Is wearable technology the future of dialysis?

How wearable technology can transform kidney care

The better the question. The better the answer. The better the world works.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current state of play</td>
<td>5</td>
</tr>
<tr>
<td>Barriers to innovation in dialysis treatments and potential for improvement</td>
<td>12</td>
</tr>
<tr>
<td>Design-led innovation – a probable solution</td>
<td>17</td>
</tr>
<tr>
<td>WAKs – the game-changers</td>
<td>24</td>
</tr>
<tr>
<td>Key implications for various stakeholders as wearable and implantable kidneys become a reality</td>
<td>28</td>
</tr>
<tr>
<td>Conclusion</td>
<td>30</td>
</tr>
</tbody>
</table>
Current state of play
Approximately 10% of the total world population is living with chronic kidney disease (CKD). The prevalence of CKD is significantly high among population aged above 70 years, making it, by some estimates, a disease as prevalent as diabetes. The end stage of most CKD patients – also known as end-stage renal disease (ESRD) – is a daunting healthcare challenge. It is estimated that by 2030, nearly 2.2 million people in Asia will be getting treated for ESRD. Every year, 100,000 new patients in the US are diagnosed with ESRD. The increased number of ESRD patients is driven by a lack of awareness and preventative measures during early-stage CKD, and the rise of lifestyle diseases such as diabetes and cardiovascular diseases. The financial burden of ESRD on national healthcare systems is significant – in the US, 7.1% of the Medicare budget is spent on 1% (ESRD patients) of the general patient population.

Prevalent treatment options for ESRD include dialysis and kidney transplant and these therapies together are termed as renal replacement therapy (RRT). The availability of RRT around the world is very diverse and depends largely on a country’s financial resources. In the US, on an average, ~15% of newly diagnosed ESRD patients eventually require a transplant, while the rest of patients rely on dialysis. On a global average, this number decreases to approximately 6% and is even lower in less developed markets. Transplant is not considered a feasible option for treating the majority of ESRD patients due to two main reasons:

- **Short supply of organs:** this results in patients waiting endlessly for organs. About four to eight patients die every day in the US, while waiting for a kidney transplant, and this number can be in hundreds (per day) in emerging markets.

- **Patients’ non-eligibility for a transplant:** this can result from a variety of reasons, such as comorbidity or other serious disorders. So, treatments such as haemodialysis (HD) and peritoneal dialysis (PD) have remained standard care procedures for a majority of the ESRD patient population. However, there is now a wave of advanced disruptions in care delivery and devices for dialysis. This paper aims to provide an understanding of the underlying science and likely implications of some of these disruptions.

Currently, key modalities for dialysis treatment and delivery of care for the majority of ESRD patients are:

I. **Haemodialysis:** a fistula is created, blood is taken out of the body and run through an external artificial kidney (i.e., a dialyser) that removes toxins and extra fluid and then returns the cleaned blood back into the body. Haemodialysis treatment is available to patients under two types of care modalities: in-centre haemodialysis (CHD) and home-based haemodialysis (home HD).

II. **Peritoneal dialysis:** a perforated hollow tube is surgically fitted into the patient’s peritoneal cavity in the abdomen. The peritoneal membrane acts as an exchange filter for toxins and fluids in the blood to pass through to be removed by the dialysate fluid.

Prevalence and adoption of treatment modalities

Globally, HD is the more prevalent treatment modality over PD – in most of the countries in the East and West, ~90% of dialysis patients receive CHD. Though CHD is the predominant care modality used globally, there is a wide variation in the use or adoption of different treatment modalities by region. This variation exists across countries and regions due to reasons related to the structure of a country’s healthcare system, reimbursement for the treatment modality, preference of care providers and physicians, patient support and education systems, availability and sophistication of infrastructure and the existing regulatory guidelines. For example, in India, PD is perceived to be more expensive as the cost of supplies is the primary consideration in assessing the cost of dialysis.

In 2015, 70%–90% of the newly diagnosed ESRD patients in the US began RRT with HD, 10%–30% started with PD, and a very small number of patients received a kidney transplant. Among the patients receiving HD, nearly 98% used CHD, while the remaining were on home HD. For the patients on PD, the uptake of CAPD and APD is nearly equal, with a slight bias towards APD (60%) in the US. Since 2010, the adoption of home HD and PD modalities in US has significantly increased. Global compound annual growth rates (CAGR) (2018–25) for HD and PD are expected to be 4.2% and 5.8%, respectively.

The adoption of treatment techniques in developed markets of Asia is similar to the trends in the West. In Japan, most ESRD patients receive CHD. However, Hong Kong is an exception, where PD adoption is the highest globally with a majority of patients on PD, driven by government policies and treatment guidelines. In 2015, PD was used for 79% of the dialysis patients in Hong Kong. This high adoption rate of PD in Hong Kong can be attributed to PD’s first reimbursement policy that reimburses HD treatment only if patients have medical contraindications for PD. PD has proven to be more cost effective largely, and following this trend and under increased healthcare budget pressures, some of the other Asia-Pacific markets such as Singapore, Taiwan, Thailand, Australia and New Zealand have been making shifts in reimbursements and guidelines to drive use of PD.

Key device manufacturers and service providers

Globally, the dialysis devices market has been dominated by leading manufacturers such as Baxter, Fresenius Medical Care, B. Braun, Nipro, Nikkiso, etc. Similarly, the dialysis service and care delivery in developed markets is consolidated and dominated by a few large dialysis organisations (LDOs). In the US, ~85% of all dialysis treatments are provided through centres owned and managed by Fresenius Medical Care and DaVita.

In contrast, dialysis service and care delivery in emerging markets is fragmented and independent hospitals and clinics typically run their own dialysis treatment centres. A few examples of players with national reach include Asia Kidney Dialysis Centre, Pacific Advance Renal Care and National Kidney Foundation in Singapore and Malaysia or Sparsh and Nephroplus in India. Additionally, both Fresenius and DaVita are expanding their clinics in emerging markets.

Is wearable technology the future of dialysis?  

13. Evercore report  
The need to challenge the status quo of current dialysis treatment
Given the significant reliance of ERSD patients on dialysis, the existing standard care procedures should be challenged from awareness, availability, cost of care and quality of life perspectives.

1. **Awareness:** about 40% of ESRD patients globally are not educated or sufficiently understand the importance of regular dialysis treatments because of a wide set of awareness issues, from reliance on traditional beliefs and methods to lack of access to healthcare professionals.

