How Technology Will Transform Kidney Disease Management

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THE MEASURE OF BETTER RESULTS.

Desperate Need to Improve Chronic Kidney Disease Management

For seven years since her kidneys totally failed, Mary Christiensen was driven three times each week to a clinic for hemodialysis. Even though this routine was draining, she stoically continued so she could feel better for a day or so after each treatment. It was only with her closest friends that she confided her underlying terror that, at any given moment, her vascular access, her link to successful dialysis, would fail, as it already had once. Mary was fortunate that time and another access was created for her to continue with the dialysis. Ultimately though, her access thrombosed and another access could not be created. She, as many others have, succumbed to end-stage renal failure.

The Patient Burden of Kidney Disease

Loss of Time

Dialysis patients must plan their lives around their treatments, which often consume 20-28 hrs/ week. This is time the patient can't spend with their family, at a job, or engaging in physical activity.

Treatment session times and transport (from cms.gov):

Time Needed for Hemodialysis

3 to 5-hour sessions, three times/ week, or 9-15 hrs/week
Median recovery time = 3 hours/ session, 9 hrs/ week
Transportation 2 - 4 hours.
TOTAL TIME/ WEEK = 20-28 hrs/week

Physical and Mental Health Issues

- Depression exists in 20-30% of ESRD patients
- Sexual dysfunction exists in nearly half of ESRD patients
- Sleep issues including insomnia and sleep apnea exist in 40-80% of all patients
- Muscle wasting/ deterioration and weakness are common
- Restless leg syndrome are common

Sources: Semin Dial. 2016 Sep; 29(5): 391–395, National Kidney Foundation

Lack of Patient Control and Empowerment

Francyne Rosenstock at Renal Reserve stated that the dialysis industry "for too long has treated people with kidney failure as unwitting victims, not educable consumers seeking the best treatment. And it's an attitude that encourages passivity and depression among the majority of its patients." Finding ways to engage patients in their treatment plan and share control of the process can significantly improve their outlook.

Sobering Kidney Disease Statistics

Over 850 million people worldwide have kidney disease

1.23 million people died globally from CKD in 2017

Patient population growing 5-7% yearly

For over 90% of patients, the only treatment option is dialysis

Sources: WHO, National Kidney Foundation

Learn how our OEM team can help you with your hemodialysis needs

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Unequal Access and Provider Shortages

Of the 2 million people who receive treatment for kidney failure, the majority are treated in only five countries – the United States, Japan, Germany, Brazil, and Italy. 80% of patients receiving treatment for kidney failure are in affluent countries with universal access to health care. Only 20% are treated in developing countries that make up the majority of the world population.

Compounding the problem is a global shortage of doctors and nurses trained in Nephrology. Even in the United States, with a sophisticated health care system, there is only one Nephrologist for every 40,000 people. The lack of necessary workforce has huge implications for individual patients and public health in general.

> Considering the shortages of nephrologists and all health workforce related to nephrology, it can be concluded that in most parts of the world, people who need kidney care receive either suboptimal care or no kidney care at all.
> - Osman et all

There are currently 39,950 people per nephrologist in the US

Sources: Kidney Int. Dec 2011;80(12):1258-1270.
Kidney Int Suppl Published Online 2018 Jan 19 doi: 10.1016/j.kisu.2017.10.009

Economic Drivers of Change

- Renal Replacement Therapy (RRT) consumes between 2% and 5% of the overall health care expenditure in countries where dialysis is available without restrictions
- In China, the economy will lose US$558 billion over the next decade due to effects on death and disability attributable to heart disease and kidney disease.
- In Uruguay, the annual cost of dialysis is close to $ US 23 million, representing 30% of the budget of the National Resources Fund for specialized therapies.
- In England, according to a recent report published by NHS Kidney Care, chronic kidney disease costs more than breast, lung, colon and skin cancer combined.
- In Australia, treatment for all current and new cases of kidney failure through 2020 will cost an estimated $12 billion.

