The Promise of Digital Health for Home Dialysis Patients

By Alex Brill, Christy Robinson, and Eric Wallace, MD

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Executive Summary

Digital technology holds great promise for people with kidney failure, also known as end-stage renal disease (ESRD). For ESRD patients who are candidates for home dialysis, digital health tools are particularly useful, but Medicare currently does not cover some of these technologies. Because Medicare is the primary payer for ESRD care, this lack of coverage not only limits patient access to existing and emerging tools, but also discourages investment in new technologies.

Medicare reimburses for ESRD care in a fixed, bundled payment for dialysis services and most related drugs. While the Medicare Physician Fee Schedule covers devices that collect and transmit patients' physiological data, these tools are not covered if ESRD is the primary diagnosis. This is unfortunate because remote patient monitoring and management have proven benefits — including improved data collection, patient compliance, and disease management — that are particularly important for home dialysis patients, who are dialyzing largely independently.

BENEFITS OF DIGITAL HEALTH TOOLS FOR HOME DIALYSIS

Dialysis is a treatment process that filters, cleans, and removes excess fluids from the bloodstream. People who are able to dialyze at home have the flexibility to do so at their convenience, as opposed to driving to a dialysis center three times a week for a session that typically takes three to five hours. Home dialysis has long been recognized as a viable and beneficial option for far more people than use it.

Remote patient management devices and apps provide remote transmission of therapeutic and physiological data that allow clinicians to see whether home dialysis treatments are being completed while also facilitating real-time interventions. Evidence shows that remote management in home dialysis is associated with reduced hospitalizations and improved clinical outcomes, among other benefits.

POTENTIAL COST SAVINGS FROM DIGITAL HEALTH TOOLS

One tangible example of the usefulness of remote patient management devices and apps in home dialysis is the prevention of fluid overload. Fluid overload, or excess fluid in the bloodstream, can create serious health problems, including hypertension and congestive heart failure, and is a common cause for emergency room visits and hospitalizations for people with ESRD. The direct cost of hospital care for fluid overload in home dialysis patients exceeds an estimated $240 million annually. Remote patient management can flag signs of fluid overload and facilitate intervention before a trip to the hospital is required. This offers better health outcomes for patients as well as sizable potential savings for both patients and the Medicare program.

To unlock the full potential of digital health tools for home dialysis, changes to Medicare reimbursement are needed. The certainty of Medicare coverage will make it possible for clinicians and facilities to utilize digital health tools and will encourage innovators to pursue further advances.

Introduction

Digital technology has expanded into practically every aspect of life, and healthcare is no exception. Many digital health technologies are being deployed with demonstrable success for a wide variety of disease states. This new frontier holds great promise for kidney care, where the patient population with chronic kidney disease or end-stage renal disease (ESRD) is large and the current treatment modalities are costly. The promise of digital health for ESRD is especially important for home dialysis, as recent technological advancements have great potential for this modality. However, current Medicare reimbursement for patients with ESRD does not cover some important digital health tools for people on dialysis. This lack of coverage not only limits patient access to existing and emerging tools, but also discourages investment in developing new technologies in this area.

For people with ESRD, quality of life is a huge concern, as being on dialysis is very time-consuming, on top of the challenges of living with kidney failure. A recognized way to improve the health and quality of life of ESRD patients is for them to be able to dialyze at home rather than going to a dialysis center several times a week for hours at a time (*Brill, 2016*). Digital tools — whether remote monitoring devices, smartphone apps, digital platforms, or software — that facilitate remote monitoring can have demonstrable benefits for home dialysis patients.

Key to the success of home dialysis is patient compliance with dialysis treatments. Digital tools that provide remote transmission of therapeutic and physiological data allow clinicians to see whether home dialysis treatments are being completed while also facilitating real-time interventions. These tools also foster at-home patient engagement and self-reporting of data, which are important for achieving positive health outcomes for those dialyzing at home.

The benefits of remote monitoring and management will be all the more important as policymakers and stakeholders lately have focused on increasing the number of people on home dialysis. Remote monitoring and management may also help address the ongoing nursing shortage by improving nurse-to-patient ratios.

