

Improving dialysis in the home

By Chris Humby, Vice-President Medical at Sagentia

Statistics surrounding chronic kidney disease (CKD) make sobering reading. An estimated one in ten people worldwide have the condition. Millions die each year awaiting an organ transplant, and millions more live in a holding pattern of clinic-based or home-based dialysis.

In the US, where one in seven people have CKD, decisive action has been taken to improve patients' lives. The Executive Order on Advancing American Kidney Health aims to remove barriers to innovation and encourage development of better dialysis options, with an emphasis on home-based dialysis.

At Sagentia, we believe there is scope for rapid and meaningful improvement of existing dialysis systems. Devices that blend technical innovation with patient-centric design could make home dialysis easier and more suitable for a greater number of patients in the near future.

The 2019 Executive Order on Advancing American Kidney Health looks set to stimulate global change and innovation in dialysis treatment for chronic kidney disease (CKD). This is a welcome development for patients. While 10 percent of the world population is affected by CKD, treatment options have largely been stagnant for the past 60 years.

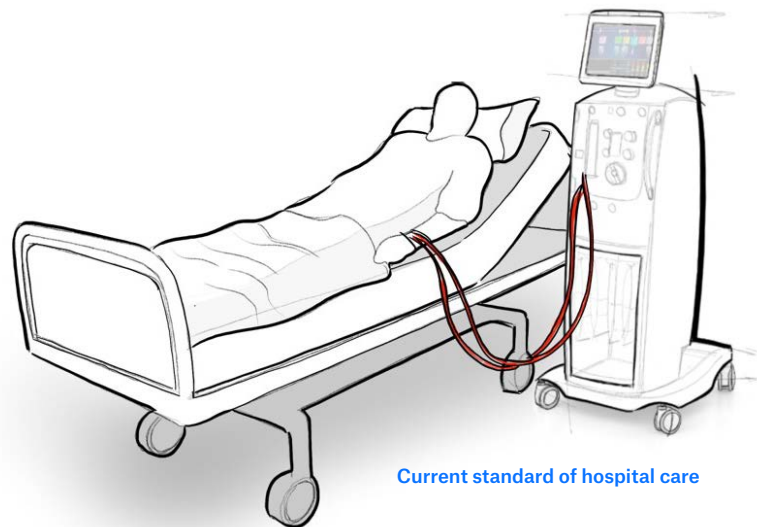
Lack of innovation is partly rooted in technical challenges – the kidney is a complex organ, and mimicking its function is far from straightforward. But market factors have also played a part. Established fiscal models in some countries have hindered progress, as a report published by the US Kidney Health Initiative highlights:

The established end stage renal disease (ESRD) coverage and reimbursement model is focused on dialysis, not disruptive new technologies, making it unclear how new innovative care and treatment options might be rewarded or reimbursed, further disincentivizing research investment.

Kidney Health Initiative RRT Roadmap (2018)

The Executive Order takes a multipronged approach to turn this situation around, seeking to improve the prognosis and quality of life for those living with CKD. One aspect of this is to improve the availability and quality of donor kidneys. Organ replacement is the best way to overcome the disease, but the probability of an individual receiving a transplant remains relatively low. Additional aspects of the order focus on treatment innovation, with an emphasis on making home dialysis more accessible. It is here that the biggest innovation steps can be taken to rapidly change the lives of those on dialysis.

Longer term innovation is likely to centre on breakthrough developments such as artificial kidneys that replicate kidney function in a wearable form. These developments are promising, but they are several years away from realization. In the shorter term, smarter and safer home dialysis is the best way to improve the CKD patient experience and overall quality of life. This will increase the number of patients who are willing and able to undertake dialysis at home, which also reduces the overall cost of care.



