

# The New HHS Kidney Innovation Accelerator

## When Innovation Stalls, HHS Says Floor it!

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“It is not the critic who counts; not the man who points out how the strong man stumbles, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena, whose face is marred by dust and sweat and blood; who strives valiantly; who errs, who comes short again and again, ...” Former President Theodore Roosevelt at the Sorbonne in Paris, France on April 23, 1910.

There are moments in time when disrespect toward public servants and rising cynicism about the motives of private sector companies, and the ingenuity of their workers to solve challenges, is so pervasive that it distracts some Americans from envisioning the possible. In these moments, history is a reminder of similar instances when handfuls of dedicated citizens, united in a noble cause and marshalling diverse talents, accepted the mantle of leadership and became catalysts for historic change. This is our shared American ethos: we confront, we solve, and we transcend. Each time we do, even if we stumble, we instill a new generation with hope and appreciation for our shared ideals.

In the fight against kidney disease, this is our moment as a community to look beyond the status quo and cynics and imagine the possible. The time is now to say “If not us, then who? And if not now, then when?” As two professionals blessed with kidney transplants and respective careers in public policy and the pharmaceutical industry, we have unlimited optimism regarding innovation. As Kidney Week 2017 concluded last November, we departed New Orleans with a clearer sense of where this community stands in the good fight. We witnessed coordinated leadership across key initiatives aimed at aligning talent, resources, and capacity necessary to triumph. For public servants, medical professionals, clinicians, clinical researchers, bench scientists, and patient advocates, we believe there has never been a better time to offer your talent and engage your professional associations in the transformation of the kidney landscape.

The urgency for innovation is fueled by grim reality. Worldwide, 500 million people have kidney disease and 2.6 million are on dialysis. In the United States, 40 million citizens suffer from kidney disease and 700,000 need dialysis or a transplant to stay alive. Nearly 120,000 new patients enter dialysis every year and our

health system bears a \$98 billion yearly cost for kidney care, of which \$33.9 billion in taxpayer funds goes to manage kidney failure and dialysis through Medicare’s ESKD program (1,2). Patient burden suffers in many ways: incalculable costs of fear and anxiety; interrupted aspirations; stress on family and caregivers; loss of jobs, earnings, and dependence on disability; and difficulties securing life, disability, and long-term care insurance.

### The Kidney Health Initiative

Launched in September 2012 by the American Society of Nephrology (ASN) and the US Food and Drug Administration (FDA), the Kidney Health Initiative (KHI) aims to address the dearth of innovation in kidney disease. The KHI is a forum in which federal regulators, researchers, and private developers apply their insights to identify potential barriers and pathways to future solutions (2). The KHI involved patient advocates from the start—the American Association of Kidney Patients (AAKP) is a founding member, and the KHI values their insights and disproportionate, independent power within the policy ecosystem. Our fellow advocacy leader, Celeste Castillo Lee, institutionalized patient voice within the KHI through the Patient Family Partnership Council (PFPC). The PFPC makes recommendations on future KHI member projects and helps shape the direction of the KHI.

### The Kidney Precision Medicine Project

Launched in 2017 by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health (NIH), the Kidney Precision Medicine Project (KPMP) seeks to ethically obtain and evaluate human kidney biopsy specimens from participants with AKI or CKD, create a kidney tissue atlas, define disease subgroups, and identify critical cells, pathways, and targets for novel therapies (3). The ASN and AAKP have supported the KPMP in meetings before the US Congress. With the KPMP, the NIH reaffirmed its role as the engine of scientific innovation and hope in the kidney space, just as it historically served as a catalyst for discovery and hope to the HIV, hepatitis C, and oncology communities.

At ASN Kidney Week 2017, the KHI and KPMP served as the backdrop as officials from the US Department of Health and Human Services (HHS),

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including Dr. Sandeep Patel, announced the Kidney Innovation Accelerator, or KidneyX (4,5). KidneyX establishes a public-private innovation fund capable of igniting discoveries in kidney disease treatments and technologies as well as leveraging expertise from the FDA, NIH, and the Centers for Medicare and Medicaid Services. Before the announcement, HHS officials met with the KHI PFPC and listened to patient insights on barriers to innovation, each of which mirrored HHS preliminary research. A Memorandum of Understanding between ASN and HHS, formalizing KidneyX, was signed on April 26, 2018 by ASN President Mark Okusa and former HHS Chief Technology Officer Bruce Greenstein.

As KidneyX moves forward, we suggest that the HHS keeps KidneyX principles in the public eye and utilizes several themes, inspired by our experiences as kidney advocacy leaders, to publicly message the strategic framework and future results.

### Patient-Centered Design

Drawing upon the Institute of Medicine (IOM) report, *“Crossing the Quality Chasm: A New System for the 21st Century,”* we suggest that patient-centered care principles be adapted into design principles (6). It bears repeating that the IOM defines patient-centered care that is respectful of, and responsive to, individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions. Following the example set by both the KHI and KPMP, we recommend that kidney patients have a seat at the table and a substantive role in defining innovation.

### Stakeholder Engagement Strategy

Black and Hispanic Americans suffer the greatest demographic effects and burdens of kidney disease. Although black people represent 13.2% of the United States population, they constitute >35% of all patients on dialysis in the United States and account for >33% of those on the kidney waiting list (7,8). They also have longer wait times and increased risk of graft failure. A comprehensive stakeholder strategy must incorporate black, Hispanic, and other minorities to ensure that future innovations incorporate the interests of highly affected communities.