2. **Availability:** dialysis treatments traditionally have been capital-and labour-intensive, making it challenging to scale the availability of treatments. In Asia, about 66% of ESRD patients who require dialysis are unable to get adequate treatment due to lack of available care facilities. Lack of trained nephrologists and care professionals further accentuates the problem of accessibility to dialysis – specifically in emerging markets. A case in point is in India, where in 2015, there were only 900 qualified nephrologists for a population of 1.2 billion (<1 nephrologist per million people), while in Malaysia, there were ~80 nephrologists for a population of around 30 million (>2 nephrologists per million people).

3. **Cost of care:** while several healthcare systems of developed markets provide coverage for dialysis, experts have raised questions on the sustainability of the cost of care. For self-pay patients in low- and middle-income countries, the average dialysis treatment lasts for 3–5 years; in developed Asia, it lasts for 10–12 years; and in the US and Western Europe, this number is about 15 years.

4. **Adverse impact on the quality of life:** several service delivery and drug innovations as well as device advancements, covered later in this paper, are working towards addressing the first three challenges. However, the largest underserved need remains the quality of life for patients. Studies have reported a poorer quality of life (QoL) in patients with ESRD than those with other chronic diseases, including cancer. Dialysis techniques have seen only incremental innovation without a significant improvement in QoL of ESRD patients. An additional challenge with the current dialysis techniques is that they are less adaptable and customisable for the needs of patients resulting in faster deterioration of their residual renal function (RRF).

Low QoL scores translate into high mortality and morbidity rates. For instance, mortality rates in ESRD patients undergoing standard HD are reported to be 17%. This number can be even higher in developing countries such as Mexico where mortality can go as high as 21%.

As per a 2017 report by the United States Renal Data System (USRDS), five-year survival rates of ESRD patients on HD and PD are around 40%–50%, which is similar to survival rates for those suffering from digestive system cancer or myeloma. These rates are also significantly lower than the rates for several cancers, indicating a need and urgency to change the status quo.

In addition to these traditional measures of QoL, it is crucial to consider certain aspects that significantly impact the life of ESRD patients. Kidney disease quality of life (KDQoL) is a type of metric that helps measure the burden, symptoms, problems and effects of kidney...
Is wearable technology the future of dialysis?

Key elements that KDQoL metrics capture are the physical component score, mental component score and the effects of kidney disease. At a more granular level, it encompasses various aspects that impact a kidney disease patient, such as physical function, bodily pain, general health, vitality, social function, emotional role, mental health, symptoms, problems, effects of kidney disease, quality of social interaction, cognitive function, social support and sleep.

Key QoL challenges for an ESRD patient

- **Mobility and frequency of treatment:** an average ESRD patient undergoing CHD typically spends 4–5 hours, three times a week in a dialysis treatment unit, excluding the additional time required to travel to the dialysis centre. For home HD patients, their mobility is restricted as they cannot easily port devices that weigh as much as 45 kilogram (kg), and need to dialyse at frequent intervals, depending on their specific needs. With the limited mobility come social burdens in terms of reduced travel options, time with family, etc.

- **Negative impact on social well-being:** current treatment modalities impose lifestyle restrictions, increase social burdens and cause psychological concerns. This is primarily due to food and fluid restrictions, changes in marital role, financial concerns, changes in social and marital relationships, frequent hospitalisations, limitations in vacations and leisure activities, increased dependency on the artificial kidney machine, medical staff and family environment and uncertainty about the future.

- **Restricted employment prospects:** due to the demands imposed by dialysis (and especially in case of CHD), only one out of five ESRD patients of working age can remain employed, and six months after starting CHD, only 43% of patients are able to maintain the same level of employment. Home HD allows for increased independence and ability to work. However, adoption of home HD by patients remains limited. We estimate that in the US, these trends (of low adoption of Home HD and dropout from employment) result in loss of productivity of approximately US$10–13 billion annually (refer to figure 5).

- **Negative impact on overall mental and physical well-being:** patients suffering from ESRD typically also suffer from other symptoms. They need to manage comorbidities such as hypertension, diabetes or cardiovascular disease and often have compromised immune systems. In emerging markets, poor quality standards in HD service centres and lack of access to home dialysis options exposes patients to bacterial and hepatitis infections. Dialysis patients generally suffer from poor sleep quality, depression and other psychological complications. Furthermore, lack of education or support leads to further complications. For example, a study of primarily low-income dialysis patients in the US found that sadness, nervousness or fear prevented around 40% of the total patient pool from complying with treatments required for their condition.

---

32. Technology roadmap for innovative approaches to Renal Replacement Therapy by KHI
33. Concerns of patients on dialysis: A Research Study

---

10 | Is wearable technology the future of dialysis?
High medication burden, disease maintenance and treatment challenges: ESRD patients often undergo repeated hospitalisations, readmissions and other interventions, while managing their disease and treatment. For example, 80% of HD patients begin dialysis using a catheter for primary vascular access, but over 70% continue using the temporary catheter 90 days later, putting them at a high risk of infection. About 10% of patients suffer from vascular access failure, which is the second leading cause of death in dialysis patients. Additionally, catheters and other types of access (e.g., arteriovenous fistulas or grafts) often require multiple interventional procedures to maintain patency. A survey by American Kidney Fund found that 30% of patients left dialysis sessions early, while 18% skipped their sessions altogether. Top reasons cited by patients for this behaviour were feeling sick and exhausted.

Burden on healthcare systems of countries: the current treatment options put a lot of burden on countries’ healthcare systems. For example, a one-year PD and HD treatments will require around ~3,650 and ~18,000 litres of dialysate, respectively, leading to a total treatment cost of around US$75,000 and US$89,000, respectively. Most patients cannot afford long-term maintenance dialysis – not to mention the lack of sufficient treatment facilities. Such high costs and infrastructural requirements lead to a gap in treatment access for those who are in dire need.

The increasing number of patients receiving RRT and the substantial gaps in treatment access reflect the need for innovation in treatment options and techniques, identification of innovative care delivery models and the need to both develop low-cost treatments and implement effective population-based prevention strategies. Significantly poor QoL suggests that the current standard HD treatment is inadequate and in need of disruption.
Barriers to innovation in dialysis treatments and potential for improvement

Dialysis treatments currently available for treating patients suffering from ESRD are sub-optimal; yet, in the last few decades, innovation has been significantly slower compared to innovation in other medical fields and disease areas. This is made clear by the fact that there are numerous startups focusing on oncology and diabetes in the US, while there are only a handful of startups innovating in dialysis care. Also, from 2005-15, there were 1647 cardiovascular approvals by FDA, of which 93 of them were pre-market approved (PMA), whereas out of the 252 renal approvals, none were PMA.