Current standard of hospital care

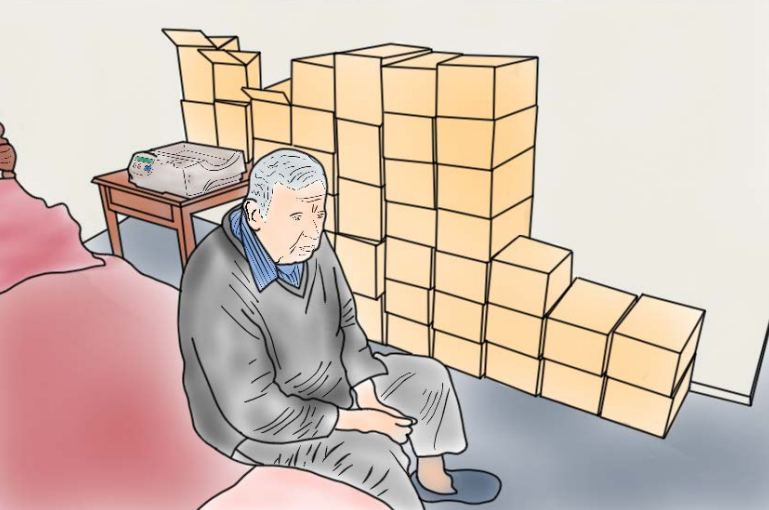
Current home dialysis options

Most CKD patients undergo Haemodialysis (HD) where the blood is filtered by an external system. This is a complex procedure performed by professionals in a healthcare setting. However, there is a drive to create a new generation of HD systems for use in the home.

A minority of patients are already treated in their homes, mainly with Peritoneal dialysis (PD). During PD, the peritoneum filters blood inside the body. The process is less complex; following training, a patient or their carer can administer the treatment themselves. However, the systems can be difficult to manage, and the treatment can also cause discomfort or infection.

So, while PD and HD offer effective disease management, both regimens have equipment-based limitations when it comes to home use. Improvements are needed so that more people can administer dialysis at home with ease.

Sagentia works with clients to improve the overall HD experience as well as HD system functionality. We're also focused on developing better home PD treatment. It is PD that we will discuss further in this paper, as the shortest route to improving dialysis in the home.



Living with dialysis in the home

Optimizing equipment for home use

If there is to be a significant increase in the number of patients successfully undergoing treatments in the home, four key factors need to be addressed:

Ease of use – it must be possible for unwell and/or elderly patients to administer dialysis independently and safely.

Durability – equipment and components such as tubing need to be robust.

Respect for the bedroom – the size, appearance and location of equipment and the storage footprint of dialysates needs consideration.

Manufacture – if more units are to be deployed in the home, it needs to become cheaper and easier to manufacture equipment and distribute dialysates.

Overcoming the limitations of legacy equipment demands a combination of technology-led development and patient-centred design. Device manufacturers that can blend these two areas effectively have an opportunity to earn competitive advantage in the home dialysis space.

We believe that PD offers immediate scope for rapid innovation. It's an inherently simpler procedure than HD and the equipment involved has a smaller footprint. Focused improvements could drive a dramatic shift towards home treatment that is smarter, easier and less obtrusive as well as more efficient from a manufacture and distribution perspective.

Stakeholder needs

Patients need home dialysis kits that are safe and easy to use; manufacturers need to focus on factors such as cost management and maintenance. The best next-generation systems will find ways to exploit synergies, enabling multiple needs to be addressed effectively and efficiently.

Multidisciplinary collaboration will be required to reconcile the priorities of different stakeholders:

Patient/carer priorities

- Safety and sterility
- Ease of use
- Feeling better after treatment
- Monitoring, including other disease states (diabetes, high blood pressure)

Manufacturer priorities

- Cost of treatment
- Cost of Goods Sold
- Cost of consumables and their distribution
- Instrument servicing/maintenance

