The Time is Now

A Perspective on the Opening Plenary at Kidney Week 2019

When I first started speaking with legislators and staff years ago, they were not familiar with the burden of kidney disease that millions of their constituents have struggled with. At this year's Kidney Community Advocacy Day, however, they were able to complete my sentences before we even finished telling them about the need for expanding transplant immunosuppression coverage and protecting living donors with the Living Donor Protection Act.

By Mukta Baweja

As representatives of the US Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), and Center for Medicare and Medicaid Innovation (CMMI) joined the audience of thousands in the nephrology community from around the world, ASN President Mark E. Rosenberg, MD, FASN, kick-started Kidney Week 2019 with the opening plenary, galvanizing the political energy and opportunity of Washington, DC.

The field of nephrology has been subjected to decades of stagnation, largely resulting from lack of sufficient funding and innovation.

Until now.

After a prolonged drought in innovation and regulatory adjustment in the kidney field, an alignment of opportunity is currently being seized by members of ASN, HHS and CMS with programs including KidneyX, the Kidney Health Initiative (KHI) and the recently introduced executive order on Advancing American Kidney Health (AAKH).

Acknowledging the struggle and lack of attention that kidney diseases have endured, HHS Secretary Alex M. Azar II remarked, "We were told that just identifying all of the problems in American kidney care, and all the opportunities we have to improve it, was more attention than federal leaders had paid to this issue in a long time."

For far too long, nephrologists and patients have been subjected to the same suboptimal treatments. Dialysis has been the accepted treatment for kidney failure despite the prognosis of those requiring dialysis being worse than that for many cancers. Many of our patients die on the transplant waiting list with a shortage of organs and significant barriers to living donor transplantation. Over 37 million patients in the United States and over 850 million in the world live with kidney disease, with exponentially rising costs on the order of $35 billion per year in the US—from Medicare alone—with unacceptable outcomes including an over 50% mortality rate for kidney failure patients after 5 years. This unsustainable trajectory has finally led to a breaking of the dam, and as Dr. Rosenberg remarked, we have begun a "War on Kidney Diseases," committing the US to a "system that pays for kidney health, rather than kidney sickness."

The 2019 ASN opening plenary began with a focus on KidneyX, a public-private partnership to accelerate innovation. As of now, with the help of KidneyX, Redesigning Dialysis has become a reality as protoypes are being developed, with a future goal of an artificial kidney. In addition to KidneyX, the AAKH has outlined a comprehensive kidney health strategy to rise to the challenges in the kidney sphere including preventive care, dialysis innovation and increasing home dialysis utilization, and tackling the barriers to kidney transplantation, including addressing the organ shortage and facilitating living donation.

Additionally, members of CMS and CMMI have developed payment models geared toward incentivizing optimal dialysis modalities and improved quality metrics with a focus on increased utilization of home dialysis and ultimately transplantation. The FDA and Kidney Health Initiative (KHI) have begun collaborative efforts to focus on novel treatments to prevent progression of kidney disease, in yet another immensely powerful tool in the process of changing nephrology.

Over the past year, the heavy groundwork for catalyzing change in kidney care was laid by several crucial figures at HHS, who received the ASN President's Medal in recognition of their commitment to helping transform nephrology for the benefit of people with kidney diseases: HHS Secretary Alex M. Azar II, HHS Deputy Secretary Eric D. Hargan, CMS Administrator Seema Verma, former Deputy Administrator for CMMI Adam Boehler, Assistant Secretary for Health Admiral Brett P. Giroir, Senior Advisor to the HHS Secretary James Parker, Open Innovation Manager Sandeep Patel, Associate Director of Innovation and Technology Murray Sheldon, HHS Chief Technology Officer Ed Simcox, former HHS Advisor Abe Sutton, and Advisor Nicholas Uehlecke.

On November 6, 2019, I had the opportunity to talk with legislators on Capitol Hill along with 15 organizations representing 30 states during Kidney Community Advocacy Day (KCAD). When I first started speaking with legislators and staff years ago, they were not familiar with the burden of kidney disease that millions of their constituents have struggled with. At this year's KCAD, however, they were able to complete my sentences before we even finished telling them about the need for expanding transplant immunosuppression coverage and protecting living donors with the Living Donor Protection Act.

Advocacy is working for our patients and the community, and transformation of kidney care is here—the time is now, and change cannot arrive fast enough.