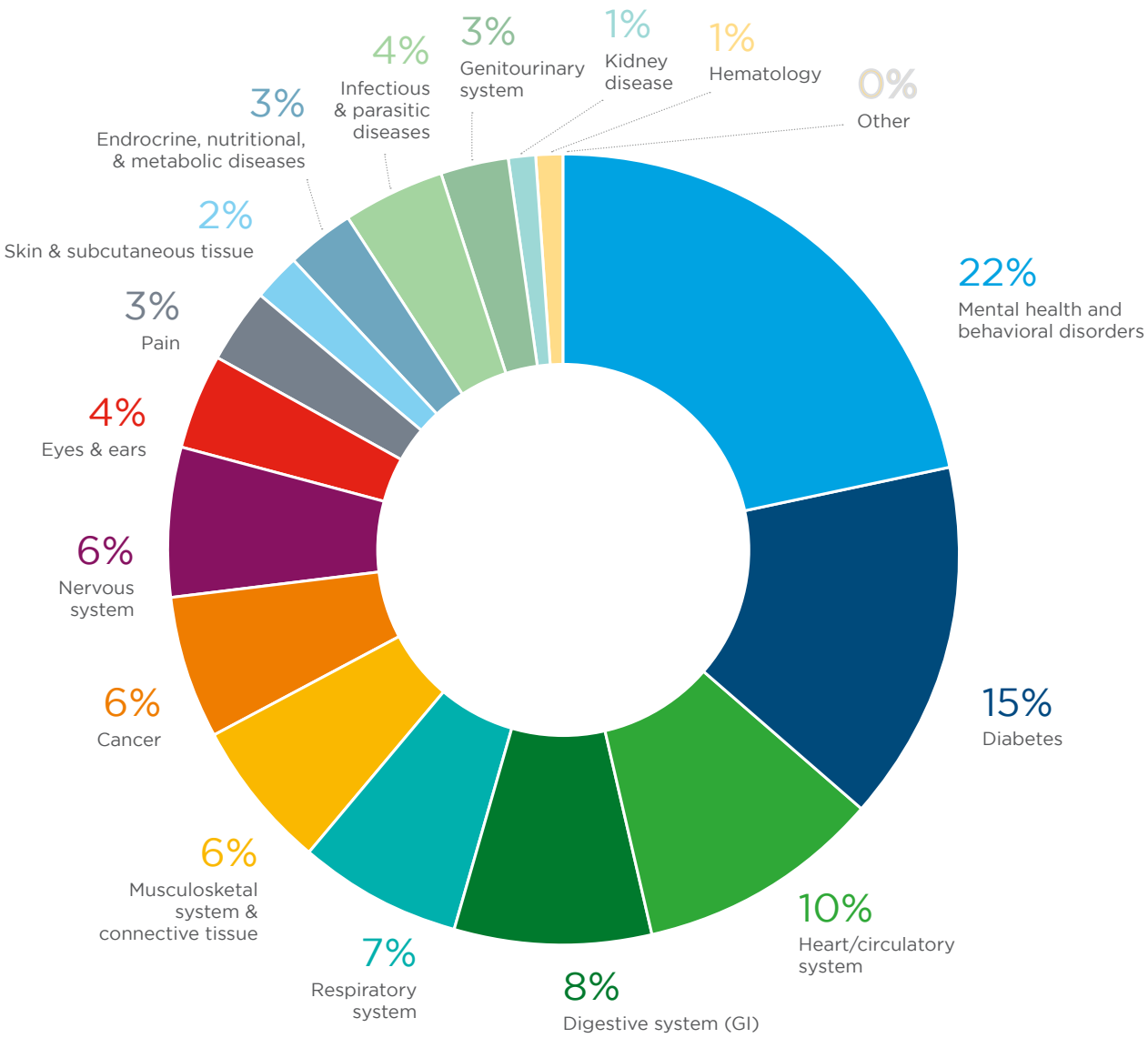
In this paper, we review the available evidence on digital health tools — particularly remote patient monitoring devices and apps — and highlight other health conditions for which these types of tools have been shown to be effective.

The promise of digital health for ESRD is especially important for home dialysis, as recent technological advancements have great potential for this modality.

Evidence on Digital Health Tools

Digital health technologies involve the application of computing platforms, software, and sensors for health-related purposes, including diagnostics and delivery of care (*FDA, 2020*). Digital health encompasses a wide variety of tools, ranging from mobile apps to consumer wearables to artificial intelligence. As **Figure 1** shows, digital health addresses many disease states, most prominently mental health and behavioral disorders (22 percent of apps) and diabetes (15 percent of apps).

FIGURE 1. DIGITAL HEALTH APPS BY DISEASE STATE, 2021



Source: IQVIA (2021).

Many stakeholders — including patient groups and payers — recognize the importance of evidence standards for digital health.

While the adoption of innovative technology has added value in the healthcare context, not all digital health tools lead to demonstrably better care or outcomes. Many stakeholders — including patient groups and payers — recognize the importance of evidence standards for digital health. Researchers as well as healthcare and tech companies are rising to the occasion. A recent report from the IQVIA Institute for Human Data Science highlights the increase, particularly over the last five years, in digital health effectiveness studies, systematic reviews, and meta-analyses. Since 2007, roughly 2,000 digital health effectiveness studies have been published, 75 percent in the last five years (*IQVIA, 2021*).

Evidence of the effectiveness of digital health tools is clearly important for the consumers and healthcare providers using them. In addition, payers look to the evidence in making coverage decisions. In the relatively new field of digital health, payers want to have assurance of a technology's effectiveness before offering it to health plan members. Where evidence shows that digital tools lead to better health outcomes, it is important that payers, including government health programs like Medicare, facilitate patient access to these products.

