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New Technology May Help Fuel Shift Toward Home Dialysis

By Bridget M. Kuehn



As a veteran of both in-center and home dialysis, patient Richard Crawford knows that dialysis is a “tough proposition” in terms of time and its impacts on the body. But he was impressed by a new experimental home dialysis device called Tablo that he tried as part of a clinical trial.

“It seemed to sync with my body much better than both in-center devices and systems I used at home,” Crawford said. He explained he found it intuitive to use, that it reduced the likelihood of user error, and gave him better biochemical clearance. In fact, he said he had enough energy after using the device to jump on the treadmill within a couple hours of finishing.

Results of the trial, which the device’s manufacturer Outset Medical (San Jose, CA) is using to apply for US Food and Drug Administration (FDA) clearance to market the device for home dialysis, were presented at Kidney Week 2019 in Washington, DC. The trial enrolled 30 patients from 8 US dialysis units and met its endpoints for safety and efficacy, and 28 patients completed the treatments. Patients received home dialysis 4 times per week for 32 treatments after first completing

32 in-center treatments and 8–16 transition treatments, according to the abstract. The device has already received FDA clearance for use in-center.

“Above and beyond anything, this device has shown that it works at home,” said Principle Investigator Troy Plumb, MD, associate professor of medicine at the University of Nebraska Medical Center. With FDA clearance for home use, “it’s going to give patients another option,” he said.

The Tablo device is one of a growing number of high-tech, user-centric home dialysis devices in development. A clinical trial for another experimental home dialysis device from CVS Health called the HemoCare Hemodialysis System launched in July 2019. The company hopes to win FDA approval for the trial and be able to market the device by 2021. A British company called Quanta also launched a US study of its SC+ home hemodialysis system in August 2019 as a step toward seeking FDA clearance.

Fresenius’ NxStage System One device, which allows patients to administer home hemodialysis without help,

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Transformation in Kidney Care Takes Center Stage at Kidney Week

By Bridget M. Kuehn

Inventor Dean Kamen said he is hoping to one day put himself out of business in both the dialysis and insulin pump industries. He created the first insulin pump and the first home peritoneal dialysis machine. The home hemodialysis machine he helped develop is currently being tested in an in-center clinical trial as part of CVS Health’s foray into home dialysis.

“We shouldn’t be making insulin pumps for kids, we should be transplanting beta cells in the pancreas,” Kamen said during a Kidney Week 2019 state-of-the-

art plenary talk. “We should not be doing dialysis. We should give people a replacement kidney.”

The inventor, who has more than 440 patents to his name including one for the Segway, acknowledged that new technologies and the disruption they bring can be frightening. But he challenged nephrologists to embrace the changes that transformative technologies are bringing to the field. Kamen was joined in the plenary by Bruce Culleton, MD, vice president and chief medical

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received FDA clearance in 2017 and has greatly expanded access to home dialysis, according to Thomas Golper, MD, Medical Director of Home Dialysis at Vanderbilt University Medical Center. NxStage currently accounts for much of the market for home dialysis in the US.

“NxStage is easier to use than the equipment we were using before, and the more frequent [dialysis sessions with the device] have reduced the complication rate,” said Golper, who also serves on the advisory board for NxStage. He explained the device also doesn’t require changes to patients’ homes to use and patients can be trained to use it in a shorter time frame.

These developments, along with Advancing American Kidney Health (AAKH), created by an executive order by President Donald Trump in July 2019, are expected to help increase the number of patients on home dialysis. The AAKH will create payment incentives to increase patient access to home dialysis and kidney transplant.

The same machine that [the patient] becomes comfortable with in the hospital can follow the patient through their journey, whether that might be in a conventional clinic setting, or in the future all the way to home.

—Outset Medical CEO Leslie Trigg

User-friendly technology

The latest generation of portable dialysis devices emphasize high-tech, user-friendly features. Tablo needs only a plug and tap water. NxStage can be combined with another device the company makes to use tap water as well.

Leslie Trigg, CEO of Outset Medical, said the Tablo device was designed to be patient-friendly in any setting, from an intensive care unit to a dialysis clinic, and if their application is approved by the FDA, eventually in the home setting. “The same machine that [the patient] becomes comfortable with in the hospital can follow the patient through their journey, whether that might be in a conventional clinic setting, or in the future all the way to home,” Trigg said.

Bruce Culleton, chief medical officer for CVS Kidney Care, said the company wanted to develop a device that would be easy to use for a broad population of patients, would ease the burden on patients and their caregivers, and help alleviate patients’ and caregivers’ fears about safety. Only half of patients trained to do home dialysis are still on the therapy one year later, Culleton noted.

