility; formerly, that threshold was 25 miles. A Government Accountability Office (GAO) report showed that many of the facilities to which CMS was providing a low-volume payment boost were near each other and prompted Congress to call on CMS to re-examine this policy. While the new low-volume payment adjustor would apply to fewer facilities, those facilities would see a larger additional payment. The rule also proposes establishing a novel payment adjustment that would give facilities in very rural areas an increase in payment.

Since the inception of the bundled payment system, CMS has withheld paying out 1% of total claims, reserving those dollars to reimburse facilities caring for costly "outlier" patients. However, stakeholders have raised concerns that the withheld dollars were not, in fact, being returned to the system as planned. To address this discrepancy, CMS proposes to recalibrate the payments to "increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments."

Concern has long existed regarding how Medicare would add new technologies to the fixed-payment bundle. Many in the kidney community are apprehensive that the lack of clarity regarding future payments has created a disincentive for industry to innovate in the ESRD space. In this rule, CMS included guidance on this topic. CMS also proposed that oral drugs with no IV equivalents that are not currently in the bundle would be added to the bundle if IV equivalents become available.

If new injectable drugs fit into the 12 existing product categories, they would be included in the bundle and considered already reimbursed under the system. CMS proposes to pay an add-on payment for novel pharmaceutical products (or other types of technologies that could affect dialysis) as they assess how these products are adopted. If a totally new type of drug is created or does not fit into any category it would not be included in the bundle; CMS would then determine whether it needs to adjust the definition of a category or add a new category. As CMS makes this determination, the agency would pay for the new drug at a rate of average sale price (ASP) plus 6% for at least 2 years.

Notably absent from the rule was any discussion regarding home dialysis. Numerous stakeholders in the community have called for increases to the home dialysis training rate as well as changes related to payment for more frequent dialysis care. In August 2014, Medicare contractors issued notice that they would not pay for dialysis more than three times per week except in cases of emergency—presenting a clear barrier to those on nocturnal and other home dialysis modalities. Despite the controversy, CMS declined to weigh in on these issues in this proposed rule.

Quality Incentive Program proposed changes

Bone Mineral Density Measure

Under statutory requirement for 2016 and subsequent years, CMS mandated the adoption of bone mineral density measures in the ESRD QIP that use oral-only drugs. In its previous rule, CMS adopted the hypercalcemia clinical measure to meet the statutory requirement. Even though this measure is not outcome based, CMS selected it because it is currently the only bone mineral density measure that meets the definition of oral-only.

Proposed Replacement of the Four Measures Currently in the Dialysis Adequacy Clinical Measure

CMS is proposing to replace four measures in the Kt/V Dialysis Adequacy measure topic—(1) Hemodialysis Adequacy: Minimum delivered hemodialysis dose; (2) Peritoneal Dialysis Adequacy: Delivered dose above minimum; (3) Pediatric Hemodialysis Adequacy: Minimum spKt/V; and (4) Pediatric Peritoneal Dialysis Adequacy—with a single, comprehensive clinical measure (the Dialysis Adequacy clinical measure) covering the patient populations previously captured by these four individual measures. The measure will be determined based on the total number of qualifying patients treated at a facility. Thus, any facility with at least 11 total qualifying patients will report to assess the quality of care.

CMS proposes to weight the single Dialysis Adequacy clinical measure at 18 percent of a facility's Clinical Measure Score Domain, which is the same percentage for the current Dialysis Adequacy measure topic. The agency proposes no other changes to the weighting for the remaining clinical measures and measure topics.

Proposed New Reporting Measures Beginning with the Payment Year 2019 ESRD QIP: Ultrafiltration

CMS proposes to add an ultrafiltration rate reporting measure. However, the National Quality Forum has not yet endorsed an ultrafiltration measure and no consensus organization on ultrafiltration rates currently exists. That said, CMS proposes adopting a measure that "is based on" the "Ultrafiltration Rate Greater than 13 mL/kg/h." Facilities would be required to report an ultrafiltration rate for each qualifying patient at least once per month.

CMS proposes adopting a full season influenza vaccination measure as a reporting measure. Facilities would be scored on whether they successfully report the data, not on measure results.

Future Achievement Threshold Policy under Consideration

CMS stated that increasing the achievement threshold from the 15th percentile to the 25th percentile of national performance during the baseline period would improve patient care, maintaining that the increased achievement threshold will add additional incentives for facilities to improve performance and quality of care.

