Kidney News Online interviewed Edwin Simcox, Acting Chief Technology Officer, Department of Health and Human Services (HHS), and HHS liaison to KidneyX.

Edwin Simcox

Tell us about your background. How long have you been with HHS?

I’ve spent the bulk of my career working to create a better healthcare system with the goals of reducing cost and increasing quality and patient satisfaction. Much of my focus has been on health IT and innovative technologies dealing with challenges like EHR usability and interoperability. But I also have experience using innovation to improve healthcare operations. During the past year or so of my time at HHS, the Office of the Chief Technology Officer (CTO) has worked on a number of important initiatives including open data, innovation, and increasing the ability of startups to access such a huge bureaucracy as HHS.

The KidneyX initiative epitomizes what we are trying to do because it combines innovation and greater access to improve healthcare for the more than 40 million Americans living with kidney diseases.

Why is the Office of the HHS CTO interested in kidney diseases?

That’s a great question. Since the creation of dialysis 60+ years ago, there has been little to no innovation in the treatment of kidney diseases. Plus, chronic kidney disease is the only disease state that can qualify people for Medicare regardless of age. Of those Americans facing kidney diseases, 661,000 have kidney failure requiring dialysis or transplantation.

According to a 2017 GAO report, Medicare annually spends $34 billion treating kidney failure, which is more than the entire budget of the National Institutes of Health (NIH) or NASA, and the costs continue to increase. We at HHS are the largest payer for kidney care, but we haven’t traditionally asked for innovation. This is what we are trying to do with KidneyX. We are trying to create a sense of urgency to develop new therapies to treat kidney diseases.

KidneyX says to innovators across the world that this is an area we care about at HHS and for which we want to see innovation. The Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS) and NIH are key partners at HHS in supporting the pipeline of innovation. With KidneyX, FDA and CMS have signaled to the world that this is an area they care about and that they are committed to clarifying the pathway to commercialization for innovators.

While the pilot KidneyX prize will focus on developing alternative treatment options to dialysis, we will then launch additional prizes that will focus on other areas, such as improving prevention and diagnostics of kidney diseases. We have to move upstream to help patients earlier so that we can reduce the occurrence of kidney failure. Chronic kidney disease is debilitating to millions of Americans, so we must focus also on prevention and diagnosis to really improve quality of life.

What is the first goal you hope to achieve through KidneyX?

We aim to “de-risk” innovation by streamlining processes, reducing regulatory barriers, and modernizing the way we pay for treatment. This is going to require innovation from outside the government. We plan to stimulate and accelerate innovation through a series of cash prize competitions.

We are getting ready to kick off the first pilot prize competition, which will focus on fostering the development of technologies for next-generation renal replacement therapy. Dialysis is the initial focus because we understand the problems there and we know what approaches have limited upside. We also intend to address the lack of innovation in the areas of diagnostics and prevention. We are working on defining where those future opportunities are and plan to launch prizes that will address those areas.

What are the biggest challenges and opportunities for KidneyX moving forward?

We are confident in our plan. We have robust support from HHS Secretary Alex Azar and widespread support within the relevant HHS agencies. That said, we understand we are creatively disrupting a large, complex, bureaucratic system, and we know this presents a challenge.

Another challenge is lack of a mature innovation pipeline in the development of medical products for kidney diseases. We have to do a better job attracting innovators who may have never worked in the kidney disease space and address any real or perceived barriers keeping them from getting new products to patients. There is a learning curve innovators who are new to this space and HHS may experience. One way the Office of the Chief Technology Officer is helping to partially address this learning curve is by doing outreach across the United States at “startup days,” which aim to demystify HHS and the regulatory processes as a first step.

Regarding opportunities, I can tell you that our team is super excited about KidneyX because we have the potential opportunity to foster innovation that brings hope to the millions of Americans with kidney diseases. We think the future is bright and we really hope we can make a positive impact in people’s lives.

Have a tip or idea you’d like to share with your fellow peers and the broader kidney community?

Send your idea to the Kidney News Fellows Corner column at kidneynews@asn-online.org