“We do not believe that home hemodialysis will be sustainable if dropout rates are as high as they are today,” Culleton said. “That’s just not a way we think home hemodialysis is going to grow.”

As a patient, Tablo clinical trial participant Crawford said the flurry of new devices in development is encouraging. Often, he said, current dialysis options whether home or center-based are not “conducive to traveling,” which limits his professional prospects. He said he hopes the new technologies becoming available make travel easier.

“Technological advancements should help reduce the cost of these systems and give the patient more options,” he said.

Training and policy needs

In addition to the need for easier-to-use technology, systems-level and policy changes are needed to make home dialysis more widely available.

“While better technology can make it easier to facilitate the use of certain renal replacement therapies at home, healthcare system-level improvements can have a larger impact by ensuring implementation of comprehensive, effective approaches to the care of patients with end stage

kidney disease,” said Leonid V. Pravoverov, MD, chief of nephrology at Kaiser Permanente’s East Bay service area.

Pravoverov was the lead author of a study published recently that showed Kaiser Permanente of Northern California was able to increase enrollment of new dialysis patients in home peritoneal dialysis (PD) from 15.2% in 2008 to 33.8% in 2018 with 80% continuing on home PD beyond one year. The results, which far outstripped the US-wide increase from 6.1% in 2008 to 9.7% in 2016, were enabled by a multi-disciplinary, systemwide initiative to expand PD. That program included identify-

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Troubleshooting in Disaster Zones

Planning, Partnerships, and New Devices to Help Kidney Patients

By Bridget M. Kuehn

The one-two punch of Hurricanes Irma and Maria in the United States and the Caribbean in 2017 was a wake-up call to the nephrology community and first responders. The twin disasters left more than 56,000 dialysis patients in the lurch, and kidney transplant patients in destroyed communities desperately seeking immunosuppressive medications.

To better prepare for future disasters, ASN created the Emergency Partnership Initiative (EPI), which held its first meeting in September 2019. The partnership aims to bring together dialysis and transplant clinicians; patients; federal, state, and local emergency responders; public health leaders; and companies that make up the supply chain to anticipate and prepare for kidney patients’ needs in future disasters, said Nicole Lurie, MD, chair of the EPI and former Health and Human Services (HHS) Assistant Secretary for Preparedness and Response.

“It comes very much out of the experience of ASN members who have been called upon or found themselves in disaster situations where the system broke down for patients,” Lurie explained. The EPI, she said, is working to anticipate such problems and be proactive in working with partners to support patients, clinicians, and first responders before and when disasters strike.

One of the challenges during hurricanes and other disasters is that dialysis patients may be displaced from their homes and usual care providers. Other providers may be unable to handle the surge of patients or may be incapacitated by the disaster.

“You have to be able to anticipate that and have a plan for how you’re going to deal with it so that people don’t get into even more emergency situations,” Lurie said. “Then, when the crisis is over, to the extent that it’s possible, you need to get patients back into their regular routine.”

That process starts with knowing who the dialysis patients are and how to reach them in an emergency, knowing how much surge capacity dialysis providers have, and preparing to provide additional dialysis as needed. To help expand capacity, HHS recently awarded a contract to Outset Medical (San Jose, CA). HHS will purchase Tablo Hemodialysis Systems devices and supplies to deploy in communities experiencing a disaster. The portable devices have received US Food and Drug Administration clearance for center-based use. Outset Medical has already delivered 25 of the 50 machines ordered by HHS and expects to deliver the other half by the end of the year.

Outset Medical CEO Leslie Trigg said that during recent disasters there was limited access to dialysis in the affected communities and many patients on dialysis were temporarily relocated to other cities across the US for weeks or months. The situation takes a psychological toll on patients and their families and is also costly for the government, she noted. To curb these costs and allow patients to stay close to home, the HHS put out a request for proposal for devices that could more easily be used in communities affected by disasters and Tablo was selected. Tablo doesn’t require as much infrastructure as other systems, Trigg said. The device only requires a plug and tap water and can handle tap water with a wide range of characteristics, she said.

“I think they chose Tablo for its flexibility,” Trigg said. “It offers a lot more options about where patients can be treated in the affected areas.”

Lurie said she’s glad both the HHS and EPI are considering patients’ experiences in their disaster planning.

