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Market Intel: Holding Out For Home Hemodialysis: Still-Modest Market Promises Bigger Growth

by Jenny Blair

End-stage renal disease (ESRD) affects 600,000 Americans, striking over 120,000 people a year, and most of these patients require renal replacement therapy, such as hemodialysis. For most, that means a several-hour treatment, three times a week, at a dedicated outpatient center run by a service company like DaVita, Inc., or Fresenius Medical Care. But getting dialyzed at home is another option. Just under 2% of patients do home hemodialysis (HHD) today, but a growing number of companies are betting that this number could increase substantially.

According to the US Renal Data System's 2015 report, 468,000 patients in the country underwent dialysis in 2013. Globally *Fresenius Medical Care AG & Co. KGAA* , the largest dialysis service provider, estimates that there are currently three million patients with kidney failure that regularly undergo dialysis. And their numbers are expected to rise, driven in part by the increase of chronic diseases such as obesity and diabetes.

The cost of treating these patients is also substantial. In 2013, the Centers for Medicare and Medicaid Services (CMS) spent $30.9bn on these patients, accounting for 7.1% of total expenditures. Many believe that alternative approaches, such as HHD, could help rein in some of the huge cost burden of treating patients at centers.

“A lot of people who are pretty smart in the clinical community and the business sector are expecting that HHD, which is now basically a niche, is poised for a rapid expansion,” said John Milad, CEO of Quanta Dialysis Technologies Ltd., a UK-based startup that has developed a personal hemodialysis system.

Bad Homburg, Germany-based dialysis giant Fresenius ranks among them. It announced on Aug. 7 that it struck a $2bn deal to acquire US-based home dialysis equipment maker *NxStage Medical Inc.* whose FDA-cleared *Solo system* allows patients to perform their own HHD without a care partner (Also see "*Fresenius Homes In On NxStage*" - Medtech Insight, 7 Aug, 2017.) (Also see "*Number To Know...30*" - Medtech Insight, 8 Aug, 2017.). The deal is subject to close by 2018, pending antitrust review.

"This acquisition is yet another writing on the wall that the current way of delivering dialysis is not sustainable in the long run — the traditional centers being very labor-intensive, capital cost-intensive, and difficult to scale to treat the rapidly growing population," said Ruey Feng Peh, CEO of the Singaporean startup Advent Access, whose first product is a device to ease vascular access for dialysis patients.

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"It's at a point where major stakeholders must pay attention to these problems and provide a better solution," Peh added.

But not everyone is so bullish.

Last June, *Baxter International Inc.*, Fresenius' chief rival in the US dialysis equipment market, cancelled its hotly anticipated HHD program, dropping the CE-marked *VIVIA* dialyzer from further development. Baxter CEO José (Joe) Almeida cited technological and cost hurdles at the time.

"Baxter will not be acquiring any home technology going forward, because we don't believe that what is in the market today is economically feasible," Almeida said in a Goldman Sachs conference call from June 7, 2016, as reported by *Mass Device*.

The company will focus instead on developing new technology with telehealth capabilities to advance another at-home modality, peritoneal dialysis (PD).

Laura Angelini, global general manager for Baxter's Chronic Renal business unit, told *Medtech Insight* that Baxter decided to invest in technologies they believe can have a much broader adoption rate.

"In general, hemodialysis is a more complex therapy [than PD], so our assessment was that there were other avenues to assure patients can perform their treatments at home that we believe are more promising," Angelini said.

Whatever happens, insiders say, the current status quo can't last forever.

In-center dialysis is expensive and limits patients' lifestyles. Trained personnel are in short supply, even as more and more patients need dialysis. Some evidence suggests selected patients have better medical outcomes with HHD, too.

Milad also believes that the current model is inherently unsustainable.

"It gives a poor experience to many patients. And it's economically inefficient. We know there are ways we could be doing a lot better for the patients," he noted.

Growing Market

The proportion of patients on HHD varies by country and even by center.

One Australian clinic reported in 2012 that 22% of its patients used the modality, with its head physician estimating that 40% of patients could likely handle it. Still, nationwide in Australia, only 9% of patients received HHD compared to 2% in the US in 2012.

NxStage's 2016 annual report valued the worldwide market for in-center hemodialysis at $10.1bn and PD at $3bn. That compares to a mere $300m (about 13,000 patients) for the global HHD market. An Aug. 8 report on Fresenius by Citi Research was more optimistic, noting a CAGR of 14% in recent years and projected that Fresenius could reach a 4.6% HHD penetration by 2022 (see Fig. 1).

