Delivering on the Opportunities of 2019
How the Kidney Health Initiative Will Provide Innovation for People with Kidney Disease

By Raymond C. Harris, MD, FASN

Nephrology has constantly fought against, and sometimes succumbed to, a narrative of decline and stagnation. There is a complaint that new therapies are not being developed or approved, there has been a paucity of successful clinical trials, and in-center dialysis remains the standard of care for kidney failure. It is time to put this negative narrative to rest. Over the past year, I have had the privilege of leading the Kidney Health Initiative (KHI) and from that vantage point have seen firsthand that today is a new day for innovation in kidney diseases.

Yes, many challenges remain for our specialty, but the actions of the federal government and the kidney community over the past year give me confidence that kidney health professionals today operate in a new world of possibilities. The Advancing American Kidney Health initiative set the priorities for a renaissance in our field. Never before had the federal government signaled such concern for the state of kidney care or proposed such bold solutions to its problems. Promoting prevention, providing alternatives to dialysis, and increasing transplantation rates are all goals that KHI supports. As a public-private partnership with the US Food and Drug Administration (FDA), KHI is in a unique position to do the translational work necessary to deliver on the promises of Advancing American Kidney Health.

The kidney community was primed to take advantage of this new environment. As the largest consortium in the kidney community, with over 100 member organizations, KHI observes and leverages the contributions that every stakeholder group makes to catalyzing innovation. This past year, I have seen every member organization engage in new activities and renew investments into bringing new drugs and devices to people living with kidney diseases.

The year 2019 is filled with examples (Figure 1). Neph-Cure Kidney International is investing in a clinical trial discovery tool for glomerular diseases and matching people with glomerular disease with specialists and clinical trials. In the last two years, the National Kidney Foundation (NKF) hosted patient-focused drug development meetings with the FDA on Alpha syndrome and IgA nephropathy. Additionally, NKF is developing a first-of-its-kind patient registry for people living with kidney diseases. Diabetic kidney disease received increased attention this year because of the results of the CREDENCE trials. The possibilities of SGLT2 inhibitors led the American Society of Nephrology (ASN) to establish the Diabetic Kidney Disease Collaborative to help prepare kidney health professionals to use these new drugs. In total, 23 pharmaceutical companies that are KHI members are conducting clinical trials today.

Today, the kidney community is benefiting from years of KHI investment into catalyzing innovation and the development of safe and effective patient-centered therapies for people living with kidney diseases (Table 1). This investment has resulted in a positive impact on the quality and quantity of clinical trials in kidney disease since its founding.

That impact is in part a result of the projects we conduct with volunteer subject matter experts from across the community to catalyze drug and device development. KHI has four ongoing projects related to catalyzing drug development that address a variety of topics.

1. Overcoming Barriers to Involving Kidney Patients in Cardiovascular Trials
Many people living with kidney disease are unaware of their associated risk of cardiovascular disease. This project addresses barriers and identifies innovative solutions to involving people living with kidney diseases in cardiovascular clinical trials.

2. Endpoints for Clinical Trials in FSGS
This project is working to provide information about current cardiovascular interventions in 2019, KHI extended its endpoints work to patient-reported outcomes (PROs) projects for novel renal devices, muscle cramping, and vascular access. Our insights and publications in drug and device development have placed KHI at the cutting edge of innovation during this historic moment. In the remaining two years of my term as co-chair, I plan on continuing to move innovation forward, to build on KHI’s success, and to capitalize on the opportunities presented to the kidney community over the past year in four ways:
First, reflect KHI’s project portfolio to tackle issues that are relevant to a broad spectrum of the kidney community. In 2020, KHI will continue to endorse and complete projects related to surrogate endpoints and clinical trial

Table 1.
design, with a focus on barriers that impact a broad group of member organizations.

Second, support an on-study culture in kidney care. This is a new focus for KHI and ASN. I believe KHI has a role to play in supporting new and exciting clinical trials and developing innovative trial design. This year, ASN is rolling out a new organizational structure, part of which will be a center with programs addressing “Research, Discovery, and Innovation,” of which KHI will be a part. Research readiness is a primary focus of this center and will provide KHI more resources to have an impact on revolutionizing the clinical trial landscape.

Third, invest in technology roadmapping. As KidneyX continues to mature, KHI will have a role in identifying barriers that need to be overcome, disseminating guidance to innovators, and providing the intellectual foundation for prize competitions. This year, KHI is launching a new roadmapping project for AKI Biomarkers that will convene experts from many stakeholder groups to outline the path forward for this important clinical area. Additionally, KHI recently announced a project extending the work of our original Roadmap to the issue of identifying endpoints and clinical trial design for innovative renal replacement therapy (RRT) products.

Last, KHI is committing to amplifying the patient perspective in 2020. During Kidney Week 2019, Health and Human Services Secretary Alex Azar II called out a new KHI project that will develop a patient preference survey for novel RRT devices. This project supports the Advancing American Kidney Health initiative and will provide the community a prioritization of benefits and risks of novel devices and additional patient preference information innovators can use to develop an artificial kidney.

Follow our progress on these goals at www.kidney-healthinitiative.org and on social media with #KidneyHealthInitiative.

Let’s not allow the cynicism of the old narrative to again become the norm in the kidney community. 2019 was a historic year and 2020 is our chance to deliver on the opportunities we have been handed. There are significant obstacles to be overcome, but the environment has never been more primed for change. KHI is available to help the community do the translational work necessary to make innovative therapies a reality for the people we serve. We have all seen too many of our patients die without new treatment options. Catalyzing innovation must no longer be just a catchphrase but an imperative to deliver new therapies for our patients. People living with kidney diseases have waited long enough.

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