Digital health is a very broad category, covering many types of platforms, apps, and software. In this paper, we focus on digital health tools that fall under the category of remote patient management or monitoring. These are devices and apps that track a patient's health data in real time and allow the patient's healthcare provider to access the data remotely, facilitating contemporaneous therapeutic adjustments or interventions as well as patient engagement and support.

BENEFITS OF EFFECTIVE REMOTE PATIENT MONITORING

As would be expected, remote monitoring is not inherently valuable; it needs to be designed and targeted effectively (*Noah et al., 2018*). When well-integrated in the healthcare context, remote patient monitoring technologies have been shown to achieve a range of positive results, including improved data collection, patient compliance, disease management, health outcomes, and cost savings.

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Data Collection

One of the key benefits of remote patient monitoring is the ability to capture accurate medical and health-related data on a real-time basis. Remote monitoring tools collect, transmit, and store patient data (e.g., vital signs) in the cloud, where they can be accessed by patients or healthcare providers in different settings (*El-Rashidy et al., 2021*). For example, by tracking an individual's heart rate, blood pressure, or other health indicators, these technologies can help identify abnormalities or warning signs and indicate the need for medical intervention before a condition worsens.

Patient Compliance and Disease Management

Remote patient monitoring can also encourage patients to take medication as directed and otherwise follow healthcare providers' guidance. With patient inputs being tracked and monitored, healthcare professionals can offer feedback or intervene to encourage healthy behavior. This type of monitoring has been shown to improve compliance by encouraging patients' self-regulation (*Ghose et al., 2022*). Of course, for patients with chronic diseases, compliance is essential for disease management. Activity tracking has been shown to have a significant relationship with medication adherence for people with chronic diseases (*Quisel et al., 2019*).

Health Outcomes

Remote patient monitoring has the potential to improve health outcomes by helping patients better manage their conditions and helping healthcare practitioners play a more proactive role and offer guidance to vulnerable individuals. When remote monitoring is designed and implemented well — for example, with appropriate targeting of patients, accurate detection of health issues, and timely interventions — it has been shown to reduce acute care use (*Thomas et al., 2021*).

Cost Savings

Improved health outcomes are often, though not necessarily, associated with reduced demand for medical care and therefore reduced healthcare expenditures. Net cost savings are achieved only if the cost of the intervention is less than the average savings achieved from reduced care. Researchers have identified potential cost savings from a variety of remote monitoring applications, including in the fields of oncology (*Kuthiala et al., 2022*) and cardiology (*Ricci et al., 2017*).

Before discussing the promise of digital health for home dialysis patients, we draw parallels with digital health tools and remote patient monitoring for diabetes and atrial fibrillation.

DIGITAL HEALTH TOOLS FOR DIABETES AND ATRIAL FIBRILLATION

Diabetes

Diabetes, a disease that affects the body's ability to produce or use insulin in digestion, is one of the most prevalent chronic diseases. In the United States, roughly one out of every ten people has diabetes, whether Type 1 or Type 2 (*ADA, 2022*). People with diabetes must monitor and control their blood glucose levels to manage their condition. Digital monitoring devices known as continuous glucose monitors (CGMs), which are attached subcutaneously to track the glucose levels of people with diabetes on a real-time basis, have revolutionized diabetes management and treatment. For the insulin-dependent, a CGM is often paired with an insulin pump, a wearable device that automatically delivers insulin when needed. Many people use a smartphone app paired with their devices to view blood sugar levels, enter dietary and other information, receive alarms and reminders, and even control insulin delivery.

Digital monitoring devices known as continuous glucose monitors . . . have revolutionized diabetes management and treatment.

The use of CGMs can yield life-changing benefits for people with diabetes and help avoid or delay problems that may lead to hospitalization or death. Multiple studies have shown that CGMs yield glycemic benefits by reducing hypoglycemia and HbA1c, a measure of blood glucose levels (*Bailey, 2017; Messer et al., 2019*). As health scholars have documented, over the past decade CGMs have "contributed to dramatic changes in diabetes care due to [their] near-continuous surveillance of glucose levels, ability to integrate

with insulin pump technology, and most recently replace necessary blood glucose checks for insulin dosing" (*Messer et al., 2019*).

With the abundance of evidence of the effectiveness and health benefits of CGMs, the Centers for Medicare & Medicaid Services (CMS) announced in 2017 that Medicare would cover CGMs for beneficiaries who meet specific criteria. CMS's decision covers CGMs under the durable medical equipment (DME) benefit, apart from any reimbursement for diabetes care. CMS determined that Food and Drug Administration (FDA) approval of CGMs met "the threshold for [DME] coverage of being necessary for treatment or diagnosis under Social Security Act Section 1862(a)(1)(A)," while the receiver component of a CGM was both medically necessary and durable (*AdvaMed, 2020*). After sustained advocacy by the American Diabetes Association and other patient groups, in July 2021 CMS removed the requirement that Medicare beneficiaries use a fingerstick glucose meter four times daily before qualifying for a CGM (*Hoskins, 2022*).