During the proposed rule-making process, ASN will continue to emphasize that CMS work in a transparent and collaborative way with the kidney community. The society will continue to urge CMS to focus on meaningful measures from a patient perspective rather than diluting the QIP and distracting dialysis providers with numerous measures of less substantial importance. CMS will likely release the final rule in early November at which time ASN will provide a detailed analysis of the final decisions and their implications for patients and the nephrology community.

Working Group Aims to Improve Care of Patients with Chronic Diseases

By Rachel Meyer

The US Senate Finance Committee in June launched an ambitious new bipartisan working group that aims to improve the care of Medicare patients with chronic diseases. Concerned that treatment of chronic illnesses—such as kidney disease, heart disease, and diabetes—constitutes 93% of the total Medicare budget, Chairman Orrin Hatch (R-UT) and Ranking Member Ron Wyden (D-OR) heard testimony in May from Centers for Medicare & Medicaid Services (CMS) Chief Medical Officer Patrick Conway, MD, and MedPAC Commissioner Mark E. Miller, PhD, about opportunities to reverse this trend, and followed that hearing with the announcement of the "chronic care working group."

Chaired by Sen. Johnny Isakson (R-GA) and Sen. Mark Warner (D-VA), the working group will identify policy solutions that provide higher quality care at greater value and lower cost without adding to the deficit—and is seeking input from ASN and other stakeholders on how to achieve those goals.

People with kidney disease stand to benefit substantially from the working group's efforts. ASN highlighted numerous opportunities to improve care and reduce cost for this population.

More than 51% of patients with end stage renal disease (ESRD) have 5 or more chronic co-morbid conditions and more than 80% have 3 or more chronic co-morbid conditions. In 2012 CMS reported on the top five most costly triads of chronic illness; chronic kidney disease (CKD) was included in four out of the five with an average cost of approximately $60,000 per capita. And although patients with ESRD make up 1% of the Medicare population they comprise over 6% of the total costs.

But policy changes related to kidney care could do more than just reduce costs. Strategies to slow the progression of kidney disease and improve transitions of care could improve quality of life for the millions of Americans with kidney disease. ASN's complete comments are available online at https://www.asn-online.org/policy/webdocs/15.6.22asninputsfcchronicconditionswg.pdf.

Table 1 summarizes ASN's recommendations to the working group. Chief among ASN's input was encouragement to improve CKD care and transitions, and increase access to transplantation.

Currently, accountable care organizations (ACOs) are tailored specifically to the general population while the forthcoming (as of July 1, 2015) ESRD Seamless Care Organization (ESCO) pilot is tailored to the specific needs of patients on dialysis. No programs or pilots exist that address the needs of individuals with advanced chronic kidney disease by promoting patient-centered care, smooth transitions of care, and improved quality outcomes. ASN proposed piloting of a "comprehensive CKD care delivery model" pilot to fill a significant gap in care coordination for this chronically ill patient population—and potentially to result in savings in the Medicare program.

This pilot would be similar to but broader than the ESCO, include patients with advanced CKD, and focus on managing and slowing the progression of kidney disease and other complex chronic conditions common in patients with advanced kidney disease. Such a pilot model would build upon and borrow from many of the same concepts in the ESCO model, but expand the patient population included. Spearheading the care coordination efforts, a nephrologist would serve as the care leader for a population of patients from the time of their diagnosis of advanced CKD and would assume responsibility for their care—in partnership with other members of the care team, including dialysis providers—through the transition periods of dialysis initiation, transplantation, or end-of-life care.

Improved access to transplantation

The chronic care working group specifically solicited ideas for policies that improve care transitions, produce stronger patient outcomes, increase program efficiency, and overall reduce the growth of Medicare spending. ASN highlighted that improved access to transplantation, including pre-emptive transplantation, would directly help achieve each of these goals.

Kidney transplantation is the treatment of choice for eligible patients and compared to dialysis, markedly improves survival (Wolfe, *NEJM*, 1999), reduces risk of chronic medical conditions that complicate ESRD, and improves quality of life. It is also one of the most cost-effective interventions. One live kidney donation has been estimated to lead to an increase of 2 to 3.5 quality adjusted life-years for recipients and a net health care savings of $100,000 [Klarenbach et al., *CMAJ*, 2006]. Yet thousands die on the wait list annually, and the number of kidney transplants remains limited by the supply of deceased donor organs—and hampered by a decreasing number of living donations.

