The Kidney Accelerator
Innovation Wanted, Nephrologists Needed

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Innovation in nephrology is long overdue. The most impactful innovations in our field arguably arrived half a century ago with the invention of maintenance dialysis and novel federal funding policies, providing life-sustaining therapy to those with kidney failure. In the interim, we saw important advances, including the introduction of erythropoietin and improved immunosuppressants. However, we continue to reward kidney failure with a life on dialysis for many, while thousands die every year on the kidney transplant waitlist. Where are the novel ways to improve life with kidney disease, and where is the hope for a cure?

As nephrologists, we have known for years that our field is lagging behind other medical subspecialties in scientific breakthroughs, translational therapies, and clinical advances for our patients (1). For instance, cardiologists have published ten times as many randomized, controlled trials as nephrologists over similar time periods (2). Medical oncology had 5890 ongoing trials at the end of 2017 and brought 29 of the 99 Food and Drug Administration (FDA)-approved drugs to market between 2015 and 2017. In the same period, nephrology had <500 registered clinical trials and two FDA-approved drugs (R. Meyer, personal communication). The urgency to cure cancer is broadcast through slogans, races, and donation drives. Although we know that kidney failure is common, expensive, and as deadly as most cancers, the urgency for action is not apparent. Our community has the data that we need to broadcast this message on behalf of people with kidney disease. Of the nearly 500,000 patients on dialysis, one half will die in <5 years (3). The Americans who live with dialysis cost the federal government $4 billion, which was highlighted in the 2017 Government Accountability Office report (4). And yet, the government reinvests <1% of the expense into research for our field. They should be clamoring to reinvest in patients on dialysis who make up 1% of the Medicare population while costing over 7% of its budget (3).

Innovation should improve the lives of patients with kidney disease. Nephrologists would benefit from this as well. For many of us, dialysis is our livelihood, but innovation could provide new options for care outside of the traditional dialysis facility. Rare is the nephrology trainee who dreamt of becoming a "dialysisologist," driving between facilities to fulfill increasing requirements in one of the most highly regulated fields in medicine. Our time spent with patients, often precious and fulfilling, is lacking, and it is one factor that has led to decreased job satisfaction (5). Innovation, no matter the source, might lead to different care models and increased satisfaction in the field.

Innovation may also help to attract the nephrologists that our patients need. One consequence of poor job satisfaction has been further negativity about the prospects in our field. This is apparent to physician trainees who are deciding on careers (6). Only six of every ten nephrology training positions were filled for Appointment Year 2018, down from more than nine in ten filled in 2010, 2011, and 2012 (7). Interest in nephrology research positions declined similarly over this period.

With a cure or at least therapies to mitigate kidney failure, we could care for more patients with kidney function instead of without it. Our patients' quality of life could improve along with our satisfaction in seeing our patients living longer, more fulfilling lives.

Along with poor job satisfaction, nephrologists experience a high rate of burnout (8). Nephrology has never been a profession of convenience. We are known to be a hard-working bunch, with a fascination for complex pathophysiology, a desire to serve the chronically ill, an interest in functional patient care systems, and deep personal relationships. However, nephrology has become an increasingly inconvenient place to practice, with systems that are poorly integrated and information flow that is far from seamless. The inconvenient truth is that nephrology has become an unpopular specialty.

We need a universal partnership that extends beyond the traditional resources to improve the field. This sums to the need for innovation—for our patients to survive better and for our field to thrive.

In this environment, the former Chief Technology Officer for the Department of Health and Human Services (HHS), Bruce D. Greenstein, announced the HHS's intent to launch a kidney innovation accelerator, also named "KidneyX," in front of an auditorium of patients and providers at American Society of Nephrology (ASN) Kidney Week 2017. This partnership of public and private groups would harness a competitive process to select early-stage companies to participate in several areas, including diagnostics and therapeutics, next generation dialysis, tissue engineering, and

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patient-centered tools. Both federal and private funds would be used for early-stage development and building prototypes to track into preclinical studies and clinical trials (9).