Sources: Journal of Clinical Medicine, 2019 Feb. 25, 2019 Feb; 8(2): 276, Published online 2019 Feb 25 National Kidney Foundation, Global Facts about Kidney Disease

Hemodialysis costs the Medicare system in the U.S. $90,000 per patient per year

Technological Advancements - Light at the End of the Tunnel

3 Areas of Innovation That Are Enabling Dramatic Change

Sensing Capabilities

- Delivered Flow. This measurement provides confirmation of dialysis dose delivery.
- Access flow and recirculation. This measurement can identify issues with a patient's fistula, including stenosis.
- Absolute and relative blood volume. These measurements are critical for ensuring adequate organ and tissue oxygenation is occurring.
- Cardiac Output (CO) and other cardiac function parameters. These measurements can provide proactive cardiac index tracking that helps avoid cardiac collapse.
- Dialyzer Volume. This measurement can potentially identify signs of clotting in the circuit.
- Clearance and electrolyte monitoring. Careful management of phosphorus, potassium, and sodium levels can help avoid heart failure.

BENEFIT: more data for better informed decision making and early warning signs of potential issues and asynchronous events

Nanotechnology and State-of-the-art Materials

- Composite metals and plastics provide strength while decreasing size and weight.
- Biocompatible materials allow for closer interaction and compatibility with the human body
- New generation of biomimetic membranes for selective filtration
- Smaller, longer lasting power supplies for portability
- Less onboard computing hardware needed due to the advent of wireless connectivity

BENEFIT: Improved mobility, portability, and potential for implantation

Advanced Communication, Data Collection, and Analytics

- Wireless communication and The Internet of Things allow the right information to get to the right members of the care team at the right time.
- Online patient health records can increasingly allow for patients to be better informed.
- Sophisticated engagement tools tied to patient data can improve compliance and reinforce positive behaviors.
- Predictive analytics can continuously monitor data and spot issues with the patient and/or the device proactively.

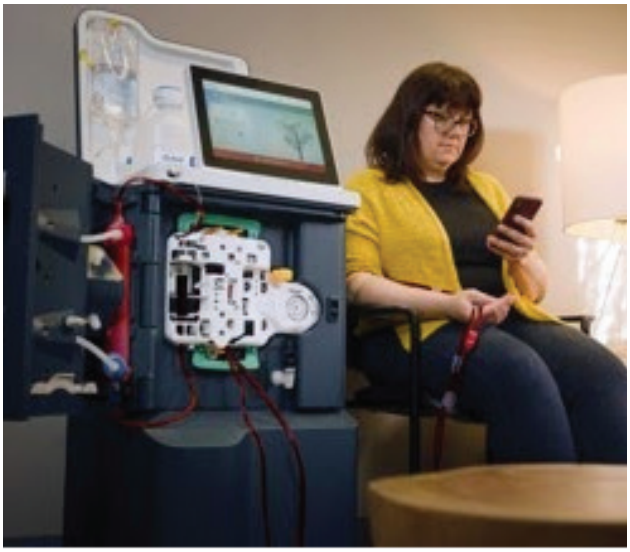
BENEFIT: Clinical decisions are supported with timely, actionable, trusted data, leading to less staff time and improved outcomes.

> Predictive modeling can provide clinicians with additional insights into the risks and benefits of treating patients earlier, with the goal of reducing the number of Americans developing end-stage renal disease in the first place" says Lauren Neal, a principal at Booz Allen Hamilton.

Technology Spotlight: Innovators Poised to Break the Paradigm

This technology spotlight features 3 new solutions being developed which are poised to enable the paradigm shift from clinic management to home and ambulatory care.

1. Outset Medical, San Jose, CA



Outset Medical, a medical technology pioneer in the dialysis field, is developing a suite of products which will serve as all-in-one home hemodialysis solutions designed to reduce the barriers that have previously limited the adoption of home treatment. The first generation product, Tablo, requires relatively minimal training, provides dialysis on-demand, and involves only 3 treatments per week. All this without the limitations and risks associated with travelling to and negotiating dialysis clinics.

The brilliance of Tablo is a unique combination of patient-friendly design and advanced technology. It takes the complexity out of home dialysis in a couple of critical ways:

- Tablo eliminates the need for water treatment. Dialysis requires water that is free of contaminants and toxins found in public water supplies. Tablo features built-in water purification and on-demand dialysate production.
- The system is remarkably easy to use and learn. It was designed with an inviting touch screen interface that guides users through treatment.

Behind Tablo's simple facade lies a sophisticated information system that automatically collects and trends treatment information, giving providers access to timely, actionable data.

Having already received FDA clearance for Tablo earlier this year, Outset now has it's first at-home dialysis patient, fifty-seven-year-old Tracey Amadi, who has been on dialysis since 2008 and received a kidney transplant in 2013. She trained to use the system at Physicians Dialysis in Somerville, New Jersey with Dr. Sunit Kabaria, staff members, and her 21-year-old daughter. "I am thrilled to be using this amazing system at home," said Ms. Amadi. "Tablo has been so easy to learn and use. It gives me a lot more control over my life and time, which saves my family and me many hours each week."