Key barriers that have resulted in a slow pace of dialysis treatment innovation can be categorised into two categories: technical barriers and market barriers.
Technical barriers

1. Biological limitations: physiology of kidney tissue is complex and researchers have faced technological roadblocks in finding better alternatives to current treatments. To develop a fully functional bioartificial or bioengineered kidney capable of reproducing the metabolic, endocrine, immunomodulatory and secretory functions of native kidneys, several challenges will need to be addressed. Existing techniques are merely a poor substitute of the normal kidney function. They partially compensate for renal glomerular filtration and correct fluid and electrolyte imbalances, and fail to replace the complex renal tubular function (endocrine, metabolic and secretory activities). Specific challenges in developing better treatment alternatives to manage ESRD include:

- Risks such as infection, clotting and bleeding due to needle or catheter dislodgement for wearable devices
- Lack of effective urea removal strategies that are essential to miniaturise devices and enhance patient outcomes
- Replacement of tubular functions, including active tubular secretion of protein-bound uremic toxin (PBUT)
- Cell sourcing, organ scaffolding and host-immune response for implantable and hybrid devices

2. Lack of a multidisciplinary approach to develop treatments and deliver care: the kidney is a complex organ, with integrated functions. A multidisciplinary approach is required to replace the function of this organ. But innovation in dialysis has typically focused on isolated solution development and thus, has not resulted in disruptive solutions. As the integrated functions of the kidney are extremely complex, repairing or replacing the various functions will require unique solutions that are able to effectively substitute the kidney’s functions. This requires dedicated resources and the development of multidisciplinary teams of researchers, technology developers, clinicians, entrepreneurs, investors and patients. Additionally, dialysis treatment and the care delivery ecosystem involves multiple stakeholders and service providers, necessitating a collaborative multidisciplinary approach for achieving better patient engagement and outcomes.

To aid innovation, the United States Food and Drug Administration (FDA) established the Kidney Health Initiative (KHI), a public-private partnership in 2012. This initiative aims to establish a conducive environment for stakeholders in the ecosystem for kidney ailments (i.e., academics, patient organisations, regulators, industry, healthcare providers, foundations, pharmaceutical and biotech companies, dialysis providers and governmental agencies) to collaborate and develop innovative therapies.

3. Regulatory barriers: the newer, innovative devices are often a combination of improved device design as well as a biological component. Due to this, the FDA and other regulatory authorities that approve clinical trials are faced with the challenge of identifying the right category under which the clinical trial can be registered. The Kidney Project is working to develop a bioartificial kidney (BAK); however, financial and regulatory barriers have delayed commercialisation timelines. The FDA has selected two renal device projects – the Kidney Project in 2012 and the Wearable Artificial Kidney (WAK) in 2015 – to join a new regulatory approval program called Expedited Access Pathway (EAP) to reduce the time-to-market and bring breakthrough medical technologies to patients faster. Recently, the FDA has launched the Breakthrough Devices Program to replace EAP and encourage development as well as expedite review
of breakthrough technologies that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. To date, the PD device from AWAK Technologies is the only wearable dialysis device which has been granted the Breakthrough Device Designation by US FDA.

4. Patient education and physician bias: CHD has remained the predominant standard of care globally, in spite of being costlier and having a more negative impact on the quality of life of patients when compared to PD and home HD. A study found that there are three key factors associated with a lower percentage of patients on PD. First factor is a higher diabetes prevalence as most studies report poorer outcomes for PD compared to HD for diabetic kidney patients. The second factor is total healthcare spend. Countries spending more on healthcare may have fewer restrictions on adopting expensive technologies such as HD and hence PD is less promoted compared to countries where healthcare spend is lower. Lastly, in countries where imported PD consumables are relatively more expensive than staffing costs (e.g., Eastern Europe), PD utilisation will be lower. Some of the reasons for low adoption of home HD dialysis and related innovation for home care delivery are:

- **Patient-level barriers**: patients often lack the information about different modalities and tend to feel more secure in a clinic compared to home. Based on empirical evidence, patients in Asia are averse to initiating home HD as they feel safer under clinical supervision. However, patients in Australia and New Zealand seek increased control of their therapy and are comfortable performing dialysis at home. Even if patients are trained and comfortable dialysing at home, other barriers such as lack of space for HD equipment and supplies, need for a trained care partner at home and poor availability of telehealth options to stay in contact with physicians, hinder the adoption of home HD.

- **Provider-level barriers**: physicians are often more inclined to prescribe CHD to patients. Typically, dialysis providers have been ill-equipped to offer advice or support for home dialysis. Lack of trained healthcare professionals and continuous education for physicians is also a challenge in keeping them up-to-date with the latest information.

- **Facility-level barriers**: the regulation and process for dialysis facilities to obtain certification for home dialysis support and training is time consuming and involves uncertainty in getting certification.

- **Reimbursement-related barriers**: lack of effective outcome-based reimbursement policies for home dialysis has resulted in lower adoption of this treatment modality. For example, various developed healthcare setups have introduced risk-sharing programs in the field of osteoporosis and outcome-based pricing for oncology. Recent changes in policy have shown that the impact of effective reimbursement policy is encouraging HD and PD utilisation, as proven by the increasing adoption of home HD and PD in the US. Until recently, Medicare did not reimburse dialysis patients engaging in a telehealth encounter with their physicians, but Medicare has reviewed this position and measures such as the Chronic Care Act have resulted in reimbursement policies that encourage home dialysis.

**Market barriers**

1. **Significant R&D and commercial investment required**: any transformational innovation in dialysis devices will require the innovator to spend several million dollars for R&D and commercialisation efforts. Additionally, the innovator must take on the high risk of development and lengthy approval processes. This large investment inhibits disruption by smaller startups. Currently, there are relatively few startups focusing on dialysis device innovation, while there are...
hundreds working in oncology and diabetes space out of the total of 7000+ startups in the US. In the last 10 years, no dialysis device has received a pre-market approval (PMA) in the US. From 2005 to 2015, FDA approved 1647 cardiovascular innovations and 93 of them were PMA. Out of the 252 renal approvals, none were PMA, all were 510K. This has contributed to only incremental innovations by the multinational companies as well as startups.