Atrial Fibrillation

Remote patient monitoring is useful in cardiac care by helping with the early detection and treatment of heart-related complications. Many devices have been developed to remotely monitor cardiovascular activity, including blood pressure, heart rate, and physical exertion.

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A growing body of evidence indicates that remote patient monitoring has the potential to improve clinical outcomes if well-integrated in cardiac care (*Bayoumy et al., 2021*). Here, we focus on wearable continuous electrocardiogram (ECG) monitors for people with atrial fibrillation (AF).

AF is a heart arrhythmia that makes the atria (the two upper chambers of the heart) beat irregularly. AF is linked to nearly half a million hospitalizations and more than 150,000 deaths each year; it is known to cause strokes and is responsible for roughly one in seven strokes in the United States (*CDC, 2021*).

Wearable ECG monitors, typically adhesive chest patches, have been developed in recent years for individuals to wear continuously for up to two weeks. The most studied of these ECG monitors is the Zio Patch, but others include BodyGuardian Heart, NUVANT Mobile Cardiac Telemetry System, Carnation Ambulatory Monitor (CAM), BioTel Heart, and MBS HealthStream (*Bayoumy et al., 2021*).

In one of many randomized clinical trials studying the device, the Zio Patch was shown to improve AF diagnosis compared with both non-monitoring and delayed monitoring (*Bayoumy et al., 2021; Steinhubl et al., 2018*). Another randomized clinical trial compared the Zio Patch with the CAM and found that the two were comparable in detecting AF, but the CAM had better ECG clarity and was better at identifying specific arrhythmias, both of which are important in making clinical decisions (*Rho et al., 2018*).

Medicare has long covered ECG monitoring, but in 2021 permanent reimbursement codes (known as Current Procedural Terminology, or CPT, codes) were established specifically for ECG monitors worn for 48 hours up to 7 days or for 8–15 days; these permanent CPT codes replaced temporary codes that had been created for this type of technology (*Poland, 2021*). With the new codes came new, lower reimbursement rates, which many in the industry found inadequate (see, for example, *ACC and HRS, 2021*).