"At this moment, a remarkable alignment exists among patients, researchers, clinicians, healthcare organizations, and policy makers. […] Today, now, is the moment for nephrology and for people with kidney diseases." – Dr. Mark Rosenberg. ■

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Disrupting Nephrology: *From Technology to Developing Organs-on-Chips*

By Mukta Baweja

Seamlessly carrying on the energy of change and transformation in the kidney sphere captured during plenary sessions at Kidney Week 2019, two sessions brought the potential for such transformation to life: Disruptors on the Move and Organs-on-Chips: Human Kidney Microphysiological Systems.

The panel of innovators and experts in healthcare innovation for the Disruptors on the Move session included current PCORI Interim Executive Director and *CJASN* Editor-in-Chief Josephine P. Briggs, MD, former Department of Health and Human Services CTO and current Kaiser Permanente VP of Medicaid Transformation Bryan Sivak, CVS Kidney Care CMO Bruce Culleton, MD, Cricket Health CMO Carmen Peralta, MD, FASN, and Outset Medical CEO Leslie Trigg.

Patient centeredness, which took center stage in the discussion on disruption, is important to the disruption of care for at least 3 reasons, Briggs stated:

1) Patients bring a sense of urgency and impatience to the discussion.
2) The questions change when patient centeredness is being evaluated on a continual basis.
3) A patient-centered approach will also bring innovation and better implementation into the process.

These sentiments were echoed by the other panelists.

"Everything comes to your phone—a taxi, food, even your friend. So why can't the care (sic) come to you?" asked

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Disrupting Nephrology

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Cricket Health's Peralta. "It's not just all about reaching [patients] geographically but also psychologically."

Meaningful disruption requires three things, according to Outset Medical's Trigg: 1) an entrepreneurial ecosystem such as that provided by Kidney X, 2) an early adopter environment, and 3) capital flow.

Investors are less excited to provide capital flow if 1) and 2) are not present, she said.

In other fields, particularly with cardiac devices, a crucial ingredient to successful innovation was alleviating practitioners' sense of fear regarding adoption of a new technology—although it may have flaws and imperfections—in order for users to learn through trial and error what could work, Trigg said.

The need to quell fear among practitioners in adopting new technology also came to mind during the session Organs-on-Chips: Human Kidney Microphysiological Systems.

Jonathan Himmelfarb, MD, FASN, spoke about "A Human Kidney-on-a-Chip for Precision Medicine" and Neil Lin, PhD, spoke on 3D Vascularized Kidney Tissues-on-Chip for Drug Toxicity and Disease Modeling.

The idea of a credit-card–sized chip that could mimic a human organ for use in precision medicine was born out of a partnership of the National Institutes of Health with DARPA and the Food and Drug Administration in 2012. The goal has been for utilization of such a chip for preclinical safety and drug testing with the benefit of genetic diversity and for conceivable use in clinical trials.

There is also the amazingly brilliant concept of a kidney organoid, "a multicellular unit in vitro containing nephron-like epithelial structures with podocyte and tubular segments," and the capabilities are being developed to create human stem cells and organoids from urine samples. The potential for revolutionizing patient care is extraordinary with this technology.

"The tools that are becoming available are now allowing us to combine those technologies [CRISPR] with microfluiditics to allow us to create a field that is personalized," Himmelfarb said.

Leadership from nephrologists needed

But what ties this basic science revolution with the innovators and industry disruptors in care is that there is a need for leadership from nephrologists and a translation from bench to product that is currently not optimal. Trigg noted that there are currently 7000 medical startups, but less than 20 of these are kidney-based startups.

Our colleagues have developed technologies that years ago were unfathomable—that even may have been considered scientific fiction, as Himmelfarb noted—but perhaps we are not tapping into the full potential of utilizing this knowledge without a willingness to take on the risks of disrupting care and embracing the leadership roles waiting to be seized.

There will be roadblocks and obstacles along the way—we need to address our current barriers in the healthcare system and disparities in care that are community based and find a way to minimize them.

No one said disruption would be easy. But we know this: the technology and science are getting bolder and more exciting, and it is up to us to start somewhere. ■

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Making the Dialysis Experience Person-Centered: The Celeste Castillo Lee Memorial Lecture at ASN Kidney Week 2019

By Zach Cahill

ASN Kidney Week is unique among medical society gatherings for elevating the patient voice during the annual meeting. Accelerating innovation and discovery in the kidney disease space makes including the perspectives of people with kidney disease in scientific meetings and other forums essential. During the ASN Kidney Week Annual Meeting, more than 10 people with kidney disease gave talks on a variety of topics.