Table 1.

ASN's recommendations to the Senate Finance Committee Working Group

1) Improve care coordination—especially during care transitions—for patients with advanced CKD and other complex chronic conditions through Medicare Advantage (MA) plan access and new care delivery pilot programs.
2) Improve access to transplantation, the optimal therapy for most patients with ESRD from the perspective of outcome and cost.
3) Permit patients with ESRD to enroll in MA plans.
4) Reduce medication errors for complex, chronically ill patients.
5) Utilize telemedicine and remote monitoring to more effectively manage co-morbidities and coordinate care for people with all stages of kidney disease.

ASN's recommendations to the working group highlighted several policy levers that could increase access to transplantation. These included asking CMS to explore strategies to incentivize nephrologists to refer patients with advanced CKD to transplant centers for pre-emptive transplant evaluation, expanding access to pre-and posttransplant care for geographically disadvantaged kidney recipients and kidney donors through telemedicine, and eliminating barriers for potential live kidney donors

Besides these issues, ASN also urged that patients with ESRD be permitted to enroll in Medicare Advantage plans; called for expanded telehealth in the Medicare Program; and delineated opportunities to reduce medication errors.

The society will continue to collaborate with the working group and the Committee to advocate for policies that improve the lives and outcomes of people with ESRD.

Congressional Reception Brings Together NIDDK Supporters

By Grant Olan

On June 23, 2015, ASN co-sponsored a Friends of NIDDK congressional reception in Washington, DC, to formally launch the new advocacy coalition. Senate Diabetes Caucus Co-Chair Jeanne Shaheen (D-NH) and Senate Minority Whip Richard Durbin (D-IL) spoke at the reception, which also featured National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Director Griffin P. Rodgers, MD.

" I want to thank you for your work on this coalition, and I can assure you that it will pay off," Dr. Rodgers said. "We combat some of the most common, consequential and costly diseases … and we are committed to doing basic, clinical, and translational research. As we plan, we will continue to seek your broad input. To that end, I look forward to working with all of you not only now but into the future."

Friends of NIDDK was established in 2013 with the goal of bringing all NIDDK stakeholders together to raise awareness about NIDDK-funded research and to build support for increased funding to maintain current projects and support new initiatives. ASN serves on the Friends of NIDDK Executive Committee, along with the American Diabetes Association, American Gastrological Association, American Urological Association, and others. To date, Friends of NIDDK includes more than 40 member organizations.

Earlier this year, Friends of NIDDK met with staff from the House and Senate committees with jurisdiction over NIDDK's budget to discuss the breadth of research funded by the institute and its impact on our nation's health. For 2016, Friends of NIDDK requested $2.066 billion for NIDDK, approximately an 8% increase over its 2015 budget and a 6.2% increase over President Obama's 2016 budget request.

NIDDK is the fifth largest institute at the National Institutes of Health (NIH) and coordinates research on many of the most serious diseases affecting public health. NIDDK's mission is to "conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life."

NIDDK funds the lion's share of kidney research at NIH. In fact, NIDDK is the largest funder of kidney research in the world. "The research NIDDK funds promises to unlock mysteries about the causes and progression of kidney disease that could lead to new cures and therapies for this silent killer that strikes 1 in 10 adults in the United States," ASN Research Advocacy Committee Chair Frank C. Brosius, MD, stated. "ASN looks forward to working with the Friends of NIDDK advocacy coalition to galvanize support for NIDDK research and funding."

PQRS*Wizard*® registration for the 2015 calendar year is now open.

The PQRS program now carries a financial penalty for physicians and other health professionals who receive Medicare payments. Manage your professional quality measures data with the PQRS*Wizard*® for the 2015 calendar year before February 2016.

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www.asn-online.org/pqrs

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Industry Spotlight

FDA Spotlight on Dangerous Drugs

The US Food and Drug Administration has issued a safety announcement about potential side effects of a class of diabetes drugs. The SGLT2 inhibitors, which aid excretion of blood sugar through urine, may cause dangerous levels of blood acidity. The drugs noted were: Farxiga (dapagliflozin) and Xigduo XR (dapagliflozin and metformin extended-release; both from AstraZeneca); Invokana (canagliflozin) and Invokamet (canagliflozin and metformin; both from Johnson & Johnson) and Jardiance (embagliflozin) and Glyxambi (empagliflozin and linagliptin; both from Lilly and Boehringer)

Between March 2013 and June 2014, 20 incidents of hospitalizations and emergency room visits for diabetic ketoacidosis, ketoacidosis, or ketosis were reported. Since then, the agency said it continued to receive additional adverse event reports of diabetic ketoacidosis and ketoacidosis in patients treated with SGLT2 inhibitors.