What lies around the corner for Outset has the potential to be even more exciting. In 2019, Outset was awarded a KidneyX Redesign Dialysis Prize for a next-generation concept device that includes accurate volume removal based on factors more reliable than weight and achieves high fidelity vascular access evaluation. The concept incorporates Transit Time Ultrasound flow technology to measure a host of other potential features, including:

- Absolute blood volume
- Relative blood volume
- Access recirculation and flow
- Cardiac function parameters
- Dialyzers volume and clotting indicator

The aim is to provide an expanded tool kit of meaningful data to guide treatment decisions, empower and engage patients, and improve outcomes.

2. Wearable Artificial Organs, Los Angeles, CA

Wearable Artificial Organs, Inc (WAO) is a development-stage medical device company in the dialysis industry which was founded by world-renowned nephrologist Dr. Victor Gura. WAO is develolping a Wearable Artificial Kidney, dubbed WAK, which has been awarded an FDA fast-track through the Expedited Access Pathway program.

Dr. Gura modeling an early prototype of the WAK

The WAK was designed to mimic the function of a normal kidney, working 24x7 to remove waste product while maintaining healthy fluid levels. Some of the key innovations which make this possible are:

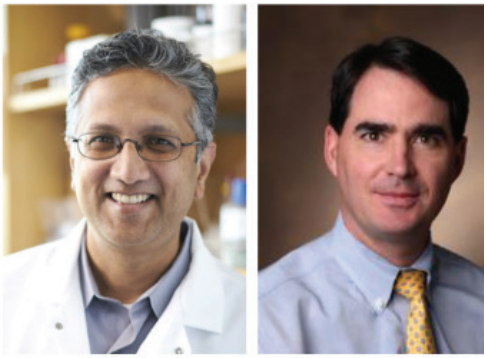
- Filtration. Continuous filtration of blood at a natural physiological rate, as opposed to the highly variable filtration that occurs with intermittent dialysis.
- Fluid removal. The WAK removes fluid continuously at the same rate as healthy kidneys, superior to the 2-3+ liters removed each 3-4 hour intermittent dialysis session.
- Phosphorus and Sodium Removal. Helping to maintain normal levels and reduce adverse events associated with intermittent dialysis

WOA's vision is of a future where dialysis patients are no longer tetheres to cumbersome machines multiple times a week, and forced into restrictive diets with countless medications. Instead, all dialysis patients will have the option to choose a mobile dialysis solution that allows them a life similar to their lives before their ESRD diagnosis.

WAO is currently working to reduce the size of the WAK from about 11 lbs down to 2-lbs, allowing patients to hide it under their clothes as they go to work or enjoy their lifestyle activities.The device will need 2 more successful clinical trials to obtain market approval. The company believes WAK has the potential to provide superior clinical outcomes, a better quality of life for ESRD dialysis patients, and dramatic cost-savings.

3. The Kidney Project, University of California, San Francisco

The Kidney Project, spearheaded by Technical Director, Shuvo Roy, PhD at UCSF, and Medical Director, William Fissell, MD, at Vanderbilt University Medical Center is developing a surgically implantable, self-monitoring, and self-regulating bioartificial kidney to perform the filtration, fluid and electrolyte balancing, and other biological functions of the natural kidney.

