

Accelerating Technology Development During a Pandemic to Bring More People with Kidney Failure Home

Position Paper

Kidney Health Initiative

Founded in 2012, the Kidney Health Initiative (KHI) is a public-private partnership between the American Society of Nephrology (ASN) and the US Food and Drug Administration (FDA) committed to catalyzing innovation and the development of safe and effective patient-centered therapies for people with kidney diseases. With over 100 member organizations, KHI is the largest consortium in the kidney community. The KHI Board of Directors considered a variety of issues impacting drug and device development in the kidney community during the Coronavirus – 2019 (COVID-19) pandemic and identified accelerating development of home therapies as central to improving care.

The COVID-19 pandemic is unmasking the shortcomings of in-center hemodialysis for people with kidney failure. Individuals with kidney failure who rely on in-center dialysis do not have the luxury of social distancing during a pandemic. In-center dialysis exposes people with kidney failure and healthcare workers to potential infection. Additionally, in-center hemodialysis patients are exposed to other discomforts and inconveniences associated with strict infection control and isolation policies necessitated by emergencies like pandemics.

The opportunity to receive kidney replacement therapy at home via home hemodialysis (HHD), peritoneal dialysis (PD), or other technology, either during the pandemic or non-emergent times could substantially improve the quality of life for people with kidney failure. Now is the time to accelerate the development of home, wearable, or implantable products that offer patients more options for their treatment.

Home therapies, including future wearable and implantable therapies, offer many benefits to people with kidney failure including:

- Providing freedom and control over treatment;
- Extending capacity for full or part time work, schooling, or other pursuits, and avoiding disability; and
- Enabling longer periods of dialysis to improve blood homeostasis.

This pandemic should impel a renewed commitment to accelerating innovation through initiatives such as the July 2019 Presidential Executive order [Advancing American Kidney Health](#), the KHI [Technology Roadmap for Innovative Approaches to Renal Replacement Therapy](#) (RRT Technology Roadmap), and the US Department of Health and Human Services (HHS)/ASN's [KidneyX Redesign Dialysis](#) prize competition. This renewed commitment will create technologies that facilitate increased access and use of currently available HHD and PD therapies, while next generation home, wearable, and implantable technologies are being developed. Such initiatives could significantly decrease the number of people receiving in-center hemodialysis while improving their quality of life, as well as provide more stable patient centered

treatment to this vulnerable population during pandemics, natural disasters, as well as during usual, non-emergent times.

The Situation of People with Kidney Failure During a Pandemic

People with kidney diseases experience tremendous fear because of their vulnerability to infection, a fear that is fully warranted given their high burden of heart disease, hypertension, diabetes, impaired immunity, and other comorbid conditions. Infection is the second leading cause of death among individuals receiving dialysis. Among the earliest victims of COVID-19 in the United States was a person on in-center hemodialysis, and that fact alone is tremendously unsettling for patients and their families as they face the same risks.

Patients who undergo thrice weekly therapy in a dialysis facility experience heightened safety concerns due to potential exposure to the COVID-19 virus. These concerns increase patient interest in home-based modalities and the development of additional alternatives now and going forward.

Advancing Patient-Centered Technology for Home Therapies and Other Alternatives to In-Center Dialysis

HHD or PD provides many advantages to in-center hemodialysis during a pandemic. The risk of exposure to pathogens would potentially be reduced in patients receiving home therapies, due to reduced physical contact with medical personnel, other patients in clinics, and during transport to clinics. Most importantly, home therapies may be associated with better outcomes and quality of life than in-center therapy.

Currently several new technologies and innovations with the potential to facilitate wider adoption of home therapies are accelerating development processes. Exciting innovations include easier-to-use HHD machines, updates to PD technologies, advances to vascular access, and enhanced communication tools for physicians, clinics, and patients. However, advances in number and ambition are needed if more medically eligible individuals are to go home for treatment.

Fortunately, policy makers, innovators, researchers, and healthcare system leaders already have a clear roadmap for making these technology advancements possible. The KHI Technology Roadmap, released in 2018, describes the milestones and minimum design criteria that must be met to deliver novel approaches to kidney replacement therapies, including wearable, portable, and implantable dialysis solutions.

New technologies and innovations that will overcome the existing challenges include, but are not limited to:

- Efficient use of water, via purification, sterilization, and reuse technologies;
- Point of care infection detection;
- Miniaturization, especially of energy sources, pumps, filters, and fluids;
- Painless, self-sealing, needle free, and patient operated vascular access;
- Blood filtration, access to a safe, effective, longer-life, easy-to-use filtration system that avoids clotting issues;

- Toxin removal and secretion for reduced presence of harmful toxins in the bloodstream that could lead to uremic toxicity and/or drug toxicity;
- Fluid regulation to allow patients to personalize and optimize the amount and rate of excess fluid removal resulting in stable blood pressure and less thirst and cramping;
- Filtrate transport and drainage processes and equipment that are safe and effective;
- Sensors, especially for fluid status, infection, electrolyte imbalance, and other physiologic status indicators; and
- Remote monitoring and telehealth services.

Focus on Individual Patients

As technological development is accelerated, vulnerable and underserved populations must receive equal access to these new technologies, especially remote monitoring, telehealth, and availability of clean water. It is imperative that patient-centered tools are developed to ensure everyone has access to home and other alternative therapies.

Approaches that stimulate creative solutions and innovation will help the kidney community and propel positive change in other sectors of society. Policy, medical and hospital system planners will have new tools in their arsenals and government leaders, including in the Department of Defense and Veterans Affairs, will have new technologies to utilize in other emergency situations.

KHI has provided tools that innovators can use to integrate patient preferences and patient reported outcomes throughout their product's lifecycles so that the innovative solutions match what people with kidney disease need.

The COVID-19 pandemic has laid bare the challenges and fears the kidney community has been grappling with for years. Those challenges are heightened in people with kidney diseases who are more vulnerable or who have reduced access to optimal treatment options and, health care. Now is the time to bring technologies to market that have the potential to reduce disparities and improve the lives of *all* individuals with kidney failure.

Researchers, innovators, and entrepreneurs must work together with the kidney community to overcome the engineering and scientific barriers that make it hard for some patients to utilize home therapies. This kind of concerted effort will create incremental and transformative technologies to dramatically improve care for those with kidney diseases ahead of the next pandemic or natural disaster.

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