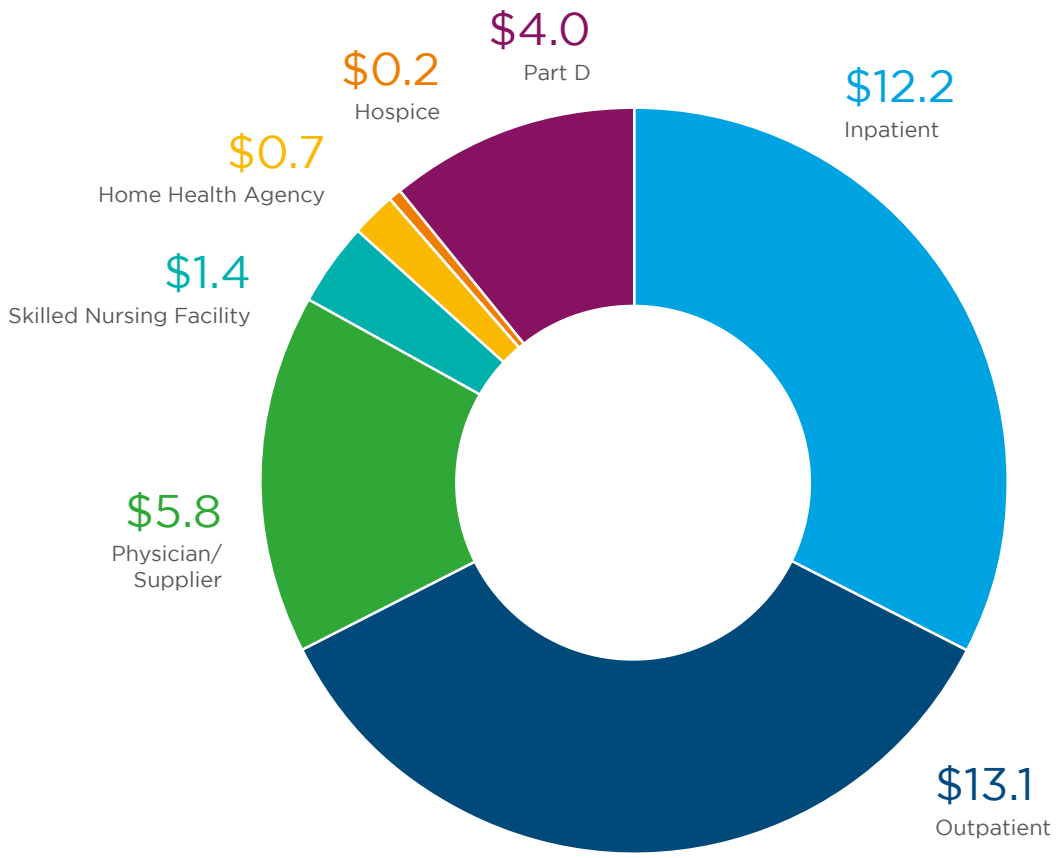
Digital Health Tools for Home Dialysis

END-STAGE RENAL DISEASE AND DIALYSIS

Dialysis is an intensive process that performs the function of kidneys for those with ESRD. In 2019 (the latest data available), more than 800,000 people in the United States had ESRD, an increase of more than 40 percent from a decade before. Among incident (that is, new) ESRD cases in 2019 (nearly 135,000), 3 percent received a kidney transplant while the rest required dialysis to live (*USRDS, 2021*).

Since 1973, most ESRD patients are eligible for Medicare, regardless of age, and thus the majority of ESRD-related costs fall to Medicare. All Medicare-related expenditures for beneficiaries with ESRD totaled $51 billion in 2019 (*ibid.*). In traditional fee-for-service (FFS) Medicare, ESRD expenses ($37.3 billion) comprised 7.1 percent of total FFS spending (*ibid.*). Inpatient and outpatient costs comprised the majority of Medicare FFS spending on ESRD — $12.2 billion and $13.1 billion, respectively (**see Figure 2**). Dialysis-related costs comprised nearly 80 percent of Medicare FFS spending on ESRD outpatient care (*ibid.*).

FIGURE 2. MEDICARE FEE-FOR-SERVICE SPENDING ON ESRD, 2019 ($ BILLIONS)



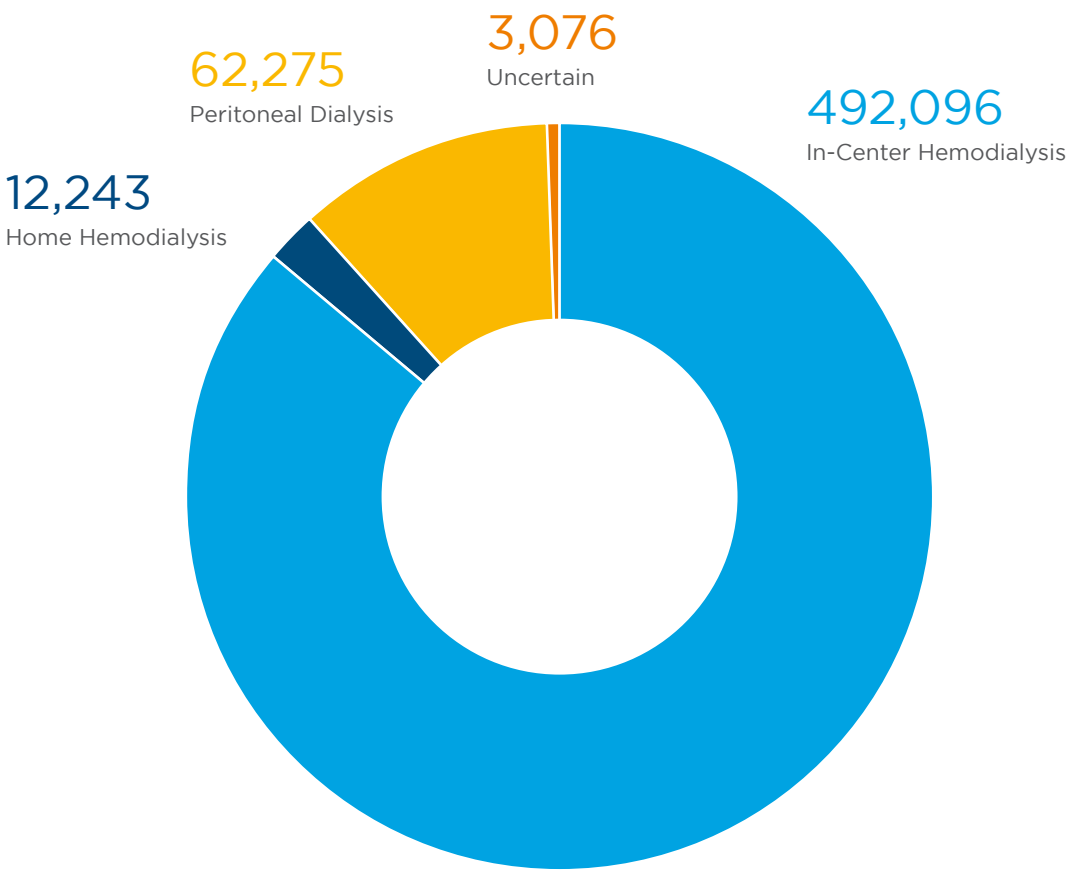
Source: *USRDS* (2021).

