

How the Kidney Health Initiative Catalyzes Innovation in a Dynamic Environment

Raymond C. Harris¹ and Zachary Cahill²

CJASN 15: ●●●-●●●, 2020. doi: <https://doi.org/10.2215/CJN.11060919>

The kidney community today is not the same as it was when the Kidney Health Initiative (KHI) was founded in 2012. KHI, a public-private partnership between the American Society of Nephrology (ASN), the US Food and Drug Administration (FDA), and >100 members, has grown to the largest consortium in the kidney community. A perception within the community that there was an underrecognition that kidney disease was a serious public health issue and a lack of innovation in treating kidney diseases prompted KHI's formation >7 years ago (1). Today, that perception may be changing. Although many of the challenges are still the same, the kidney community has a renewed commitment and new tools to change the status quo. The kidney community has a unique opportunity as a result of increased industry investment and government attention to a significant public health need.

The Advancing American Kidney Health initiative, announced on July 10, 2019 by the US Department of Health and Human Services (HHS), places the kidney community in the national spotlight for the first time in decades and outlines a national strategy for kidney diseases for the first time (2). In order to achieve the Advancing American Kidney Health initiative's lofty goals and make good on the KHI's commitment to people with kidney diseases, drug and device innovation needs to accelerate.

Achieving the Advancing American Kidney Health's core goals of reducing the risk of kidney failure, improving access to and quality of person-centered treatment options, and increasing access to kidney transplants will require different and better drugs and devices than those available today. During its first 7 years of existence, the KHI has overseen projects that have facilitated development of new therapeutic options for kidney patients. Going forward, it can continue to bridge the gap between today's treatment realities and tomorrow's novel therapies through its unique ability to bring together diverse stakeholders (patient groups, industry, professional organizations, academia) in a precompetitive environment to promote and work together with the FDA to promote innovation while ensuring patient safety. KHI members are already working to achieve the goals set out in the Advancing American Kidney Health and this announcement should catalyze additional drug and device development.

Today, new drugs are being developed for kidney diseases, both common and rare, and the number of

clinical trials is steadily increasing (3). Glomerular diseases, such as IgA nephropathy and FSGS, are receiving new attention from sponsors (4). The blossoming of clinical trials in this area prompted the creation of the Kidney Health Gateway (www.kidneyhealthgateway.com) by NephCure Kidney International, a new initiative that connects people with glomerular kidney diseases with clinical trials. New treatments for more common kidney diseases, such as diabetic kidney disease and cardio-renal disorders, have also seen recent successes. The recent publication of the results of the Evaluation of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Participants With Diabetic Nephropathy (CREDENCE) trials (5) and investment of multiple sponsors into SGLT2 inhibitors and other novel therapies give hope that at least one of these treatments will make it into the hands of the people who need them. These and other efforts in drug development are built on federal investments in basic research through programs such as the National Institutes of Health's Kidney Precision Medicine Project and the APOL1 Long-term Kidney Transplantation Outcomes Network study (6).

In addition to drug development, innovation and discovery are advancing for medical devices. The call to action for an artificial kidney has arrived in the national spotlight with Advancing American Kidney Health and multiple companies are investing in innovative vascular access technologies. These advances have been made possible by a regulatory posture from the FDA that emphasizes the risk to patients of not providing access to life-saving new devices in a timely manner (7). A wearable artificial kidney could be in clinical trials in the near future and manufacturing artificial organs is a new possibility on the horizon. To accelerate this process, the KHI released its *Technology Roadmap for Innovative Approaches to RRT* to support current and new innovators with a guide on how to direct their research. KidneyX's Redesign Dialysis Prize Competition is providing additional funding to individuals and companies who are developing innovative alternatives to dialysis.

Innovative drug and device development will only be successful if it is built around the needs of people with kidney disease and focused on improving their quality of life. The KHI Patient and Family Partnership Council (PFPC) is a model the kidney community can

¹Division of Nephrology, Department of Medicine, Vanderbilt University School of Medicine, Nashville, Tennessee; and ²American Society of Nephrology, Washington, DC

Correspondence: Raymond C. Harris, Medicine/Nephrology, Vanderbilt University School of Medicine, C-3121 MCN, Nashville, TN 37232. Email: ray.harris@vanderbilt.edu

follow for how to include patient input in drug and device development. With support from the patient organizations and foundations that are a part of the initiative, the KHI PFPC ensures that the patient voice is included in everything the KHI does, from what projects to endorse, to leadership on the Board of Directors.

The kidney community cannot miss the opportunity presented by Advancing American Kidney Health. The KHI and the members of the kidney community it represents are renewing their commitment to innovation and discovery, and a world without kidney disease. These efforts will be amplified by the KHI's inclusion in the ASN Alliance for Kidney Health, along with KidneyX, Nephrologists Transforming Dialysis Safety, and KidneyCure. In this context, here are the steps the KHI will take to address today's gaps in innovation and discovery.