2. **Significant infrastructural investments:** existing dialysis centres have invested large sums in setting up infrastructure and purchasing current generation dialysis devices. The centres require to recoup their investment over a long period of time as the sunk and fixed costs are high, and these costs should be spread across a large number of patients. This inhibits innovation and adoption of disruptive technologies.

3. **Discrepancy in funding and reimbursement expense for kidney disease in the key markets:** nephrology as a specialty has received insufficient funding for research as compared to other specialties such as oncology and internal medicine. In the US, there was a huge discrepancy in Medicare cost of care for patients with kidney disease (US$33 billion) and National Institute of Health (NIH) funding for kidney research (US$0.56 billion) in 2016 – less than 2% of total Medicare costs for the care of patients with kidney disease was spent on research. Current reimbursement models focus on dialysis and do not have a process for reimbursing disruptive new technologies, resulting in R&D investment being disincentivised.

In Asia and markets with low healthcare spending, most of expenditure goes towards preventive programs, family welfare and nutrition, staff salaries and maintenance of basic hospital infrastructure. Attention to specialist-, technology-and resource-intensive treatments such as dialysis does not occupy high priority.

As shown in the chart below, in 2014, cost of care for cancer was three times as much compared to kidney disease; however, the R&D expenditure on cancer was more than 10 times that on kidney diseases.

Figure 1: comparison of R&D spending and cost of medical expenses for key diseases in US

---

### A comparison of R&D spending and medical expenses for key diseases in the US, (values for 2014 in US$ billion)

<table>
<thead>
<tr>
<th>Disease</th>
<th>NIH R&amp;D Funding</th>
<th>Total medical expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td>3.2%</td>
<td>105.4</td>
</tr>
<tr>
<td>Cancer</td>
<td>6.1%</td>
<td>87.8</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.1%</td>
<td>91.3</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.4%</td>
<td>50.4</td>
</tr>
<tr>
<td>Infectious</td>
<td>12.2%</td>
<td>5.0</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>1.7%</td>
<td>32.6</td>
</tr>
</tbody>
</table>

Sources: EY Analysis, NIH Categorical Spending, Medical Expert Panel Survey (MEPS) by AHRQ

Notes: (1) total medical expenses include hospital outpatient or office based-provider visits, hospital inpatient stays, emergency room visits, prescribe medicines and home health

---


4. Lack of patient advocacy and representation: generally, kidney diseases disproportionately affect a demographic that is largely disenfranchised, lacking sufficient advocacy, public attention and funding. People with kidney diseases struggle to advocate for their own needs because of sociodemographic variables (including lack of health literacy and economic status) and health limitations caused by comorbid conditions. Studies have found that certain ethnicities in the US have a greater risk of developing CKD, due to their demographic, socioeconomic, lifestyle and clinical factors. African-Americans are 3.5 times more likely to develop kidney failure, while Hispanics are 1.5 times more likely. Awareness of CKD is low even in risk-prone populations in the US that have visited a physician in the past one year – less than 50% of ESRD patients are aware of their condition. In risk-prone ethnicities specifically, the incidence of CKD is 14.7 patients per 1000, where 3% of the CKD patients lack access to healthcare insurance. In the other comparable ethnicities, CKD incidence is 12 per 1000 patients, with only 0.3% lacking access to healthcare insurance.

Advocacy by patients suffering from cancer, cardiovascular disease and HIV/AIDS has resulted in higher clinical investigations and reduced costs of recruiting patients for trials because more patients are willing to participate in clinical trials. Patient engagement will be critical for driving innovation in treatment of kidney diseases.

5. Few dominant players in service delivery and device manufacturing: in 2015, ~85% of dialysis treatments in the US were delivered by dialysis centres run by large dialysis organisations (LDOs), such as Fresenius and DaVita, and 70% of dialysis treatments are delivered using devices from just two manufacturers, i.e., Fresenius and Baxter. Such consolidation has largely resulted because Medicare insures more than 80% ESRD patients, thus putting pressure on the dialysis players to reduce outpatient dialysis costs. Presence of few players on care delivery and device offerings, consolidation trends across industry, and high cost of innovation and R&D has resulted in a slower pace of innovation.
Design-led innovation – a probable solution

The crux of the biggest challenges around quality of life for patients and high infrastructural and financial requirements of dialysis centres lies in the design of solutions and treatments. A miniaturised device or an implanted kidney will help resolve significant patient issues and disrupt the current standard of care.
Is wearable technology the future of dialysis?

Figure 2: Four stages of future ESRD treatments

**Enhanced Dialysis**
- **Benefits**
  - Increased flexibility for patients on treatment
  - Reduced disease complications
- **Example devices**— automated PD systems; improved dialysers with extended range of toxins that can be filtered from the blood
- **Key players**— Baxter, Fresenius Medical Care
- **Time to market**— continual incremental improvements to existing dialysis therapy

**Portable/home-based**
- **Benefits**
  - Higher patient independence and freedom of movement (work and travel)
  - Continuous or near-continuous treatment
- **Example devices**— Portable Artificial Kidney (PAK)
- **Key players**— NxStage (Fresenius Medical Care), Quanta Dialysis Technologies, Outset Medical, Diality
- **Time to market**— portable devices already in market

**Ultra-portable/wearable**
- **Benefits**
  - Much higher patient independence and freedom of movement (work and travel)
  - Reduced treatment impact for patients on work, mobility, travel
  - Continuous treatment
  - Improved social and physical well-being
  - Significantly lower fluid requirement
- **Example devices**— Wearable Artificial Kidney (WAK) for HD or PD with sorbent dialysate regeneration
- **Key players**— AWAK, Nanodialysis, Triomed
- **Time to market**— 3–5 years; currently in early clinical stages

**Implantable/Biohybrid/Regenerated Kidney**
- Closely mimics normal physiology of kidney and restores endogenous biological kidney function
- **Benefits**
  - Duplication of kidney functionality
  - Continuous treatment
  - Recovered and maintained kidney function
  - Elimination of disease impact on patients (e.g., unrestricted diet, return to work)
  - Unlimited, readily available supply of organs when needed
- **Example devices**— implantable Bioartificial Kidney (BAK), replace fibrosis with normal nephrons and vasculature; implantable hemofilter with filtrate processing and drainage, iRAD
- **Key players**— MiroMatrix, The Kidney Project, Innovative BioTherapies Inc
- **Time to market**— biohybrid may take 10–12 years; regenerated kidney may take 10–15 years to market