“I’m very excited that we have some forward thinking and proactive thinking about dialysis and disasters [through the EPI and HHS’s purchase of Tablo devices],” Lurie said. ■

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ing and educating patients with advanced chronic kidney disease about their options, providing continuing education and support for clinicians on how to provide PD, and a streamlined system process, noted the senior author of the work, Alan S. Go, MD, a research scientist in the Kaiser Permanente division of research.

“We firmly believe that there are additional opportunities to grow the population of kidney disease patients receiving home-based therapies, including peritoneal dialysis,” Go said. But he noted improvements in current regulations are needed, such as support for new models of care, including assisted-at-home dialysis, dialysis in skilled nursing facilities, and simplified rules for respite care.

A major hurdle to expanding home dialysis in the

US is training physicians how to do it, said Golper, who runs a course called Home Dialysis University. But many physicians have not been trained, and Golper said he’d like to see parts of his course taught in every training program across the country.

“A big part of the problem is that doctors don’t know how to do home dialysis,” he said.

More telehealth is also needed to support patients doing home dialysis, agreed both Crawford and Golper. Crawford explained that it would be helpful to have easy audio and video conference access to a support team who could help home dialysis patients when issues arise.

Starting in January 2019, Medicare began covering telehealth visits for home dialysis patients, Golper noted.

“That in and of itself should have caused an explosion of home dialysis,” Golper said. But physicians, he noted, are still learning to use the technology. Additionally, there can be technical hurdles. For example, he and

his colleagues will only start offering telehealth in January because changes had to be made to their electronic medical records system to enable it.

“There’s no question, no question that technology is going to play a role [in expanding access to home dialysis, whether it’s simpler to use equipment, or communication, or telehealth,” Golper said. “All those things will be positive, but none of it can happen until the physicians know how to do the therapy.”

Culleton said that “systems changes are more important than technology,” for example, implementing some of the changes outlined in the AAKH. It’s also important, he said, to address the overall costs of care to enable providers to improve the way they care for patients receiving dialysis at home.

“There are a lot of things that need to happen to change behavior at the provider and physician level,” he said. ■

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officer of CVS Kidney Care, and ASN Executive Vice President Tod Ibrahim.

“We’re not going to slow down the pace of the advancing technology,” Kamen said. “You can be on the bus or you can be under the bus of this accelerated pace of technology. I plan to be on it.”

Stalled progress

Inequity and poor outcomes currently plague the more than 850 million patients with kidney disease around the world. Many patients globally die without access to any care, Ibrahim noted. Additionally, 13 die each day on the US transplant waitlist while 77 usable kidneys are discarded and most dialysis patients die within 5 years, he said. Patients who are not white are more likely to progress to kidney failure and less likely to have access to home dialysis, he said.

Culleton cited a letter he received from a 72-year-old patient who had been on dialysis since 2018. She deals with low blood pressure, vomiting, and vertigo and is often unable to go to church, family engagements, or even on a hike with her dogs.

“It’s very isolating and depressing,” Culleton said. “It shouldn’t come to anyone’s surprise that about 20% of all patients who are on dialysis that die, do it intentionally and withdraw from dialysis.”

Despite these pressing needs, progress in the field has stalled technologically, Ibrahim noted. He cited underfunding from governments and investors in nephrology as one contributor. He noted that dialysis was created the same year as the mainframe computer.

“Seventy-six years later, we carry a more powerful computer in our pocket, yet mostly rely on the same technology to treat kidney failure in in-center dialysis,” Ibrahim said.

Home dialysis still lags, with only about 12% of dialysis patients receiving it, Culleton said. Most dialysis patients, he noted, begin with a catheter in their neck and at least one-third of patients with kidney disease receive no care prior to kidney failure, he said. The Centers for Medicare & Medicaid Services (CMS) pays more than \$110 billion annually caring for patients with chronic kidney disease and kidney failure, Culleton said.

From dialysis- to patient-centered

But the speakers were optimistic that a combination of emerging technologies and the Advancing Ameri-