First, today's environment provides an opportunity to transition the KHI's efforts away from projects related to discrete diseases or isolated problems and toward more universal projects addressing obstacles that affect multiple members and that will provide value to the whole community. For example, as efforts to develop an artificial kidney progress, there will be need for clarity over how to conduct a clinical trial for an artificial kidney. Questions around end points, trial design, inclusion/exclusion criteria, and animal models will need to be resolved. Projects such as this would provide significant value to the community and benefit multiple stakeholders.

Second, improving treatment options through research, discovery, and innovation requires that the kidney community embodies an "on-study" culture to better support clinical trials. The wave of new trials around novel therapies emphasizes the need for health professionals and dialysis clinics to be prepared to enroll and perform clinical trials (8). Additionally, the Advancing American Kidney Health initiative emphasized the importance of conducting clinical trials and initiating new trials through a partnership between the HHS and the Department of Veterans Affairs. In the coming months, the KHI will undertake a variety of projects to equip the kidney community and address issues around clinical trial readiness.

Third, the KHI will continue to provide the community the direction it needs to develop innovative new drugs and devices through publishing roadmaps and guidance on clinical trial end points. These efforts will be particularly important as the community considers what needs to be done to reach the new federal goals for kidney disease. The KHI recently produced a report on *Innovations in Fluid Management* that could serve future KidneyX prize competitions and is prepared to do so for other topics that KidneyX identifies.

Fourth, the KHI always strives to keep our patients' concerns and needs at the forefront of all of its activities. As one example, collecting and utilizing patient preferences is necessary for the development of novel medical devices. The Advancing American Kidney Health initiative highlighted this issue by stating the FDA's interest in developing a patient preference survey for novel devices. The KHI is committed to helping the FDA meet their strategic priority through collaboration with the patient community.

People with kidney diseases are finally receiving the interest, investment, and innovation they deserve. It is incumbent on the kidney community to capitalize on this moment and produce new treatment options. Every day, people with kidney failure die without seeing the new drugs or devices promised them. The KHI will continue to work with the FDA and the membership to address barriers to innovation so that drug, device, and biologic development has the best chance of success. People with kidney failure have waited long enough.

Acknowledgments

The content of this article does not reflect the views or opinions of the American Society of Nephrology (ASN) or CJASN. Responsibility for the information and views expressed therein lies entirely with the author(s).

Disclosures

Mr. Cahill is an employee of ASN. Dr. Harris has nothing to disclose.

Funding

The Kidney Health Initiative is funded by a grant from FDA.

References

1. Archdeacon P, Shaffer RN, Winkelmayr WC, Falk RJ, Roy-Chaudhury P: Fostering innovation, advancing patient safety: The kidney health initiative. *Clin J Am Soc Nephrol* 8: 1609–1617, 2013
2. US Department of Health and Human Services: Advancing American Kidney Health initiative. Available at: <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>. Accessed September 12, 2019
3. Chatzimanouil MKT, Wilkens L, Anders HJ: Quantity and reporting quality of kidney research. *J Am Soc Nephrol* 30: 13–22, 2019
4. Gipson DS: The complex landscape of drug development for children with chronic kidney disease, 2019. Available at: <https://www.kidneynews.org/kidney-news/current-issue/the-complex-landscape-of-drug-development-for-children-with-chronic-kidney-disease>. Accessed September 12, 2019
5. Perkovic V, Jardine MJ, Neal B, Bompoint S, Heerspink HJL, Charytan DM, Edwards R, Agarwal R, Bakris G, Bull S, Cannon CP, Capuano G, Chu PL, de Zeeuw D, Greene T, Levin A, Pollock C, Wheeler DC, Yavin Y, Zhang H, Zinman B, Meininger G, Brenner BM, Mahaffey KW; CREDENCE Trial Investigators: Canagliflozin and renal outcomes in type 2 diabetes and nephropathy. *N Engl J Med* 380: 2295–2306, 2019
6. Freedman BI, Moxey-Mims M: The APOL1 long-term kidney transplantation outcomes network-APOLLO. *Clin J Am Soc Nephrol* 13: 940–942, 2018
7. US Food and Drug Administration/Center for Devices and Radiological Health- Innovation Challenge: End-Stage Renal Disease, 2012. Available at: <https://wayback.archive-it.org/7993/20170111191653/http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/ucm286140.htm>. Accessed September 12, 2019
8. Flythe JE, Narendra JH, Hilliard T, Frazier K, Ikeler K, Amolegbe A, Mitchell D, Dorrough A, Lee SD, Ordish A, Wilkie C, Dember LM; Building Research Capacity in the Dialysis Community at the Local Level Stakeholder Workshop Participants: Cultivating a research-ready dialysis community. *J Am Soc Nephrol* 30: 375–380, 2019

Published online ahead of print. Publication date available at www.cjasn.org.