Increasing complexity of technologies | Increasing potential time to market
1. Enhanced dialysis

Unlike other lifesaving treatments, dialysis is not a cure and does not return patients to full health or normal lifestyle. Weekly dialysis is physically and emotionally tiring and infections, thrombosis and severe exhaustion are common side-effects. Several dialysis equipment manufacturers and care providers are continuously innovating the dialysis landscape to improve vascular access and treatment outcome, minimise complications and maintain patients’ quality of life for both HD and PD. One company dedicated to reducing treatment cost and restoring patients’ QoL is Advent Access, a spin-off from Singapore’s governmental Agency for Science, Technology and Research (A*STAR). The company has developed a proprietary implant technology that provides access to the arteriovenous fistula (AVF) of the HD patient without being in contact with the dialysis vein. This arrangement reduces the wear and tear of an AVF and allows a reliable and less-painful vascular access that can potentially reduce the need for surgeries and hospitalisation, bringing down the associated costs.

Recently, Fresenius Medical Care (FMC) has also been actively innovating on the HD treatment front. For example, upon FDA approval, the company will obtain commercial rights for a human acellular vessel (HAV) developed by Humacyte, a medical company. HAV provides vascular access for haemodialysis and is potentially more effective compared to synthetic grafts and fistula, due to lower failure rates, less complications and lower cost of care. Another innovation from FMC is an algorithm that uses a data-driven artificial intelligence (AI) model to assist CKD patients in managing anaemia, and a fluid management software providing recommendations on the rate of fluid removal. The AI model generates personalised IV dose recommendations for iron and red blood cell-stimulating agents. Initial testing resulted in better anaemia management as proven by higher and more stable haemoglobin levels, and potentially a lower cost of care due to less use of erythropoietin (EPO) stimulating agent. The fluid management software aims to cut cases of fluid overload and depletion, and thereby, reduce and prevent adverse cardiovascular events, morbidity and mortality. It has received breakthrough device status from FDA. One example of PD product and service innovation is Baxter’s AMIA© automated peritoneal dialysis (APD) system that comes with a remote patient management platform. The platform guides ESRD patients with their home PD treatment and allows healthcare providers to securely view their patients’ treatment data that is automatically collected after each PD session. Healthcare providers can, then, act on this information by remotely adjusting their patients’ home therapy prescription without requiring them to travel to the clinic.

2. Portable/home-based devices

A few versions of portable devices exist today and after initial challenges of reimbursement, care guidelines are gaining increasing acceptance. While portable devices facilitate home or remote care, it has some similar drawbacks with respect to the standard of care. Portable devices are heavy (25–40 kg) and require electrical connection and large volumes of dialysate. Two examples of established portable devices available in the market include NxStage’s System One (US) and Quanta’s SC+ (UK). Given below is a brief description and comparison between the two devices.

---

3. Ultra-portable/wearable devices (HD and PD)

The limitation of portable devices in improving QoL of kidney disease patients, has encouraged miniaturisation efforts and led to innovation of dialysis-on-the-go with wearable artificial kidneys (WAKs) devices.77

WAKs provide a portable, continuous and unobtrusive dialysis option that is light weight. Most devices typically weigh between 1–3 kg. The key challenge in case of WAKs is to achieve a target clearance on the minimum amount of sorbent material while maintaining biocompatibility, optimised shelf life and stability of the sorbent, and enclosing these functionalities in a miniaturised device. Recent developments in sorbent technology have aided miniaturisation efforts.78

Anticipated benefits from HD-based wearable devices are greater flexibility and more frequent and longer dialysis sessions outside the hospital. This increases the patient’s mobility and autonomy. PD-based wearable devices can also enhance blood purification and increase technique survival of PD.

Whether patients want to wear a dialysis unit continuously or for extended periods of time, is not yet clear and may vary by region. As with home PD and HD, WAKs will place more responsibility for self-care on the patient, and not all patients (or their caregivers) may be comfortable with or capable of managing the processes involved.

Given below are some early movers and pioneers in the WAK PD space79, 80:

- **AWAK Technologies, Singapore**: AWAK is developing a wearable PD device that has successfully completed first human trials on 15 patients in October 2018. In total, over 100 AWAK therapies have been delivered. The clinical trial proved safety of the device with no serious adverse events reported. Although efficacy

---

**Table: Comparison of WAX and Quanta (SC+)**

<table>
<thead>
<tr>
<th>Approach</th>
<th>Quanta (SC+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Easily usable portable device for dialysis at home</td>
<td>• Unique disposable dialysis cartridge which incorporates all the dialysate fluid management activities, without compromising performance</td>
</tr>
<tr>
<td>• User-friendly touchscreen for effective use</td>
<td>• Reduced infection risk</td>
</tr>
<tr>
<td>• In centre or critical-care centres available</td>
<td>• Disposable sorbent cartridge automatically prepares and mixes dialysate fluids; reverse osmosis used for purification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Technique</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Easy-to-use drop-in cartridge and no special disinfection measures required</td>
<td>• Intuitive touch-screen interface and flexible design for easy transition across continuum Of care</td>
</tr>
<tr>
<td>• Device linked to NxStage’s Nxe2me Connected Health@ telehealth platform for effective patient monitoring</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Journey so far</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• First home HD device approved by FDA in 2005; acquired by Fresenius in 2018</td>
<td>• Commercialised in June 2018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key challenges in adoption</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• No incentive or support in medicare payment policies for home dialysis</td>
<td>• Requires larger quantities of tap water as it uses reverse osmosis</td>
</tr>
<tr>
<td>• Cost issues in purchasing or renting devices</td>
<td></td>
</tr>
<tr>
<td>• Physician comfort levels in prescribing home HD</td>
<td></td>
</tr>
</tbody>
</table>

---

was not the primary outcome, the results showed a downward trend of the toxins (such as urea, creatinine and phosphate) in the body. AWAK is one of the first players across the globe to conduct human trials for a wearable PD device. Some of the benefits of AWAK’s technology include patient empowerment and autonomy, easily manageable fluid logistics and less protein loss. AWAK PD, a wearable/ultra-portable device is one of the few devices from Asia that have been accepted into the FDA’s recently launched Breakthrough Device Designation pathway program so far.81

AWAK’s device uses sorbent technology to regenerate the used dialysate – thereby, reducing the volume of dialysate needed from eight to twelve litres to one to two litres per day and enabling the development of ultra-portable and wearable devices. This portability and ease of use of the device allows therapy to be delivered where the patient chooses – enhancing their quality of life as well as compliance to the therapy. One of the potential commercialisation challenges that AWAK may face is building awareness among patients and physicians to adopt PD and further adopt a wearable device.

