## Reducing the Risks of Home Dialysis Innovation and Uptake

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Reducing the Risks of Home Dialysis Innovation and Uptake: The Case for Human-Centered Product Design

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Reducing the Risks of Home Dialysis Innovation and Uptake: The Case for Human-Centered Product Design

A disruptive innovation is a technologically simple innovation in the form of a product, service, or business model that takes root in a tier of the market that is unattractive to the established leaders in an industry. - Clayton M. Christensen (1)

There are times in our nation’s history when the urgency of immediate events is so overwhelming that it can distort our perspective on what really matters. Over the past twenty-four months, the COVID-19 pandemic has taken nearly a million American lives and significantly more across the globe (2). Yet, amidst the chaos, people throughout the world have marveled at the heroic and collaborative efforts medical professionals, researchers, the pharmaceutical industry, regulators, policymakers, and patient advocacy organizations have undertaken to deliver timely innovations, save lives and prevent even further human suffering. Seasoned policy and medical experts understand these timely innovations rest upon two decades of imaginative thinking, intentional policy frameworks, collaborations, and substantial investments across the public, private and non-profit sectors. Together, these components created the springboard for rapid innovation and medical victories the world has applauded.

The aggressive push for technology development to address the crisis of COVID-19 focused on the urgent public health need to save lives. Understanding the tremendous ongoing risk to people with kidney diseases during COVID-19, the kidney community should pause and ask if it has dedicated the same thought and focus to calibrating technology advancements to the lives it is committed to saving.

Throughout the pandemic, kidney stakeholders have responded boldly, and with unified purpose, to the address the critical needs of highly vulnerable immunosuppressed and immunocompromised people with kidney diseases. The actions of frontline kidney health professionals, operating under extraordinary conditions and within the confines of emergency policy waivers and current technologies, has been heroic. Still, the cost COVID-19 exacted upon people with kidney diseases, especially people on in-center hemodialysis, has been horrific. A 2021 study of the nearly 500,000 people on Medicare-covered dialysis showed that in the first year of the pandemic, the rate of infection was 12% and post-infection mortality was 26%, compared to a 17% mortality rate for people on dialysis who had not been infected by SARS-CoV-2. The study also showed disturbing data concerning infection and mortality rates among minorities on dialysis. (3) The pandemic is a sobering reminder of the ongoing vulnerabilities of people on dialysis and the cumulative negative consequences of disparate care access and the lack of care choices, especially among underserved communities. People on in-center hemodialysis are precisely the tier of the dialysis market that would most benefit from greater innovations in home-based hemodialysis technologies.

This is the moment when the kidney stakeholder community must ask ourselves what lessons have we learned about the weaknesses of status quo hemodialysis? And, if the COVID-19 tragedy does not spur us to change, what will change our outlook toward hemodialysis and our urgency to transform it?

Over the past ten years, patient advocates, health professional organizations, emerging dialysis providers, and others that make up the kidney community have constructed a springboard for rapid innovation. We established policy and scientific frameworks through the Kidney Health Initiative, launched KidneyX, and facilitated the Executive Order on Advancing American Kidney
Health. We aided ground-breaking U.S. Food and Drug Administration actions to accelerate substantive patient engagement and the utilization of patient insight data across the product development lifecycle. (4, 5) We nudged the Centers for Medicare and Medicaid Services to create new models and incentives for more patient-centered care approaches, including home dialysis expansion. We witnessed competitive forces take hold as new companies entered the dialysis market. Yet, from a hemodialysis consumer perspective, product developers could take greater advantage of our innovation springboard to produce disruptive home-based hemodialysis technologies designed to function simply in the way, and in the places, people with kidney failure want to live.

People with kidney diseases are informed consumers who should have input on technologies that impact their health and quality of life. In the example of home-based hemodialysis, they may be reluctant to start and continue treatment options that: require extensive training, cannot be accommodated in their home environment, do not fit their active lifestyle, or address a need to stay engaged in their local community or maintain their individual peace-of-mind. Home-based hemodialysis should also consider the needs of people whose overall health care might depend on other at-home medical devices or have limitations such as strength, mobility, or disabilities. This lack of understanding on the broader patient need is highlighted by a significant percentage (6) of those who initially transitioned from facility-based to home-based dialysis, only to eventually return to facility-based treatment.