Evolving and improving PD technology

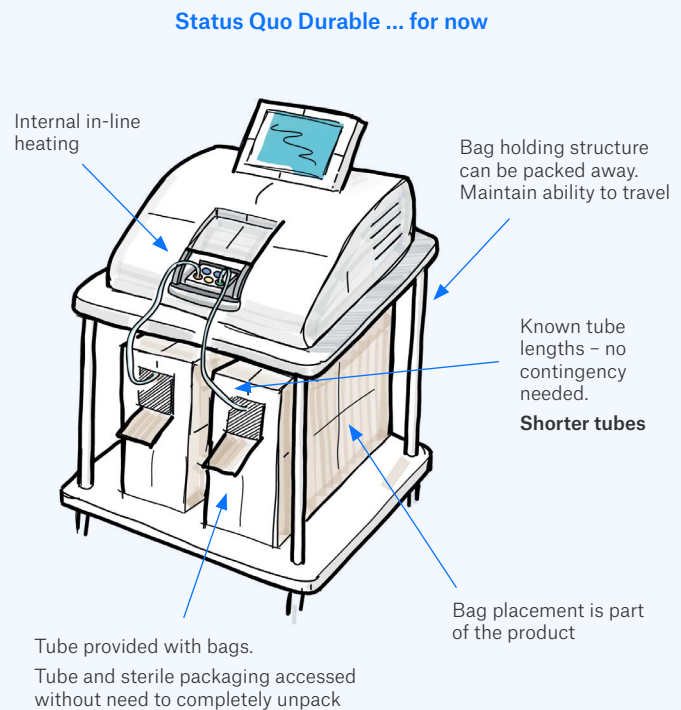
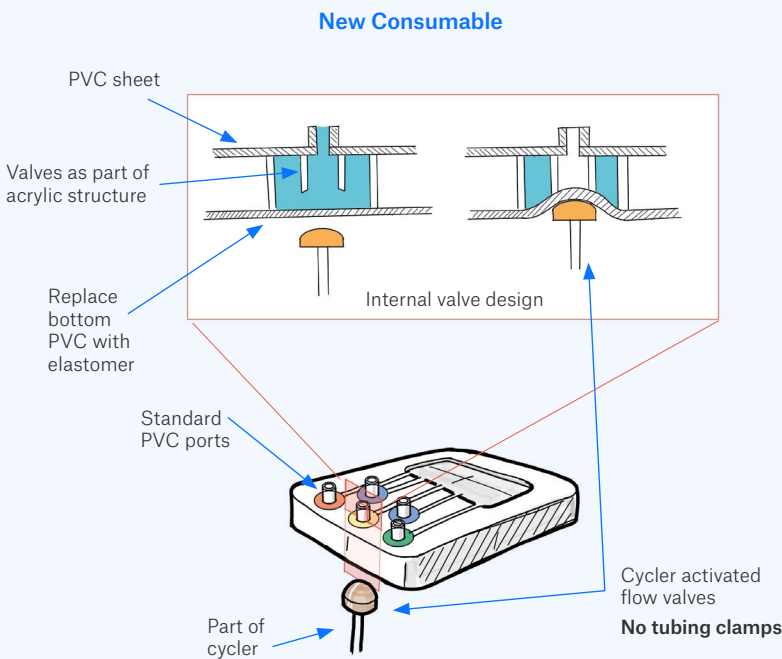
Transitioning more CKD treatments from the hospital to the home presents both challenges and opportunities. PD is a proven home-based method, but how can issues such as safety, sterility and ease of use be addressed so it is a viable and attractive option for more people?

A design concept we've developed at Sagentia centres on simplifying the user experience whilst innovating the technology. The aim is to create a smarter system which is easier to use, at a lower cost point.

With current equipment, it takes around ten minutes and many user steps to prepare for PD. However, when we minimise the need for the patient to handle multiple tubing lines, the set-up process becomes more straightforward. It's also possible to make it

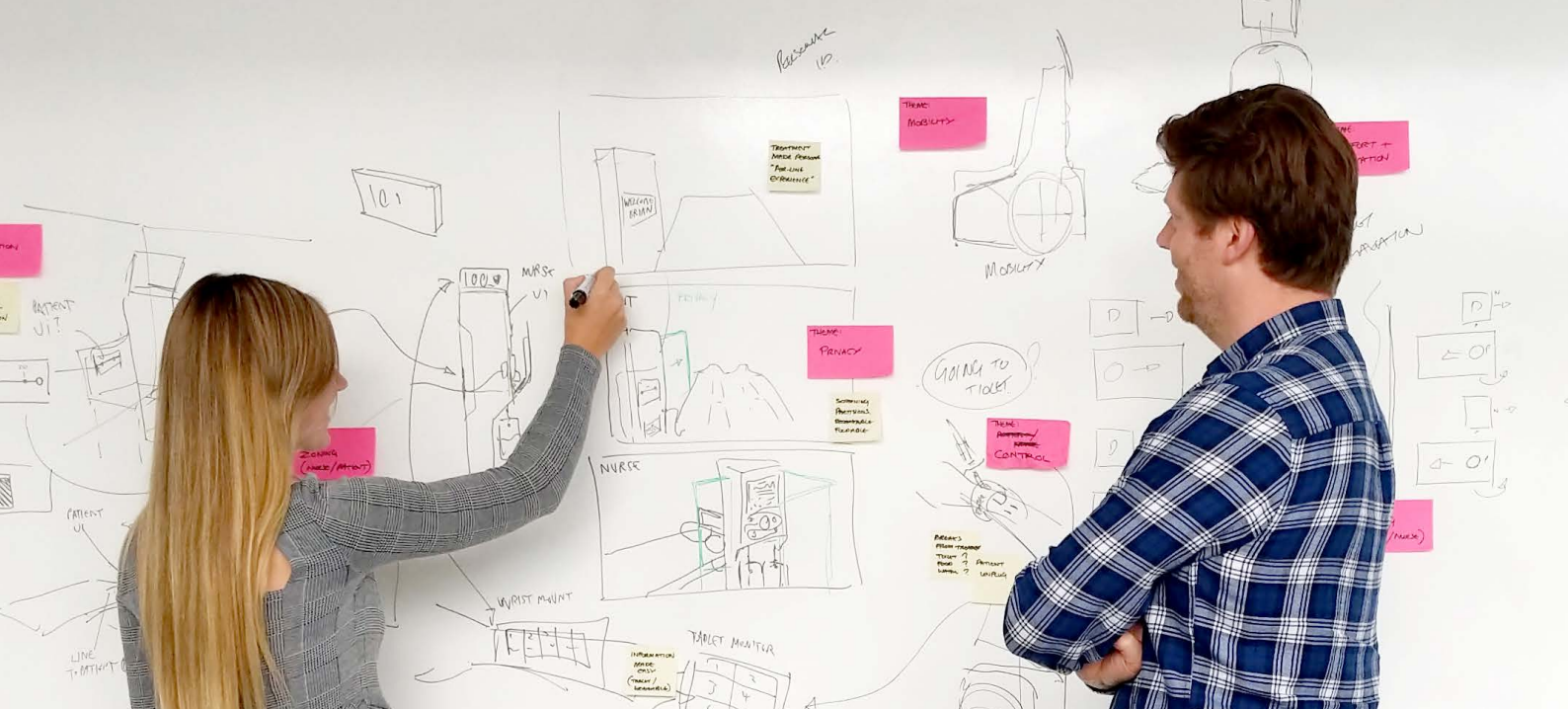
easier to connect and disconnect the tubing, so people with limited dexterity can manage independently. What's more, the connection process can be optimized to sterilize the catheter interface automatically, reducing the risk of infection. Automating the priming and draining process removes another step that can pose problems for patients.