▶ **Nanodialysis BV, Netherlands**82, 83: the Wearable Artificial Kidney (WEAKID) by Nanodialysis is a wearable device delivering continuous PD with ongoing regeneration of dialysate, removal of waste products and better patient outcomes. It plans to complete early feasibility, first in-human trial by 2019 and another cross-over study in 2020. Some potential benefits of this technology (as claimed by Nanodialysis) are that it is twice as effective as current dialysis techniques, more cost effective and offers better blood purification using absorption and increases life expectancy.

Nanodialysis uses sorbent cartridge containing ion-exchanger and activated carbon to regenerate dialysate and conduct overnight dialysis. It maintains optimal glucose concentration in dialysate, allowing for longer PD membrane survival, thus making PD feasible for longer use.84, 85

▶ **Triomed AB, Sweden**: Triomed86 is developing two wearable PD devices; Carry Life Renal and Carry Life Ultrafiltration (UF); to provide continuous and wearable therapy to PD patients and chronic heart failure patients, respectively. Some of the benefits of these devices include reduced logistical burden, lesser infection risk of peritoneal dialysis and effective fluid volume management, thus leading to better quality of life for patients.

Carry Life Renal may allow patients to remain longer on PD as it alleviates challenges of peritonitis and inadequate dialysis or ultrafiltration. Carry Life Renal’s technology involves lower glucose levels, reducing the osmotic stress on the peritoneum. Carry Life UF is suitable for cardiac patients as it helps maintain stable intraperitoneal glucose concentration (crucial for cardiac patients) and allows for glucose level customisation. Triomed has used the double-loop dialysate system that makes the device relatively bulky.

In March 2018, first in-human trials were completed on five patients with no adverse events reported, but clinical trial results were not conclusive about the efficacy. Carry Life Renal was linked to low albumin removal and was well tolerated by patients. Triomed plans to conduct further studies to understand the relationship between stable intraperitoneal glucose concentration, ultrafiltration and individual patient characteristics.

---

83. [http://www.nanodialysis.nl/](http://www.nanodialysis.nl/)
86. [http://triomed.se/renal/](http://triomed.se/renal/)
Given below are some early movers and pioneers in the WAK HD space:

- **Blood Purification Technologies Inc.:** Dr. Gura’s team at Blood Purification Technologies Inc. was one of the first players in the Wearable Artificial Kidney (WAK) HD space to conduct in-human trials in 2007.87 Trials of the first-generation WAK device were unsuccessful due to several device-related technical complications requiring device redesign and putting a premature end to trials. Since then, the company has been working on tackling the challenges, evolving its technology and developing second-and third-generation WAKs. It has generated strong preliminary data through three human trials to prove that WAK is safe and effective and two more such trials are planned soon. Once the technical complications are resolved, WAK is expected to provide better clinical outcomes, liberalise diet and fluid intake and improve quality of life for patients. WAK 3.0 uses carbon as the only sorbent and weighs around 5 kg.88, 89 It will be small enough to wear and seamlessly fit within patient’s clothing. The in-human trials, which are expected to commence soon, will evaluate “human factors” such as patient’s interaction with the device and impact of device usage on quality of life of the patient.90, 91, 92 Patients who have undergone earlier WAK trials report greater satisfaction with WAK than with conventional HD specifically in terms of convenience, freedom, lifestyle fitment, reduced treatment-related side-effects and less discomfort during treatment.93

---

<table>
<thead>
<tr>
<th></th>
<th>AWAK</th>
<th>Nanodialysis BV (WEAKID)</th>
<th>Triomed AB (Carry Life Rental &amp; UF)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approach</strong></td>
<td>• Miniaturise and develop a wearable kidney for PD to improve overall Kidney Disease Quality Of Life (KDOOL) for patients and treatment outcome through increased toxin clearance</td>
<td>• Enhance effectiveness of current PD and offer longer peritoneal membrane survival thus, allowing longer duration on PD</td>
<td>• Enhance peritoneal ultrafiltration and dialysis to reduce logistic burden and infection risk and allow for effective volume management</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Suited for cardiac patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Allows patients on PD longer</td>
</tr>
<tr>
<td><strong>Technique</strong></td>
<td>• Sorbent used for regenerating dialysate</td>
<td>• Nanostructured sorbent</td>
<td>• Ion-exchanger based sorbent</td>
</tr>
<tr>
<td></td>
<td>• Can be used across multiple care delivery options</td>
<td>• Uses continuous flow PD and resolves main challenge of current PD</td>
<td>• Maintains stable glucose concentration and allows to customise dosage</td>
</tr>
<tr>
<td><strong>Journey so far</strong></td>
<td>• First in-human trials for phase 1 successfully completed in October 2018</td>
<td>• Early feasibility first in-human trial (phase O) will be completed by 2019</td>
<td>• Clinical trial results are not conclusive about the efficacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• First in-human trial planned in 2020</td>
<td>• No adverse events reported</td>
</tr>
</tbody>
</table>

Figure 4: overview of sample ultra-portable and wearable devices
4. **Implantable devices/bio-hybrid devices/regenerated kidneys**

In an attempt to eliminate the need for dialysis, researchers focused on the miniaturisation of the in-series coupling of a hemofilter with a cell bioreactor, or RAD. This resulted in the development of a prototype model for the first implantable Bioartificial Kidney (BAK). BAKs are significantly further away from a clinical application as compared to the other techniques discussed above.