HOME DIALYSIS

Two types of dialysis exist: hemodialysis (HD) and peritoneal dialysis (PD). HD uses a machine to remove, clean, and replace an individual's blood, while PD performs this filtering inside the person's body using the abdominal lining. People on PD are generally able to dialyze at home, which has many advantages. While HD can also be performed at home, **Figure 3** shows that the vast majority (more than 492,000 patients, or 86 percent) of people on dialysis in the United States receive dialysis in an in-center setting.

For people with ESRD, home dialysis offers significant advantages compared with in-center dialysis (*Brill, 2016*). People who are able to dialyze at home have the flexibility to do so at their convenience, as opposed to driving to a dialysis center three times a week for a session that typically takes three to five hours. This yields better quality of life for many as it allows people to manage their own time and maintain a higher degree of normalcy in their daily lives (*Mendu et al., 2021*).

FIGURE 3. US DIALYSIS PATIENTS BY DIALYSIS TYPE, 2019



Source: USRDS (2021).

CASE STUDY

Fluid Overload in Home Dialysis Patients

To better understand the usefulness of digital health tools for people dialyzing at home, consider the incidence of fluid overload, a common clinical problem and cause of emergency room visits and hospitalizations for home dialysis patients.

Healthy kidneys perform the vital function of filtering, cleaning, and removing excess fluids from the bloodstream. Fluid overload (also called hypervolemia), which is simply excess fluid in the body, can create serious health problems, including difficulty breathing (dyspnea), hypertension, and congestive heart failure.

An ESRD patient has two options for dialysis: hemodialysis, which cycles blood through an external machine to clean it and remove excess fluid, or peritoneal dialysis (PD), which uses the patient's peritoneum (the stomach membrane) as a filter. In PD, an electrolyte solution called dialysate is introduced through a catheter into the patient's abdomen. This solution helps clean the patient's blood by drawing waste and excess fluid from the bloodstream into the abdominal cavity. The dialysate, excess fluid, and waste are then drained from the abdomen.

Fluid overload can be caused by excess sodium intake or missed or inadequate duration of dialysis treatments. If ESRD patients are not aware of excess fluid in their blood, the problem may progress until a trip to the emergency room or hospitalization is necessary. This highlights one way that digital health tools like remote patient management can be essential for people dialyzing at home.

If someone with fluid overload were using a device or app to track dialysis treatments, they or their healthcare provider could see warning signs. Increased weight or blood pressure could signify an increase in fluid for the patient. This information is not enough in a dialysis patient, however. The provider must know what is going on with the dialysis treatments in order to respond appropriately. Data coming from the dialysis machine can help by showing whether patients are performing their treatments, absorbing fluid from their dialysate, and getting alarms on the machine. Unlike non-dialysis patients, dialysis patients need both remote physiologic and treatment monitoring.

As noted later in this white paper, hospital care for just fluid overload in home dialysis patients exceeds an estimated $240 million annually. And this is just one of the complications in dialysis patients that remote patient management can help address. Others include peritonitis (or inflammation of the peritoneum) and catheter malfunction. In addition to improving health and quality of life for dialysis patients by helping reduce and avoid complications and hospitalizations, remote management devices and apps can generate substantial savings for Medicare and private health insurance payers.

Home dialysis also helps people with ESRD maintain employment, with studies showing that being able to undergo treatment outside of work hours "was viewed by young and working-age participants as a key advantage of home dialysis" (*Walker et al., 2016*). And home dialysis provides clinical benefits for ESRD patients (*Wallace et al., 2017*).

Medicare FFS costs for home dialysis patients are lower than for in-center patients. In 2019, the average per-patient per-year cost for HD patients was roughly $94,600, compared with roughly $81,100 for PD patients. Total Medicare FFS costs for HD were $29 billion, compared with $2.7 billion for PD patients (*USRDS, 2021*).

Many stakeholders, including policymakers, recognize that home dialysis is a viable and beneficial option for far more people than are currently using this modality.

Many stakeholders, including policymakers, recognize that home dialysis is a viable and beneficial option for far more people than are currently using this modality. In the section of the Social Security Act establishing Medicare coverage for ESRD, Congress called for the use of home dialysis.[1] More recently, the 2019 Executive Order on Advancing American Kidney Health directed the Secretary of the Department of Health and Human Services (HHS) to set up a payment model to explore offering financial incentives to providers for home dialysis use and kidney transplant (*Executive Office of the President, 2019*). In elaborating on this payment model and other features of the Advancing American Kidney Health initiative, HHS announced a goal of having 80 percent of new ESRD patients receiving home dialysis or a kidney transplant by 2025 (*HHS, 2019*). Remote patient management and other digital health tools can play an important role in ensuring that such an exponential increase in the home dialysis patient population is successful.