These changes have the added benefit of reducing the cost of each dialysis set by up to 50 percent. Figure 1 illustrates the concept.



Another potential route to rapid improvements is reducing the volume of dialysate patients need to store at home by introducing a reconstitution or admix system. As well as lessening the impact on the home environment, this offers benefits in terms of distribution costs. At present it can only be achieved

with added complexity and expense related to the dialysis cyclor. However, next-generation systems could benefit from a multidisciplinary approach to overcome this by integrating an admix solution with the core device.

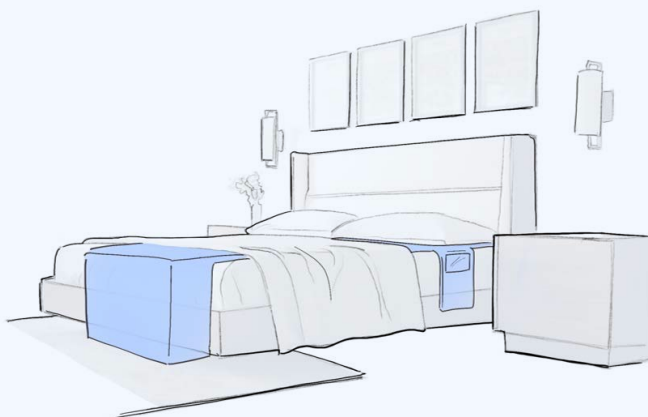


Patient-centric PD design

Empowering the patient to confidently and competently take control of their dialysis and achieve a good quality of life must be the focal point of home PD innovation. Ease of use is just one aspect of this. Transitioning from HD administered by a healthcare professional in a dialysis centre towards self-administered PD in the home could be stressful and traumatic for some people. They may initially feel abandoned by the healthcare system, rather than energized by their new independence. Finding ways to reduce the emotional burden of the change, as well as ensuring it is easy to use the equipment safely, is critical to success.

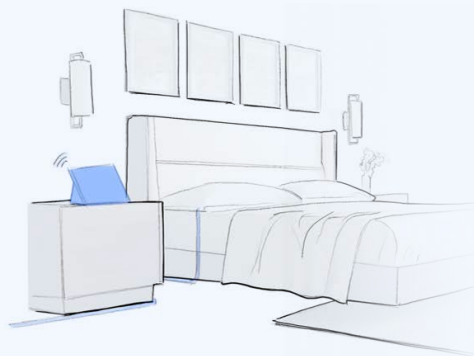
Recognizing the importance of making home feel like home (not a hospital) we've developed early ideas surrounding 'respect for the bedroom'. Figure 2 shows how PD equipment can be integrated into the home more sensitively, with noisy equipment potentially located in a bathroom rather than the bedroom to minimize sleep disruption for the patient and family members. This design also incorporates a more discrete connection to the drain and minimizes the visual impact of the pump and dialysate bag.