Implantable renal assist devices (iRADs) utilise microelectromechanical system (MEMS) technology to scale down the original RAD design into a compact, implantable and self-sustainable BAK. iRADs combine a long-life hemofilter made of silicon nanopore membrane (SNM) with a renal tubule cell bioreactor. The miniaturisation capabilities inherent to MEMS technology allow for a total surface area of 0.1 m² for the device. Long-term stability of hemofiltration was demonstrated for almost 100 hours of continuous in vitro filtration using anticoagulated blood. High permeability of the SNM allows filtration based on arterial-venous pressure difference alone and eliminates the need for additional pumps, tethers or immunosuppressant drugs.\(^94\)

One major challenge for iRAD will be the reabsorption of water from the filtrate. For clinically relevant clearance of small water-soluble uremic toxins, at least 15 liters of filtrate needs to be produced daily. The Kidney Project is raising funds for a first-in-human trial. Two companies that are currently at the forefront of BAK research and development include:

- **Innovative BioTherapies, Inc.** (Ann Arbor, Michigan) is developing a Bioartificial Renal Epithelial Cell System (BRECS) – a wearable bioartificial kidney grown from an adult, progenitor kidney cells sourced from non-viable donor organs. According to the company website, preclinical trials followed by human trials are expected within the next three to five years.

- **Qidni Labs Inc.** (Kitchener, Ontario) is investigating potential nanotechnologies for miniaturised dialysis components in implantable systems.
Although there are still a few hurdles to overcome before wearable devices can be routinely implemented in dialysis treatments worldwide, WAKs have the potential to completely change the paradigm for patients with impaired kidney function. At a minimum level, WAKs offer treatments that are as effective as traditional dialysis and can maintain and even restore the patients’ quality of life. In addition, they can reduce the economic burden on the healthcare system and increase overall healthcare productivity. Patients acknowledge these benefits, as supported by a study that showed ~60% of eligible American patients may choose to use a WAK over their current dialysis treatment. The four areas in which WAKs can be considered as game-changing are healthcare productivity, treatment access, digitisation of care and quality of life.

1. Reducing the dialysis treatment cost burden on the healthcare system: a study by the Economic Cycle Research Institute (ECRI) forecasted that treatment by WAKs will cost less than conventional dialysis care due to repurposing and/or reduction of staff, increased bed capacity and reduced requirement of raw materials, provided that remote patient monitoring systems are in place. Given a total healthcare spend of US$42 billion on ESRD in the US (2015) and with ECRI logic applied, an approximate of US$17 billion can be saved annually in healthcare costs (see waterfall chart on cost reductions below). Also, when WAKs eventually come in the market, ESRD patients will gain back their mobility and will be able to remain employed. The result of this is a full potential productivity gain that is estimated around US$2–2.5 billion annually (see waterfall chart on productivity gains below; assumed a 20% prevalence of PD treatment).
a. Reducing cost and capacity on hospitals: a key contributor of the total ESRD treatment cost is hospital admissions. In Australia, over 10% of total hospital admissions are due to kidney dialysis treatment.99 Hospital dialysis units are labour-heavy as they require a variety of staff from charge nurses, patient care technicians (PCT) and administrators to dietitians and biomed technicians – each having a value-adding role to play in the treatment process. As WAKs offer patients with the ability to undergo dialysis “on-the-go” instead of multiple hour-long treatments on a weekly basis in specialty centres or hospitals (as in the case of HD patients), these devices will reduce or even eliminate repeat admissions and staff requirements, alleviating the cost burden and any bed capacity issues that hospitals may have due to dialysis treatments. Additionally, given the continuous physical connection of a WAK device with the patient, the level of treatment compliance will increase significantly. Currently, patients spend half a week undergoing treatment on an average, which proves to be a major burden to compliance. 31% of HD patients end their dialysis session early, while 18% of patients cancel or skip a treatment session.100 Many patients are put on HD for standard delivery of care. Change from HD to PD modality can save up to US$20,000 per year per patient. The PD-based compliance approach, which some of the WAKs offer, is a highly cost-effective way to keep patients on treatment.

b. Reducing treatment cost through less use of raw materials: further cost reductions can be achieved through reduction of raw materials required. Key cost drivers for traditional PD and HD treatments include high volumes of expensive dialysate fluid and high requirements of erythropoietin (EPO).101 WAKs’ innovative sorbent technologies drastically reduce the required quantity of raw materials, as toxins are extracted from the used dialysate and fresh dialysate is produced in real time.

2. Making dialysis treatment available for thousands of patients: traditional dialysis treatments require physical infrastructure and investments. In developing markets especially, there is a lack of high quality care facilities, resulting in a major impediment for widespread treatment access. WAKs can expand treatment access to thousands of patients worldwide as they bypass the need for any physical treatment infrastructure (if remote monitoring services are in place).
3. Driving digitisation and care coordination in dialysis:
future product versions will be able to provide digital connectivity within the larger healthcare spectrum, enabling remote care coordination for dialysis patients. ESRD patients benefit greatly from coordinated care, and digitisation can significantly reduce healthcare costs by reducing the need for duplicative tests and providing patients with holistic care that focuses on health and, not just a specific disease. Dialysis patients receiving integrated care experience 25% less hospital visits, 51% less readmissions and 66% fewer catheters.102 A digital WAK will capture crucial data and provide a better understanding of a patient’s health and treatment requirements from which care efforts can be coordinated within the healthcare spectrum.103

4. Increasing quality of life: lastly, but perhaps most importantly, WAKs manage to deliver dialysis treatment in a way that almost fully retains the patients’ quality of life, a true breakthrough when compared to traditional PD or HD. Both traditional treatments do not restore kidney health and disrupt a patient’s daily life. At the very minimum, WAKs have proven to be as safe and effective as conventional forms of dialysis,104 while allowing “on-the-go” dialysis without major disruption to daily routines, work and leisure activities of patients.

Figure 6: Illustrative cost reductions to healthcare system driven by WAKs (%)
105, 106, 107

<table>
<thead>
<tr>
<th>Total expenditure</th>
<th>Reduction/repurposing of staff</th>
<th>Increased bed capacity</th>
<th>Reduction of raw material requirements</th>
<th>New expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100</td>
<td>15</td>
<td>15</td>
<td>10</td>
</tr>
</tbody>
</table>

---

102. Leigh-Ann Topfer, Wearable Artificial Kidneys for End-Stage Kidney Disease, January 2017
103. Monthly cost of three exchanges a day peritoneal dialysis is same as of thrice a week haemodialysis in self-paying Indian patients, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3263061/, accessed February 2019
Is wearable technology the future of dialysis?
Key implications for various stakeholders as wearable and implantable kidneys become a reality

The possibility of wearable kidneys will open a range of possibilities for healthcare stakeholders; each will play a critical role in ensuring a smooth transition for patients and caregivers.