Fig. 1

Many insiders believe currently niche home-based modalities are set to grow

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Sanford C. Bernstein & Co., LLC. Lisa Bedell Clive. Global Dialysis: A Primer on the Dialysis Products Market (September 17, 2015). NxStage Medical, Inc. data and estimates.

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The Trouble With In-Center Dialysis

In-center dialysis centers typically schedule the patient for several hours, three days a week; a nurse or technician hooks the patient to a machine and runs it, with the patient being a passive participant.

This setup requires a large capital outlay and skilled staff. The burdensome schedule forces patients into a position of dependence, which can also make it tough for patients to hold down a job. It also requires that patients go without dialysis for an extra day once a week, causing mortality to spike as toxins build up before the next week's cycle—a phenomenon called "Monday-morning syndrome."

Some nephrologists believe that more frequent dialysis -- that removes toxins from the blood more slowly for longer periods, such as in a nocturnal at-home setup -- may lead to better outcomes.

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Lockridge, who helped launch what he described as the first nocturnal HHD program in the US, said, "So we need to change how we're doing it. The only place that that can happen is at home."

Barriers To HHD

However, barriers to wider HHD adoption remain high.

Many nephrologists are untrained in the modality or reluctant to take the road less traveled and are part owners of dialysis centers, which means patients may not be offered the option. For those wanting to go the HHD route, training can take weeks.

For others, the prospect of managing complex, life-saving machinery without immediate medical backup may be overwhelming; as can having to needle one's own fistula, the surgically created artery-vein connection in the arm that allows dialysis access.

Most approved machines also require a caretaker, which rules out HHD for patients who don't have a caregiver at home. Dialysis sessions are typically longer and more frequent at home, reflecting the limits of home plumbing systems. Patients' unreimbursed water bills can be substantial. Many patients who begin HHD give it up and return to in-center care.

Insurance setups can also work against it.

In Citi Research's August report on Fresenius, the authors wrote that covering a week's worth of HHD requires the equivalent reimbursement of 4.5 days.

"While this has not been an issue for the full commercial market, around 80% of dialysis patients are covered by Medicare, and as a result a large part of the market is dis-incentivized to switch to HHD," the authors wrote.

Market Drivers

That said, there are powerful forces that make HHD look attractive.

With both diabetes and hypertension rates skyrocketing, more patients will experience chronic and eventual end-stage kidney damage. Well over two million patients used dialysis worldwide in 2010, and one model suggests that number will double between 2010 and 2030, according to an article in *ClinicoEconomics and Outcomes Research*.

At-home technologies could cut the number of skilled personnel needed to care for dialysis patients at a time when labor accounts for much of the cost of running a clinic and nephrologists are in short supply.

"To treat all these patients 10 years down the road, there will be a need of almost another 30,000 clinics," Angelini said. "The number of nephrologists over the next 10 years will need to grow by 10 percent on a year-by-year basis … How do you pursue technology innovation that is going to allow treatment of more patients, so that a physician that today treats an average of 80 patients, can now treat 200 patients per year?"

She joins others who believe technology can help fill that gap.

According to Citi Research's report, “Both HHD and PD are liked by insurers because of their cost efficacy, with patients needing less direct intervention and often superior clinical outcomes due to more frequent dialyzing.” (See Fig. 2)

Fig. 2

Home hemodialysis gaining US market share

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Atop gradual growth in the last decade, Citi research projects future HHD share at 4.6% by 2022. Note: Bar shading not to scale.

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Another driver of HHD is a younger or more educated patient population wishing to reclaim more control over their schedules, Advent Access’ Peh noted.

“I think the change in the dynamics will motivate more patients to say, ‘Hey, can I have better quality of life while I wait for my [kidney] transplant? Can I have my time back? Am I able to go back to work?’”

Fresenius’ NxStage Acquisition

For years, NxStage had been the main player in the US HHD space with Fresenius’ machine *2008H@Home* being the only real US alternative. Fresenius, for its part, is the only US manufacturer with its own clinics and the global leader in dialysis products and services (see Fig. 3).

Fig. 3

“Fresenius Medical Care (FMEG.DE). NXTM acquisition – Homerun or Homewrecker?” Patrick Wood and Catherine Tennyson.

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NxStage, founded in 1998, won FDA approval for its portable System One dialyzer in 2005 for HHD. In 2014, the company also won FDA approval for home nocturnal dialysis, a real-time approach that creates a dialysis solution using patient’s home water supplies and a pre-mixed

bag of concentrated substances (Also see "*DIVE INTO DIALYSIS: NxStage Aims To Transform Home Hemodialysis Into $2bn Market*" - Medtech Insight, 7 Dec, 2015.).