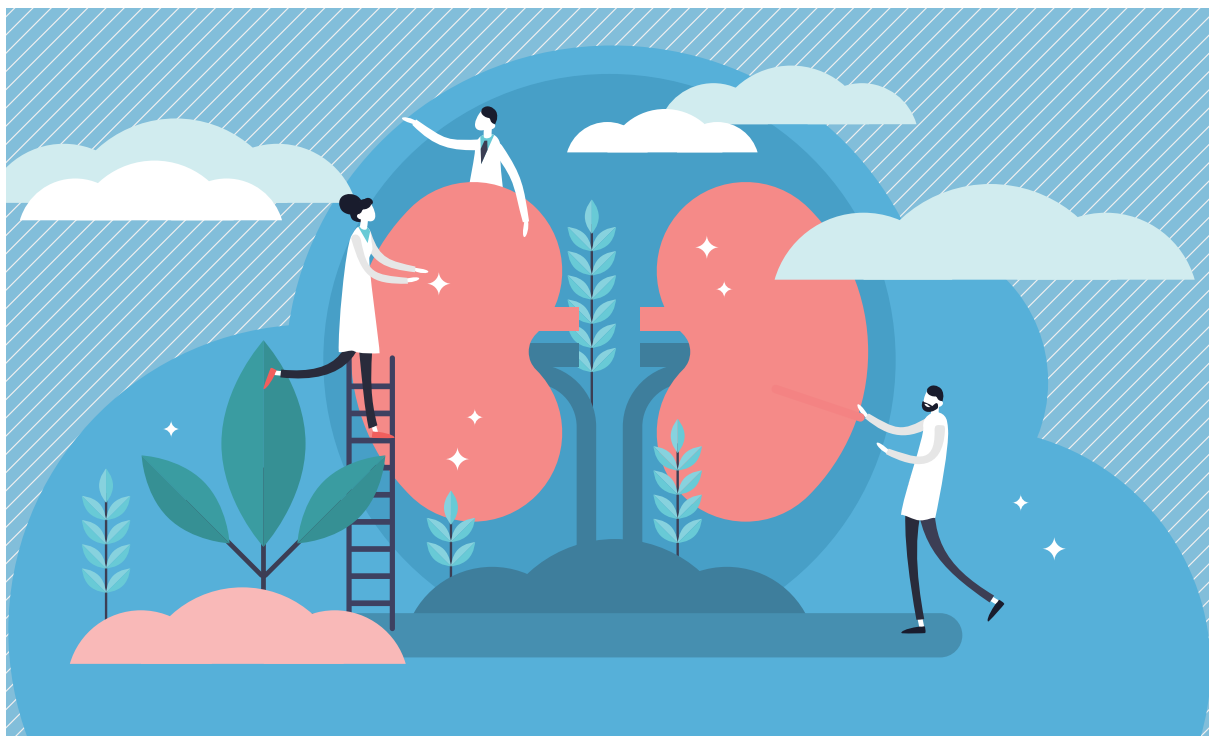
can Kidney Health initiative, announced by President Trump in July 2019, would help jumpstart progress in the field. Ibrahim noted that the ASN worked closely with the US Department of Health and Human Services to craft the program.

“This historic plan—the nation’s first kidney health strategy—aims to reduce the number of Americans with kidney failure by 25% over the next decade,” Ibrahim said. “The US government also intends to double the number of kidneys available for transplant and provide more options for people with kidney failure such as greater emphasis on alternatives to in-center dialysis.”

lead to innovation. “The invention part is easy,” he said. “Getting the world to accept change is hard.” He noted it took 20 years to get CMS to cover the insulin pump despite endocrinologists’ enthusiasm.

“We need as a community to embrace these changes and fully move forward,” argued Culleton. “Nephrologists need to lead the way.”

Culleton acknowledged that being a nephrologist isn’t easy given the complexity of care and the regulatory demands in the field. But he said the field is in a position to reorganize kidney care around patients’ needs and that technology will play an important role, for example



Kamin said progress is being made to speed the production of new technology for kidney care. For example, he noted the creation of the Advanced Regenerative Manufacturing Institute, which is working to scale up bioengineering technology. The institute has 150 members and has received \$80 million in funding from the US Department of Defense and \$214 million in matching funds from technology companies. They have already been able to demonstrate a system for generating induced pluripotent stem cells, which through an automated process can generate a 7-centimeter segment of bone and ligament in 40 days. They hope to be able to eventually create processes for making more sophisticated organs.

Kamen warned, however, that technology itself won’t

through better dialysis machines, telehealth, or machine learning to help identify patients with kidney disease.

“This is a once in a generation opportunity to change the kidney care paradigm in this country,” Culleton said.

Ibrahim urged the field of nephrology to make the most of this opportunity by demanding government and public support, and by revamping nephrology training, reimbursement, and career paths in the field.

“Together we must demand attention,” Ibrahim said. “We must advocate for kidney health. By thriving as a meaningful specialty, nephrology will extend the lives and quality of life for millions who otherwise will continue to die prematurely and unnecessarily, unjustly, inequitably.” ■