1. Manufacturers and Innovators: manufacturers and innovators will need to ensure access and affordability of innovative dialysis devices enabled by a manufacturing and operations set up that can be scaled easily and by identifying the right go-to-market models and necessary partnerships:

   a. Manufacturing capacity and quality: the innovators will need to ensure that a sustainable manufacturing capacity is set up to scale. Investors, particularly venture capital and private equity will need to understand the cost effectiveness, efficiency and quality of management to manage production. They will also be required to consider the risk of dependency on suppliers and the durability of the product. In this context, the manufacturer will need to ensure and uphold contract management good practices with suppliers and internal capabilities of quality, from the beginning. Lastly, as WAKs make wearables a lot more central to dialysis treatment, insurance for the device itself may be a key consideration and opportunity for both insurers and manufacturers. Given the reliance on the wearable device for a key medical procedure, ensuring rapid replacement in case of damages without significant cost to the patient will also be critical.

   b. Go-to-market model: patients’ preference to use the product is expected to be home-based once the adoption hits critical mass; however, hospitals and private centres will also be key channels. Hence, both direct-to-consumer (patient) and an institutional go-to-market model and the right sales force deployment will have to be planned accordingly.

   c. Innovative partnerships: given the likelihood of remote care, innovative digital partnerships for establishing telehealth infrastructure (e.g., track the refill of cartridges, coaching/real-time feedback to patients) will be additional revenue opportunities. Additionally, innovative partnerships can play a crucial role in financing a patient’s device and ensuring timely maintenance (e.g., by tapping into a network of skilled biomedical engineers), especially in self-paying emerging markets. Given the disruptive nature of these devices, innovative business models, such as rental, pay-per-use and so on, can be explored to achieve maximum penetration of such technologies in the markets.

   d. Cost-effective value proposition in self-paying emerging markets: a key driver of access to the device in self-pay emerging markets will be ensuring affordability through mass-scale production or reduced raw material costs.

2. Government agencies: regulators and related agencies will have to ensure that they develop a clear pathway for approval of such disruptive products. With new revolutionary technologies, it is often seen that the path to adoption has been stifled by confusion on regulations and vagueness of processes to be followed. Key areas where regulators will have to intervene:

   a. Product specifications: these cover clear guidelines on product specifications, quality, certifications. Such specifications become especially important in emerging markets where value segment players are likely to try and emulate and replicate the chemistry/technology.

   b. IP protection: a fair length of patent protection needs to be considered. Given the long years of investments in developing the wearable kidney and its disruptive nature, a long protection of patents may be a fair reward for the innovators. However, to keep costs in check, opening access to more manufacturers will be important. Specific co-marketing and licensing guidelines will also have to be established. In most countries, a patent will last for 20 years.
c. Reimbursement: while most reimbursement policies work on reducing standard care costs, payor regulators should place emphasis on the economic benefits of keeping dialysis patients employed and the gains in productivity. Additional analysis will be required before any decisions are made on coverage (e.g., reimbursement rate, patient co-funding) and widespread clinical implementation. The cost of dialysis with WAKs will amount to a sum that many dialysis patients will not be able to afford out of pocket. However, generally, medical devices which have proven successful and effective are products that insurance provides cover for. Providers may also want to explore equipment rental or subscription options, which can improve capital control, increase flexibility and reduce time-to-treatment at lower cost for the patient. Lastly, the likely savings from the procurement of equipment for in-clinic and in-centre approach today will be critical to ensure that the true benefits of wearable kidneys are realised from a total cost of ownership perspective.

d. Facilitate funding: regulators will need to facilitate funding through various vehicles in the areas of R&D, provide institutional support and offer financial incentives such as tax and customs duty waivers. In addition to funding, competitive policies and guidelines need to be in place to ensure a level playing field is set up and maintained.

3. Key Opinion Leaders (KOLs): KOL advocacy will be essential to drive the adoption of the product. Prescribing KOLs will play the role of counsellors or coaches as the new modalities of care will mean that the patient would not be visiting the centres as often. The conversations that happen between a KOL and patient will shift from procedural details to additional quality of life management areas. In this aspect, the value proposition for KOLs can be crucial for manufacturers and innovators to consider during development.

WAKs can have a transformational impact on the dialysis landscape. The technology may enable hundreds of thousands of current dialysis patients to improve their quality of life through portability, which shall enable them to continue their existing occupations and get back in the employment pool. While annual productivity gains are ~US$2 billion theoretically in the US, the global impact – even if a fraction of the gain is achieved – is enormous in the current socioeconomic context where productivity gains are becoming increasingly challenging to achieve.

WAKs are likely to see higher adoptions in developed and payor-based markets; in emerging self-paying markets, if costs are same as standard of care, they will be prohibitive. Mass market production or reduced spending on raw materials can be drivers of lower costs.

Innovators and startups have made the bold foray in trying to improve WAKs from concept to reality in an industry, where a few big players have traditionally dominated and innovation has been only incremental. As innovators try to shake up the innovation inertia, government, regulators, payers and healthcare institutions have a unique opportunity and large responsibility to ensure the successful production of WAKs. Large manufacturers too, who have been at different stages of experimenting with WAKs, can play a pivotal role. However, in addition to using the traditional lenses of optimal care at cheapest price, stakeholders will also have to consider new dimensions such as socioeconomic benefits that the technology brings. As Rudolf Christoph Eucken said, “Technological progress becomes even more exciting when it enters the service of the social idea, which demands that not only a small elite, but humanity at large should profit by it.”

**Conclusion**

Technological progress becomes even more exciting when it enters into the service of the social idea, which demands that not only a small elite but humanity at large should profit by it.
Is wearable technology the future of dialysis?

About AWAK Technologies:
AWAK Technologies Pte Ltd. is a pioneering, patient-centric medical technology company with a mission to enhance the lives of dialysis patients and their caregivers by providing solutions to deliver better outcomes and improve their quality of life. Headquartered in Singapore with office in Burbank, California, USA, the company is dedicated to the research, development and marketing of novel, sorbent-based kidney dialysis machine for the treatment of patients with end-stage renal disease. For more information, please visit: www.awak.com
About EY
EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

EY refers to the global organisation, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organisation, please visit ey.com.

© 2019 EYGM Limited.
All Rights Reserved.

EYG no. 003253-19Gbl

ED None

This material has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax or other professional advice. Please refer to your advisors for specific advice.

ey.com