BENEFITS OF DIGITAL HEALTH TOOLS FOR HOME DIALYSIS

Patients on home dialysis typically see their healthcare providers monthly. In between visits, as they dialyze at home, patients use a flow sheet or treatment log to manually track physiological and therapeutic information, such as weight, vital signs, dialysate volume, and dialysis duration. These data help inform clinical decisions at the patient's monthly visit. It is therefore very important that home dialysis patients make timely and accurate entries in their flow sheets.

Given this, home dialysis is clearly an area where remote patient monitoring (RPM) devices and apps could help patients and clinicians by providing precise, contemporaneous physiological and therapeutic data that would facilitate timely treatment adjustments or interventions. As one study summarizes:

> Existing home dialysis RPM platforms allow direct transmission of both biometric information (ie, blood pressure, blood glucose level, temperature, and weight) to providers and home HD and automated PD treatment parameters (ie, treatment completion, duration, interruptions, alarms, and ultrafiltration). RPM obviates the need for paper dialysis treatment logs and provides information in key domains of dialysis access, blood pressure, target weight, and ultrafiltration management while identifying treatment adherence challenges and in some cases allowing remote changes to the prescription. (*Lew et al., 2021*)

[1] *Section 1881(c)(6) of the Social Security Act reads, "It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated."*

Since patients are dialyzing largely independently, remote management tools have the important function of helping ensure that the treatment is being performed and having the desired effect. In one study of PD patients, 30 percent of people missed more than 10 percent of their prescribed therapy in the first month, a level that is associated with negative health outcomes (*Firanek et al., 2017a*). According to a group of health experts exploring evidence related to remote patient management and home dialysis:

> The ability to monitor treatment adherence is of the utmost importance with respect to patient outcomes, as it has been shown to be an indicator for the risk of developing peritonitis, hospitalization, hospital days, technique failure, and death. . . . Data such as initial and total drain volumes, [ultrafiltration] values, adherence to and duration of therapy, lost dwells, and so forth can all be collected and used to monitor and intervene. (*Wallace et al., 2017*)

Since patients are dialyzing largely independently, remote management tools have the important function of helping ensure that the treatment is being performed and having the desired effect.

One tangible example of the benefits of remote management devices and apps is their usefulness in preventing fluid overload in home dialysis patients and avoiding consequent hospital trips (see case study on page 10). Fluid overload is a common cause of hospitalization for home dialysis patients, particularly for new patients who are not accustomed to choosing their dialysate volume. Remote patient management can allow a healthcare provider to intervene earlier to have the patient reduce their fluid intake before hospitalization is necessary. The data on fluid amounts that remote management tools collect can also help in training patients to choose the appropriate amount of dialysate.

Other benefits include reduced risk of peritonitis, or inflammation of the peritoneum, the abdominal membrane used in PD (*Ariza et al., 2020*). Remote management for home dialysis patients can help reduce technique failure through early identification of catheter malfunction, one of the leading causes of technique failure.

Digital health also holds promise for future benefits. For example, to the extent that remote management of home dialysis facilitates more ESRD patients receiving treatment at home instead of in center, it could help mitigate the ongoing healthcare worker shortage in the United States.

Implementing and using remote patient management for home dialysis is not without challenges. These include dialysis centers needing more staff to monitor remote data. In addition, some patients may not have internet access or the means to afford the necessary devices. Provider education on home dialysis also remains limited. While these challenges are not insurmountable, they are important to recognize and address.

EVIDENCE ON DIGITAL HEALTH TOOLS FOR HOME DIALYSIS

Important developments in digital health for home dialysis include digital platforms, software, connected peritoneal dialysis cyclers, and smartphone apps. For example, Nx2me Connected Health from NxStage Medical and Sharesource from Baxter International are digital platforms that facilitate the transmission and review of patients' physiological and therapeutic data. Different devices or apps are used to collect patient data, and data are transmitted to clinicians via these platforms, enabling the clinicians to monitor and intervene when necessary. This type of digital platform has been shown to have demonstrable benefits for home dialysis patients (see, for example, *Weinhandl and Collins, 2018*; *Ronco et al., 2020*) and to facilitate efficiency for healthcare providers (*Firanek et al., 2017b*).

Milan Manani and coauthors (*2019*) found that people using remote patient management over a two-year period saw reductions in key areas, including hospital admissions, overhydration episodes, technique failure, patient dropout, and prescription noncompliance. Two retrospective cohort studies in Colombia found that remote management of patients on automated PD was associated with lower dropout and hospitalization rates (*Sanabria, et al., 2018*) and improved clinical outcomes, lower hospitalization rates, and fewer days spent in the hospital (*Sanabria et al., 2019*).

Paniagua et al. (*2021*) compared PD patients with and without remote monitoring in a randomized clinical trial of 815 patients and found that, after controlling for age, gender, and certain comorbidities, patients without access to remote monitoring experienced higher risk (hazard ratio) of all-cause mortality, cardiovascular disease–related mortality, and time to first adverse event. Finally, Sanabria et al. *(2022)* found that remote monitoring of patients on automated PD was associated with significantly more time on therapy, an indicator of the effectiveness of dialysis.