The foremost of the patient presentations was the Celeste Castillo Lee Memorial Lectureship, a rare example of a lecture endowed in the name of a patient and presented during a medical society meeting. Established in 2017, the lecture continues the legacy of Celeste Castillo Lee, who championed people with kidney disease for 30 years. She served in many leadership roles throughout the community, including on the Kidney Health Initiative (KHI) Board of Directors and as the founding chair of the KHI Patient and Family Partnership Council, bringing her experience with peritoneal dialysis, hemodialysis, and transplantation to drug and device development. Her life inspired and motivated a generation of people with kidney disease and kidney health professionals.

Derek Forfang, a 10-year veteran of advocacy on behalf of people with kidney diseases, delivered this year's lecture, which focused on the topic, "How can patients be treated as individuals?" For 20 years, Mr. Forfang has had kidney failure. He experienced in-center hemodialysis before receiving a kidney transplant. His experience in and with people on dialysis provided firsthand knowledge into the culture of dialysis clinics and how the current system is not designed to be people centered.

A need for patient-centered measures?

The emphasis on current healthcare measurement in clinics demonstrates how the system is not people centered such that measurement approaches often do not align with patient and family preferences and values. He said people with kidney disease are not involved in meaningful ways in developing the measures, resulting in the feeling that they are subjects of measures rather than decision-makers or drivers of care. For example, the Centers for Medicare & Medicaid Services (CMS) End-stage Renal Disease Quality Incentive Program, used to evaluate and pay kidney health professionals, is primarily driven by measures that are clinical in nature, rather than metrics that are important to patients. This system results in people feeling disengaged and that they are just being moved in and out of treatment.

Mr. Forfang posited that even the Advancing American Kidney Health initiative could benefit from additional focus on patient preferences where transplantation and home dialysis utilization are concerned.

A person-centered experience helps people with kidney disease navigate their dual lives, respects them as individuals, and acknowledges how their identity evolves over time. Mr. Forfang applied this philosophy to clinical measures and emphasized that it is possible to align such measures so they are meaningful to people with kidney disease.

True patient-centered measurement is driven by a patient's expressed preferences, needs, and values and informs progress toward better health, better care, and lower costs. CMS is already evolving to provide better measures. The agency's Meaningful Measures Initiative proposed measures that empower patients and emphasize the person as a partner in care. The National Quality Forum is investing in patient-centered planning and coordination. Mr. Forfang served on a CMS Technical Expert Panel that evaluated patient-reported outcomes (PROs) for kidney failure. The group was expected to recommend quality of life or recovery time after dialysis as PROs, but because of meaningful input from the patients on the panel their actual PRO recommendation was life goal–directed care. That recommendation pivots CMS's priorities toward the values and priorities of people with kidney disease.

Mr. Forfang attributed these institutional evolutions to a growing knowledge of a person's experience with kidney disease. Kidney disease, he explained, is a journey, and priorities and values change over time. The identified needs and priorities of people with kidney disease should drive care. Payers are realizing that care plans should be built around what matters most to people as individuals.

Care plans are a tool dialysis providers may use to provide more individualized care. Typically care plans are discussed once a year, are problem-centered, and are focused on umbrella clinical outcomes. They often do not feel meaningful and are not individualized.

Aligning dialysis care with patient goals

In contrast to a problem-centered plan, Mr. Forfang proposed a person-centered dialysis care plan that aligns dialysis care and the goals of people with kidney disease. Patients and care teams jointly develop an individualized plan that includes patient-identified needs and priorities. A person-centered care plan is a feasible approach that can work in the current care and regulatory context.

Kidney care professionals may start forming a person-centered care plan by asking open-ended questions about what a patient's life is like outside the clinic and what their life goals are. This approach requires advance preparation. The patient should be provided educational materials and invited to attend a meeting off the dialysis floor. Second, the care team should hold a care planning meeting that addresses the following:

- Identifies patient needs, priorities, and barriers.
- Discusses options to align dialysis care with needs, priorities, and barriers.
- Works with the patient to make decisions and develop an individualized care plan.

Last, a person-centered care plan will include timely follow-up and regular check-ins. Mr. Forfang helped develop My Dialysis Plan with the University of North Carolina Kidney Center to expand on the ideas of the person-centered care plan and provide kidney health professionals and people with kidney disease the tools they need for more individualized care. ■

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