Human-centered design is a proven methodology (7) that links a consumer’s needs and the problems they want solved into a product’s design and evaluation. Consumers expect products to meet their needs and accommodate their day-to-day lives, and maybe less inclined to significantly alter their way-of-life to adopt a new technology. This framework starts with understanding and prioritizing problems that a consumer is looking to solve without a specific solution in-mind (8). This process identifies obvious and less-obvious needs and highlights lifestyle burdens that might be mitigated. Collectively, these considerations are evaluated and translated into the design of a product to increase likelihood of adoption and sustained use during health emergencies and regular life.

The lessons of COVID-19 demand patient outcomes be redefined by less mortality and greater access to safer and home hemodialysis technologies. This requires a holistic approach that maintains a focus on desired outcomes and encourages disruptive innovations that empower patients to gain the freedom they need to live longer and reach their highest aspirations. Applied to home-based hemodialysis, a human-centered design process recognizes people with kidney failure as the ultimate consumers by increasing the value of their unique insights and needs, beyond physiologic health improvement, and integrating these within the product ideation and development processes. In short, human-centered product design must incorporate not only clinical needs and patient needs, but also non-clinical needs arising from the context a person lives in and how a person would use and maintain a product. These factors contribute to the total product system in which an innovation will be utilized and supported by the market. The total product system is a product design and development framework that includes non-technology considerations for sustained use in the commercial marketplace.

Obvious considerations include patient desires for greater independence and control over personal and family schedules; administration of convenient and more frequent dialysis to increase effectiveness of treatment; increased freedom to pursue part-time or full-time employment or community activities; and, increased ability to receive at-home treatment safely and avoid exposure to infectious diseases such as COVID-19. Product designs should also
consider less-obvious issues related to medicalization of the home environment and compartmentalization of dialysis/non-dialysis life, such as increased caregiver burden to support treatment; need for a private treatment space isolated from daily home activities; hesitancies about using needles and self-cannulation to perform treatment; need to reduce risks of needle dislodgement and bleeding; requirements for at-home infection control and prevention measures; limited storage availability for supplies and consumables; and supply and waste management (9). Device designers and developers should consider that people may incur additional costs with at-home treatment and have differing access to reliable infrastructure for water, power, and broadband network connectivity. Human-centered design provides tools to assess these different and sometimes conflicting needs, and communicate tradeoffs to people with kidney failure in terms of what burdens are added and what are taken away.

After a prototype is designed and developed, it should be further evaluated by focus groups to identify opportunities for further optimization. The cycle repeats itself until an equilibrium is found between intended health outcomes, consumer non-clinical needs, and cost-effective technology improvement, providing an off ramp to commercialization that limits resource-heavy technological perfection beyond what is “good-enough”. This process of identifying and maintaining a continuous link to consumers’ needs not only aligns product development, but it is also a critical component of design control processes necessary for regulatory approval of medical devices (10). The US Food and Drug Administration (FDA) has also signaled the importance of human factors engineering, another aspect of human-centered design (11).

The innovation risk for kidney diseases is that people on dialysis are often not considered as consumers. Now is the time to include their choices and preferences as part of the innovation springboard to reverse the numbers returning to facility-based treatment options after a limited time on home-based hemodialysis. Two years of COVID-19 showed the impact of having people on dialysis travel from the safety of their homes to receive treatment. If solutions are based solely on advancing science or technology, or simply miniaturizing a device in a dialysis clinic for a person’s home, patients and their care partners may not be willing to adjust other parts of their lifestyle to receive treatment at home. Unnecessary complexity in the technology also inherently adds cost to the consumer and payors, which neither may be willing to accept. To do this right, innovators need to expand their respect and true empathy towards the lives and contexts of people on dialysis through meaningful conversations that empower patients to share how, when, and where they want to receive treatment, and use that framework to guide the development of much needed innovations.

Disclosures:

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References:


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