Among several recommendations, the FDA advised health care workers to:

- Encourage patients to read the Medication Guide or Patient Package Insert they receive with their SGLT2 inhibitor prescriptions.
- Inform patients and caregivers of the signs and symptoms of metabolic acidosis, such as tachypnea or hyperventilation, anorexia, abdominal pain, nausea, vomiting, lethargy, or mental status changes, and tell them to seek medical attention immediately if they experience the signs or symptoms.
- Evaluate for the presence of acidosis, including ketoacidosis, in patients who have signs or symptoms of acidosis; discontinue SGLT2 inhibitors if acidosis is confirmed; and take appropriate measures to correct the acidosis and to monitor glucose levels.
- Make sure supportive medical care is started to treat and correct factors that may have precipitated or contributed to the metabolic acidosis.

After the safety announcement surfaced, analysts started forecasting which companies might benefit from the news. Reuters reported the announcement "could benefit other oral diabetes drug classes such as the DPP4 inhibitors," according to Bernstein analyst Tim Anderson. "The biggest of the DPP4s, by a wide margin, is Merck's Januvia."

Januvia, Merck's best-selling drug, reached sales of approximately $6 billion in 2014.

New Personal Dialyzer on Horizon

Outset Medical (San Jose, CA) has eclipsed an initial funding level of $9.5 million thanks to Warburg Pincus, a private equity investment firm. Warburg Pincus reported recently that it had invested $60 million in the company.

Outset has plans for a user-friendly at-home dialysis machine that uses a home's water supply and purifies it for dialysis-level usage. The device also generates dialysate on demand. Warburg was a leading venture investor of the company in 2010. The investment firm noted online that the new device's simplicity lets patients "manage treatments independently whether in clinic or at home."

The machine, called Tablo, makes dialysate continuously using regular tap water. "Tablo …makes clean water, produces dialysate, takes blood pressure and delivers medication all in a compact table-height package according to the company's website.

Outset is also appealing to consumers through an online marketing campaign.

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- Critical Care Nephrology: 2015 Update
- Curing Kidney Disease: At the Crossroads of Biology, Infrastructure, Patients, and Government **new!**
- Diagnosis and Management of Disorders of Acid-Base, Fluid, and Electrolyte Balance: Challenging Issues for the Clinician
- Fundamentals of Renal Pathology
- Geriatric Nephrology: Caring for Older Adults with Kidney Disease
- Glomerular Disease Update: Diagnosis and Therapy 2015
- Kidney Transplantation
- Maintenance Dialysis
- Maintenance of Certification: NephSAP Review and ABIM Modules
- Polycystic Kidney Disease: Translating Mechanisms into Therapy
- Women's Renal Health across the Decades **new!**