MEDICARE COVERAGE AND POTENTIAL SAVINGS

The Medicare Physician Fee Schedule (PFS) reimburses for devices that collect and transmit physiological data. An eligible technology does not need to be FDA-approved — it just needs to meet the FDA's criteria for a medical device. But Medicare's ESRD bundled payment does not cover remote patient monitoring tools for dialysis patients, and providers cannot bill for these under the PFS if ESRD is the primary diagnosis. While there have been some meaningful developments in remote monitoring devices and apps for home dialysis, the lack of reimbursement for these tools could dampen the incentive for R&D in this therapeutic area and prevent patients, and the healthcare system, from benefiting from technologies that might be developed. More immediately, the lack of coverage for existing technologies that improve health outcomes impedes their adoption, limits patient access, and hinders the savings the healthcare system could realize.

One recent study estimated the potential cost savings from utilization of effective remote patient monitoring for PD patients based on a parameterized model of clinical outcome risks and costs for PD patients treated with and without remote monitoring. According to this model, remote monitoring is likely to result in net cost savings within the first year (*Ariza et al., 2020*).

To appreciate the savings opportunity from effective remote patient management for home dialysis, consider the impact of remote management in helping to reduce fluid overload

EXAMPLES OF DIGITAL HEALTH TOOLS FOR HOME DIALYSIS

Alio SmartPatch
A wearable patch for hemodialysis patients, with data transmitted to clinicians for monitoring

CloudCath
A device for night time remote monitoring of patients on peritoneal dialysis

MyPD from Baxter
A mobile app for peritoneal dialysis patients that transmits exchange and vitals data via the digital platform Sharesource

and associated hospitalizations for home dialysis patients. As the case study on page 10 highlights, fluid overload is one complication that remote patient management can help address.

The direct cost . . . of hospital care for fluid overload of home dialysis patients exceeds $240 million annually. Cost-effective remote patient management that significantly reduces just this one complication offers sizable savings.

Fluid overload can lead to hypertension and congestive heart failure, resulting in an emergency room visit, hospitalization, or observation stay, depending on duration and severity. Assimon et al. (*2016*) estimate that nearly one-quarter (24.4 percent) of a sample of hospitalized dialysis patients were diagnosed with fluid overload during the period January 2010–June 2013.

Arneson et al. (*2010*) estimate that the cost for Medicare HD patients with a *primary* diagnosis of fluid overload treated between July 1, 2004, and December 31, 2005, was $5,961 for inpatient treatment, $1,511 for a hospital observation stay, and $969 for an emergency department visit. The weighted average cost for these patients was $4,408. (In a broader sample of patients with fluid overload and a primary diagnosis of fluid overload, heart failure, or pulmonary edema, the average cost per treatment episode was higher, $6,372.) Since that time, medical cost inflation has increased 74.8 percent (*BLS, 2022*).

An estimate of the cost of fluid overload hospitalizations for a home dialysis population of more than 74,500 can be derived using an adjusted hospitalization and observation stay rate of 1.73 per patient year in 2019 (*USRDS, 2021*) and the average cost for patients with a primary diagnosis of fluid overload. Based on these inputs, the direct cost (adjusted by medical cost inflation to 2022) of hospital care for fluid overload of home dialysis patients exceeds $240 million annually. Cost-effective remote patient management that significantly reduces just this one complication offers sizable savings, net of the cost of remote management. And remote management for home dialysis has the potential to reduce other costs as well, including the costs associated with other types of hospitalization, surgery, technique failure, and prescription noncompliance. There also could be additional cost savings if remote patient management facilitates greater efficiency for care teams.

Conclusion

Digital health holds great promise for advancing the care and treatment of ESRD patients, particularly those on home dialysis. In particular, remote patient management devices and apps can improve health outcomes and facilitate cost savings. To unlock the full potential of remote management for home dialysis, Medicare reimbursement reforms are needed. The certainty of Medicare coverage for these tools will make it possible for clinicians and facilities to utilize these tools with their patients and will encourage innovators to pursue further advances. Policymakers should consider Medicare coverage for effective ESRD digital health tools, particularly those targeting home dialysis.

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ABOUT THE AUTHORS

Alex Brill is the founder and CEO of Matrix Global Advisors (MGA), an economic policy consulting firm. He previously served on the staff of the House Ways and Means Committee and the White House Council of Economic Advisers.

Christy Robinson is a principal at MGA.

Eric Wallace is a Professor of Medicine at the University of Alabama at Birmingham (UAB). He is also the UAB Medical Director of Telehealth, the Co-Director of the UAB Home Dialysis Program, and the Director of the UAB Fabry and Rare Genetic Kidney Disease Clinic.

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