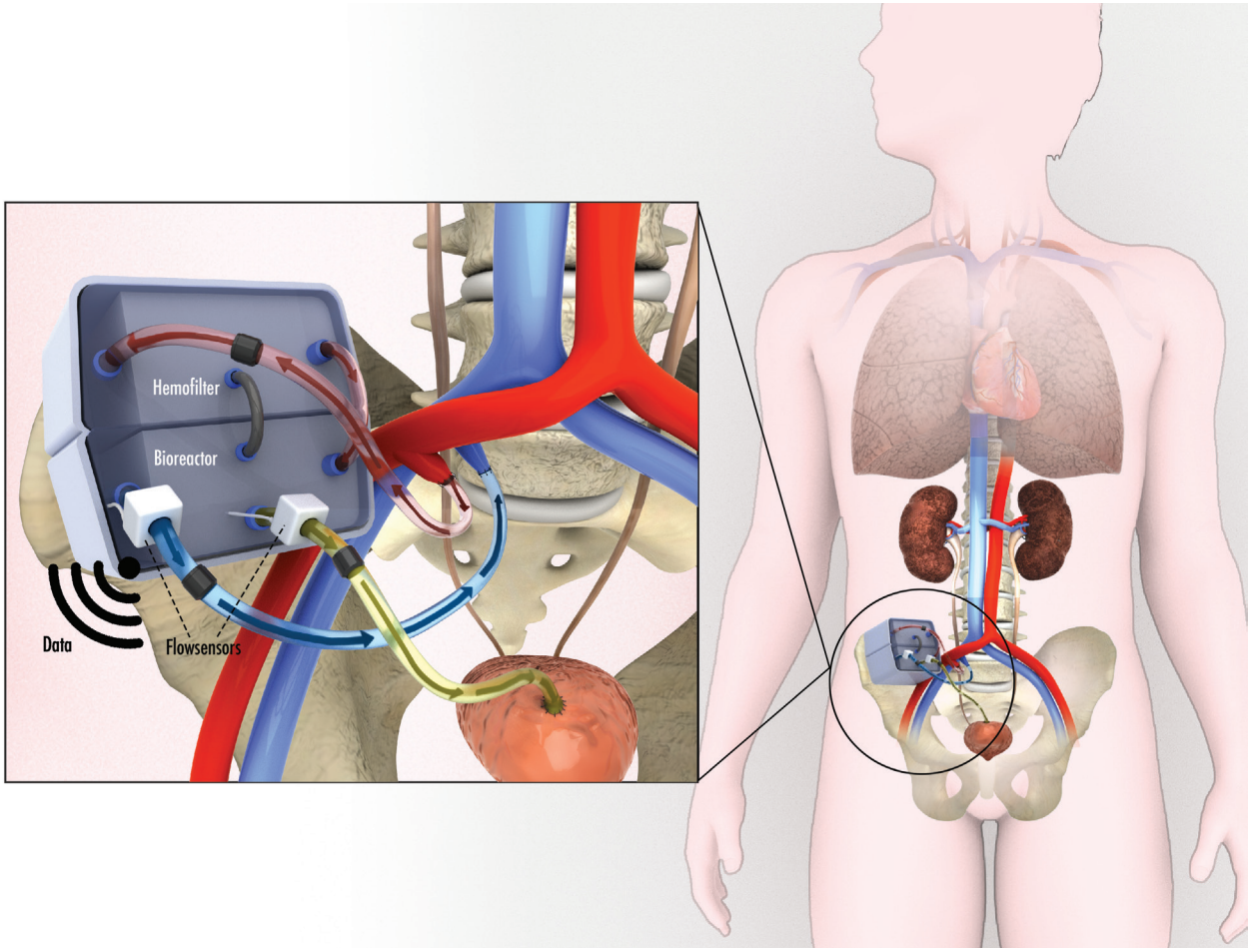


Left: Technical Director: Shuvo Roy, PhD University of California, San Francisco
Right: Medical Director: William Fissell, MD Vanderbilt University Medical Center

About the size of a coffee cup, the device is powered by the body's blood pressure without the need for external electrical connections, batteries or immunosuppressant drugs. After a single surgery to establish a permanent blood connection, the bioartificial kidney will process blood 24 hours a day, eliminating the need for hemodialysis and its inconveniences.

Courtesy of Shuvo Roy, UCSF

The Kidney Project team is leveraging recent developments in silicon nanotechnology, biocompatible materials, and tissue engineering to create an implantable device that continuously filters toxins from the blood while also providing the other biological functions of a healthy kidney.



The device consists of:

- a compact hemofilter comprised of highly efficient silicon nanopore membranes that uses the body's own blood pressure to perform filtration, without needing pumps or a power supply
- a renal tubule cell bioreactor that reabsorbs salts and water, regulates blood pressure, and produces vitamin D.

Incorporating physical and biochemical sensors, the device will be self-monitoring and self-regulating – that is, able to detect and monitor blood flow, urea clearance, and electrolyte balance. Information on device performance and the patient's health status can be wirelessly sent to the provider. While still a few years away from commercial availability, The Kidney Project team believes this device can be an effective alternative to a kidney transplant, or dialysis, helping millions of ESRD patients to lead normal lives.