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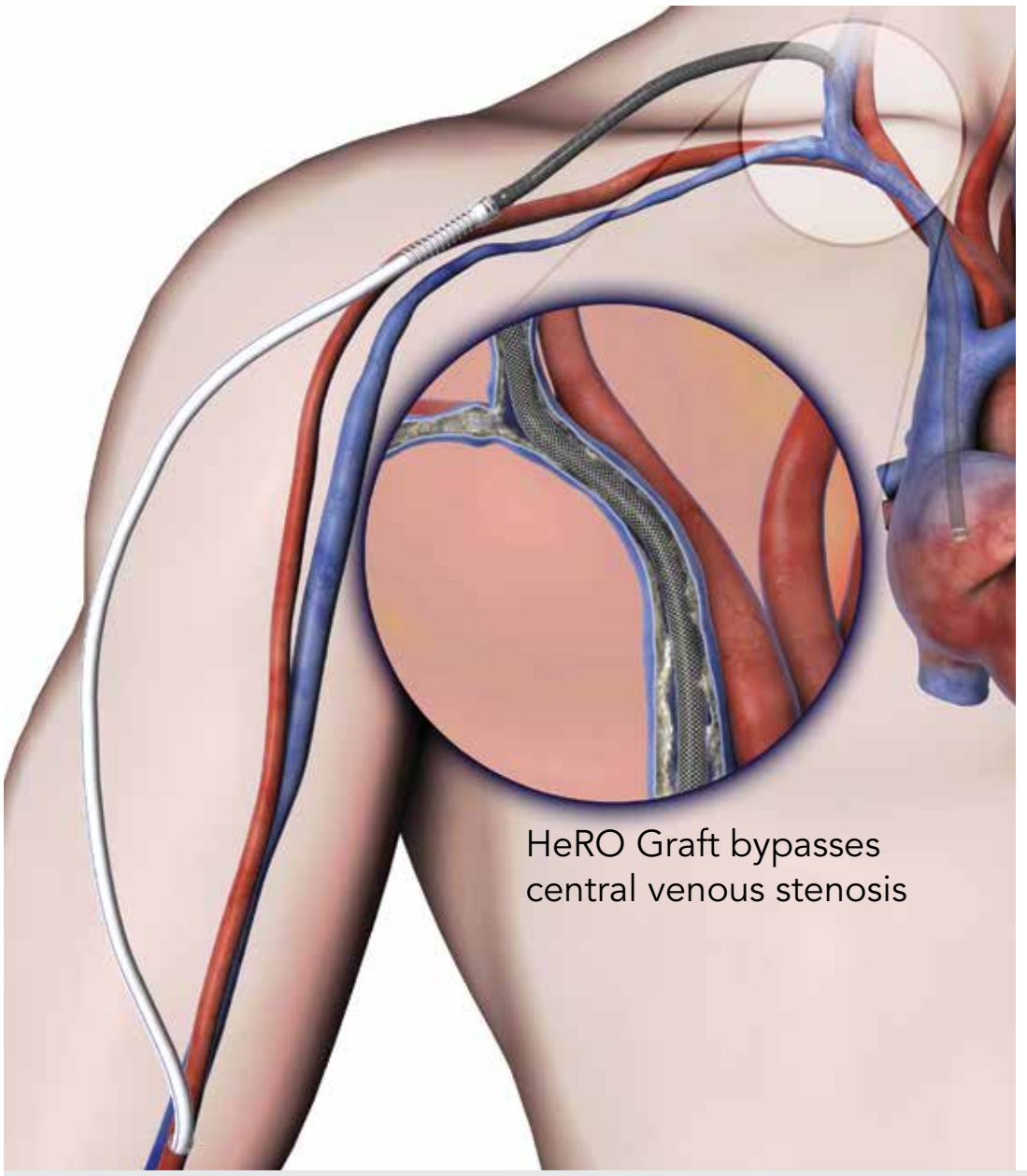

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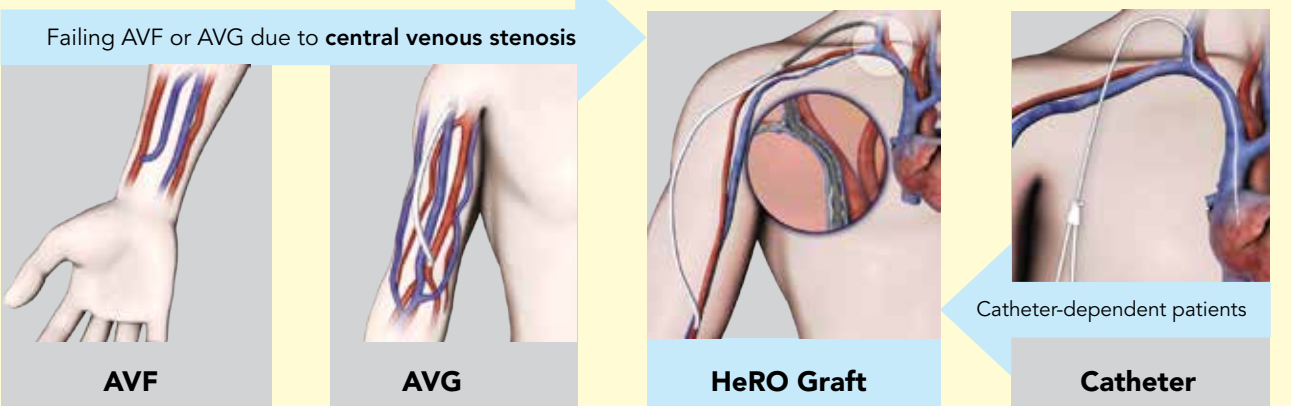

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References:
1) Katzman et al., J Vasc Surg 2009. 2) Gage et al., EJVES 2012. 3) Dageforde et al., JSR 2012.

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