Scenario A Alternative Bedroom integration



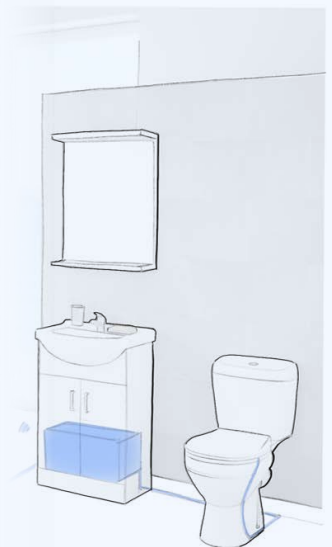
- Integrating bulky, often noisy equipment into the bedroom
- All key touch points easily accessible to a carer, but not dominant aesthetically for the patient

Scenario B Discrete Bedroom implementation



- Placing bulky and noisy equipment in a bathroom or adjoining room in an effort to keep the bedroom environment clutter free, more intimate and comfortable for the patient
- Discrete line installation and management

Discrete bathroom integration

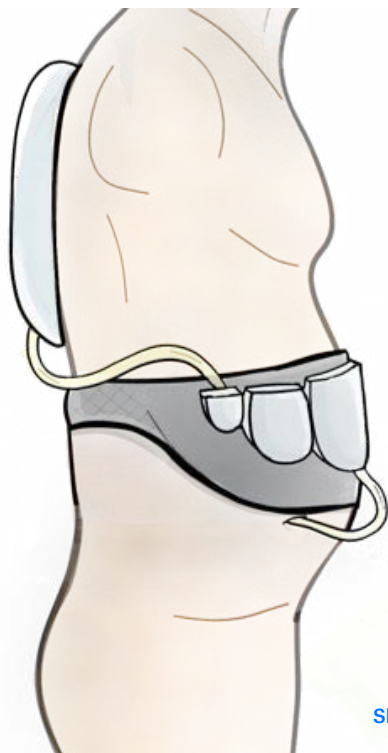


- Discrete and sensitive implementation of information that is useful to the patient e.g. was my treatment successful, any problems, reminders, setup help and trouble shooting.

Next-generation PD and beyond

Artificial wearable kidneys of a practical size and nature are unlikely to emerge in the near future, but the appeal of mobility for CKD patients is enduring. Home PD systems are mainly used overnight when mobility is less of an issue, but they do reduce movement and comfort, impacting sleep quality. Sagentia created the idea of a 'sleepable' device, which allows freedom of movement during sleep and has fewer tubing issues. The patient will go to sleep confident and wake up treated after a good night's sleep, similar to plugging in a phone charger overnight.

It's important for device development roadmaps to keep one eye on the future while delivering products which meet more immediate needs. For instance, the integration of modern sensors with PD equipment might enhance the management of patient wellbeing in the near term while harnessing insights for future innovation. Vital signs could be assessed unobtrusively during treatment and early symptoms of infections could also be monitored.



Sleep pack

Making life with CKD better

The momentum generated by the Executive Order on Advancing American Kidney Health could significantly improve the lives of people with CKD. Better availability of flexible dialysis choices will enable patients to maintain family and social life while managing their disease effectively. The changes will make it easier to work, travel and enjoy a more fulfilled and active life.

While organ replacement remains the best option, there is new hope on the horizon for the millions of people worldwide that are waiting or unsuitable for a transplant. Home-based dialysis will become more ubiquitous and easier to use, with both incumbent manufacturers and start-ups innovating to affect real change for CKD patients.

This will have positive repercussions for patients and healthcare systems all over the world. And it creates an opportunity for device manufacturers to optimise existing treatments, so patients can live better sooner.

About Sagentia

Sagentia is a global science, product and technology development company. Our mission is to help companies maximize the value of their investments in R&D. We partner with clients in the medical, consumer, industrial and food & beverage sectors to help them understand the technology and market landscape, decide their future strategy, solve the complex science and technology challenges and deliver commercially successful products.

Sagentia employs over 150 scientists, engineers and market experts and is a Science Group company. Science Group provides independent advisory and leading-edge product development services focused on science and technology initiatives. It has ten offices globally, two UK-based dedicated R&D innovation centers and more than 350 employees. Other Science Group companies include OTM Consulting, Oakland Innovation, Leatherhead Food Research, TSG Consulting and Frontier Smart Technologies.


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