Even those who are not prize winners can advance gaps in knowledge, much as other "X Prize" competitions have done. The race to cure kidney disease can bring teams together to foster the same zeal that brought the Seattle community together over 50 years ago to help those with kidney failure survive their end stage condition.

People with kidney disease not only need better possibilities for kidney survival and improved experience, but also, they need hope for a cure. Our patients remind us of this often. "We have horse and buggy technology, and I need a self-driving car" (L. Stern, personal communication). Creating a sense of urgency is essential and a main goal of KidneyX, the Kidney Innovation Accelerator. We have seen some innovation recently, including patient engagement projects and telehealth opportunities. However, the excitement generated by KidneyX can drive more substantial change, with a wider array of partners. We must embrace this opportunity as a solidified community. The specific areas being developed to attract increased participation include the following.

Derisking the commercialization process—coordination by the National Institutes of Health, the Centers for Disease Control and Prevention, the FDA, the Centers for Medicare and Medicaid Services, and the Health Resources and Services Administration to clear a predictable path to commercialization.

Providing direct funding to seed, incent, and accelerate breakthroughs of promising innovators through a competitive process.

Offering participating innovators access to investors and business experts and repositioning the kidney space as an attractive untapped market.

The objectives outlined above pave the way for a synergistic approach, attracting private investors with clear paths toward public approvals and attracting public partners with access to private resources and expertise from the private sector that have been otherwise unavailable.

The initial memorandum of understanding to launch KidneyX was signed on April 26, 2018 between the HHS and the ASN. On May 16th, patients with kidney disease and physicians met with officials from the HHS to tell their story. Governance structure is currently being formalized. Three town halls around the country are being held in 2018 for public comment and finalizing rules around awards and structure. These include patient groups, nephrologists from community and academic centers, research groups, and investors. KidneyX's pilot round of funding to accelerate next generation dialysis products will begin accepting applications in late 2018, with the goal of awards in the spring of 2019.

The initial funding calls for a lofty $250 million: $25 million per year for 5 years from public sources and the same from private sources. The ASN is contributing an initial $25 million, with an aim to raise $100 million more over the next 5 years from private sources. The current administration has set aside $50 million this fiscal year for chronic disease initiatives with public/private partnerships. The kidney community is reaching out to the US Government to request appropriation of a portion of these funds to KidneyX over time. Thereafter, the innovations from this accelerator would aim to recoup some initial investment, paving a self-sustaining pathway for this partnership.

The accelerator aims to bridge the gap between research and market-ready products, providing merit-based funding to promising investigators through a competitive process. The potential benefit of this competition to the nephrology community cannot be underestimated. With innovation, dialysis could become a bridge—to transplantation, three-dimensional printable devices, wearable kidneys, and organs grown in a dish. For those who we do assist on dialysis, we can harness telehealth, improved technology for communications, more holistic care approaches, expanded patient independence, patient empowerment, and wellbeing. For those patients who avoid dialysis and benefit from these advances, we become their CKD specialists. We can curtail "windshield time" that takes us away from our patients. Our lifestyles improve along with our patients. Our field generates excitement, attracting trainees and researchers who want to be on the forefront of a kidney cure.

We can be the leaders of this movement to innovation that makes our patients' lives more convenient, giving them back the time that they want and the need for the quantity and quality of life that they deserve. Let us change our field from one that is suffering to one that is providing new hope for future patients and care providers alike. Fortunately, our field is starting to embrace the need for innovation. Groups, including the American Association of Kidney Patients, the ASN, and Kidney Care Partners are organizing Congressional debriefings to focus on innovation, including the Kidney Accelerator. An industry-wide innovation work group, begun in early 2018, also emphasizes this need.

Forty million people are living with kidney disease. Six hundred eighty thousand have kidney failure. And there is no cure. KidneyX aims to transform kidney care and reinvigorate our field. Let us start with innovation.

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Disclosures

S.W. is the current Chief Medical Officer for Northwest Kidney Centers, a not-for-profit dialysis organization.

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See related article, "The New HHS Kidney Innovation Accelerator: When Innovation Stalls, HHS Says Floor it!," on pages 1747–1749.