### Downstream Innovation versus Upstream Innovation

We recommend that KidneyX address both downstream innovation, short-term, and upstream innovation, long-term.

**Downstream Innovation.** Of the 700,000 patients living with ESKD, almost three quarters of these patients are on dialysis and the balance are transplant recipients. There is an immediate need to improve the quality of life and mortality rates for both populations. Initiatives aimed at aligning treatment, including home dialysis and transplantation, to patient aspiration is the best guarantor for greater independence and for ending the default reliance upon disability, especially when medically unnecessary.

**Upstream Innovation.** The KPMP will improve scientific understanding of kidney diseases, including those caused by metabolic syndrome, diabetes, hypertension, and vascular disease. Findings may lead to more innovations in

care delivery systems and provide insights for leveraging big data for prevention, intervention, and earlier treatments. New companies entering the kidney arena, such as CVS, will look to combine electronic health data and technologies such as telemedicine to revolutionize care on the front-end, and disrupt care delivery through more preemptive transplants and more home therapies. KPMP findings may spur the pharmaceutical industry to develop treatments for AKI and CKD. We recommend that KidneyX build on the work of the CKD Biomarkers Consortium, including the recent National Kidney Foundation-FDA-European Medicines Agency scientific workshop. Biomarkers and surrogate trial end points will support new clinical trials focused on earlier intervention of CKD (9).

### Patient Engagement

Self-care skills among many kidney patients are an unmet need and we recommend collaborating with the Office of the National Coordinator for Health Information Technology (ONC), which has identified advancing person-centered and self-managed health as one of its strategic goals. To support this goal, ONC contracted with Accenture Federal Services to publish a white paper outlining how patient-generated health data can be incorporated into care delivery and research (10). Patient-generated health data utilization has the potential to improve outcomes, lower health care costs, and better engage patients in their own care.

Among lawmakers, interest in these initiatives has expanded. On March 29, 2018, the ASN and AAKP conducted a congressional fly-in to Washington, DC to educate Congress on innovation demand, KidneyX, and private sector interest. In 8 hours, 75 professionals and patients connected with dozens of congressional leaders while a simultaneous ASN and AAKP KidneyX social media campaign reached over 90,000 opinion influencers with only 460 tweets.

During our congressional meetings, the ASN and AAKP asked lawmakers to send letters to HHS Secretary Alex Azar in support of KidneyX to expand interest among companies and potential investors. Iowa Senator Charles Grassley, a leader on the health and budget issues, was moved by the appeal offered by constituent Nicole Jefferson, a kidney patient and AAKP Ambassador, and sent an immediate letter to the HHS. Senator Grassley cited past collaboratives involving the federal government, including the fight against polio, US Department of Defense Advanced Research Projects Agency efforts to increase accessibility of common pharmaceutical products, and the US Department of Defense collaboration with the private sector in the 1960s to create the resilient alternative communications system we know today as the internet (11). In each instance, the government recognized it was not the solution and instead used its power to capture public interest and convene talent across multiple sectors to drive for solutions.

We encourage everyone who reads this article to leverage your networks and encourage more professionals and patients to enter the arena. Remind them there is no credit among spectators or cynics. Tell them honor lives only among those who choose to fight, especially for the lives of the innocent.

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### References

1. National Institutes of Health: Kidney Disease Research Funding and Priority Setting. GAO-17-121, 2016. Available at: <https://www.gao.gov/products/GAO-17-121>. Accessed August 19, 2018
2. 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
3. Available at: <https://www.niddk.nih.gov/research-funding/research-programs/kidney-precision-medicine-project-kpmp>. Accessed August 19, 2018
4. ASN Society News: January 9, 2018. Available at: <https://www.asn-online.org/news/item.aspx?ID=144>. Accessed August 20, 2018
5. ASN Kidney News Online: April 27, 2018. Available at: <https://www.kidneynews.org/policy-advocacy/leading-edge/newly-launched-kidneyx-aims-to-accelerate-the-commercialization-of-innovative-therapies-in-kidney>. Accessed August 19, 2018
6. Institute of Medicine (US) Committee on Quality of Health Care in America: Crossing the Quality Chasm: A New Health System for the 21st Century, Washington, DC, National Academies Press, 2001
7. National Kidney Foundation: African Americans and Kidney Disease. Available at: <https://www.kidney.org/news/newsroom/factsheets/African-Americans-and-CKD>. Accessed August 19, 2018
8. HRSA US Organ Procurement and Transplantation Network (OPTN): Based on OPTN Data as of July 12, 2016
9. National Kidney Foundation: Accelerating New Clinical Trials and Treatments for Kidney Disease. Available at: <https://www.kidney.org/news/accelerating-new-clinical-trials-and-treatments-kidney-disease>. Accessed March 16, 2018
10. Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024 January, 2018. Available at: [https://www.healthit.gov/sites/default/files/onc\\_pghd\\_final\\_white\\_paper.pdf](https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf). Accessed August 19, 2018
11. Letter from Senator Charles Grassley to US Health and Human Services Secretary Alex Azar, April 2, 2017. Available at: [https://aakp.org/wp-content/uploads/2018/04/2018\\_04\\_02-Alex-Azar-regarding-Kidney-X.pdf](https://aakp.org/wp-content/uploads/2018/04/2018_04_02-Alex-Azar-regarding-Kidney-X.pdf). Accessed August 20, 2018

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