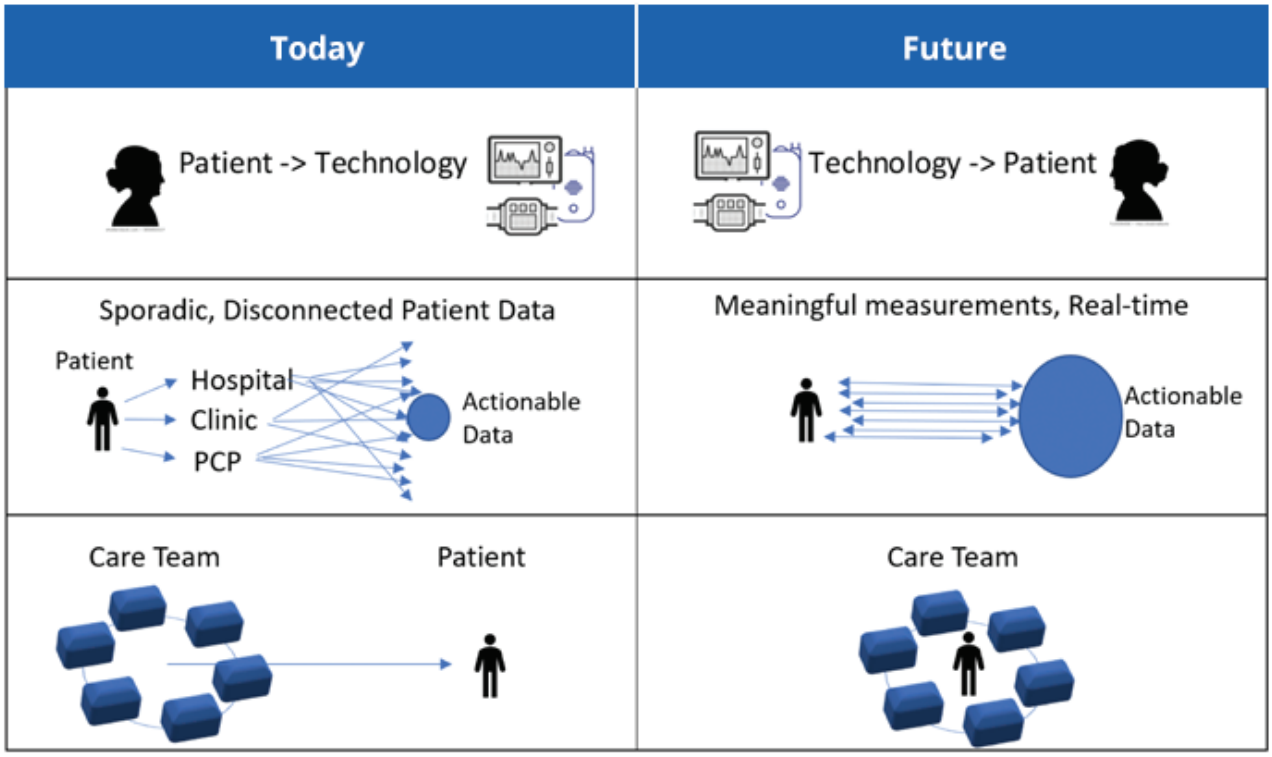
A Brighter Future for Patients with Chronic Kidney Disease

The technological advancements outlined in the previous chapter hold huge potential upside for patients with CKD:

1. Instead of patients travelling to treatment centers to access technology, technology will travel with the patient in the form of home, ambulatory, and implantable devices.

2. Sporadic, hard-to-access measurement data will transition to real time, clinically meaningful, and highly actionable information for care teams.

3. The patient mindset will evolve from that of a passive participant to a highly engaged and empowered member of the care team.



From a population-based, disease management perspective, these technologies also offer significant potential for improvements in access, quality, and cost:

1. **Access.** Healthcare infrastructure and workforce issues can be overcome by affordable technology that allows for patients to be managed remotely, virtually anywhere in the world.

2. **Quality.** New sensing capabilities and active monitoring of measurement data will enable care teams to provide optimal, timely treatment, helping to improve clinical outcomes.

3. **Cost.** By reducing the dependence on brick and mortar infrastructure and patient transport, significant health care savings can be realized. In addition, timely, meaningful measurement data will help avoid adverse events and expensive hospitalizations.

Ultimately, the most meaningful impact will be on patient quality of life. 84 year old Ward Shanahan, an CKD patient now on a home-based treatment, says it very simply:

> I like to be able to get up in the morning, take a shower, and go around in the world. [This] gives me a life again."

Sources: NPR, All Things Considered, 2019

Ready to get started? Contact our team today.

Contact the team