The acquisition looked like a natural fit to Jefferies analyst Raj Denhoy.

No other company but DaVita would have made sense as a buyer, Denhoy said, because access to HHD machinery and training would naturally go through a large service provider.

“At the end of the day [the clinics] do control the path,” Denhoy said. “NxStage has only been able to achieve less than 2% market share after trying in this for 10 or 12 years, and I think it just suggests that there are these intractable problems out there and this access issue has always been the biggest one. But now with Fresenius buying it, it sort of opens the road.”

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He speculated that the need to build less fixed clinic capacity may be an incentive for Fresenius.

“If they can start to lower their cost of in-center care by not building as many facilities, maybe they can start to make that whole equation bend towards where home starts to look more attractive,” he said.

If a rising tide lifts all boats, DaVita and other dialysis clinic companies may have to hustle to find a way to offer HHD more widely.

“There are a multitude of players who are heavily invested in legacy solutions, both on the machine side and on the service provision side,” Milad said. “For a long time, nobody wanted to make the first move to cannibalize and disrupt a market that was very comfortable for many people. Now that Fresenius has done that, it means others can’t afford to be complacent anymore.”

Quanta: Use It Anywhere

Quanta Dialysis Technologies, a private company in Alcester, UK, is betting that a machine versatile enough to be used both in the clinic and at home will open up a bigger HHD market (Also see "*Quanta Brings Oxford Uni Money Man On Board*" - Medtech Insight, 22 Sep, 2015.).

Its *SC+ dialysis system* is designed to be user-friendly and small while maintaining the high efficacy and dose of typical clinic machines. No pre-mixing of dialysate is required — a step that can take hours and force HHD patients to plan ahead (Image 1).

Dialysate fluids are generated and managed by a single-use disposable cartridge, which its CEO Milad calls the "key breakthrough, enabling a small, user-friendly and powerful device."

With disposable fluid paths, SC+ is also intended to reduce the risk of cross-contamination.

Over the past couple of years, Quanta has piloted SC+ with the UK's National Health Service, where it is generating performance data under a clinical study. Milad expects that the commercial version of SC+ -- which will include wireless uploading of runs sheets and treatment records for physicians -- will debut in the UK in H2 2018 with anticipated FDA clearance in 2019.

Founded in 2008, Quanta's investors include Air Liquide/ALIAD, b-to-v Partners, IMI, Kuwait LifeSciences Company, Stage Capital, Seroba Life Sciences, Seventure Partners and Wellington Partners. The company has raised over £60m in funds to date, Milad said.

Image 1

Sized at 45x48x37 cm and weighing 35 kg, SC+ is designed for use either at home or in-center

Quanta Dialysis Technologies

What sets SC+ apart is its compact size and high performance, he noted.

"You have the full flexibility to crank up the device to provide a high-dose treatment like it's done today in the clinic, and then to ease it back and to do it in the more gentle ways that a patient might wish to do in the home," Milad explained.

Milad believes the SC+ is especially suited to a transitional care delivery model, in which patients take weeks or months to gradually learn to self-dialyze in a center before going home with a

personal dialysis system.

“We’ve taken typical dialysis patients, not cherry-picked, and treated them as part of the normal clinical work flow, using their existing prescriptions,” Milad said. In post-treatment measures, all patients hit their therapy targets, he added.

In a poster presentation at the EDTA conference in Madrid in June, Quanta showed that in 915 treatments between June 2015 and May 2017, dialysis was adequate and there were no serious adverse events.

Outset Medical: In-center Self-Care

Meanwhile, Leslie Trigg, CEO of privately held San Jose, California-based *Outset Medical Inc.* told *Medtech Insight* that her company is currently the only US venture-backed startup focused on hemodialysis machine technology (Also see "*VC Deals Analysis: From Famine To Feast, 2017 Bloats With May Haul*" - Medtech Insight, 7 Jun, 2017.).

“The lack of innovation to date really baffles the mind when you think about the size, the market opportunity, in terms of the number of episodes of care each year, and the number of patients receiving dialysis,” Trigg said.

Outset was originally capitalized in 2010 by Warburg Pincus with the aim to rival NxStage in the HHD space, Trigg said. The company closed a series C round in mid-May for $76.5m, which was led by T. Rowe Price Associates, Inc. and included existing investors Fidelity Management & Research Company, Partner Fund Management LP, Warburg Pincus, Perceptive Advisors and the Vertical Group. To date, the company has raised a total of $190m.

Outset's technology, *Tablo*, which received FDA clearance last November, is heavily automated and designed to be patient-friendly. It is also far less intimidating than the clinic machines, using a touch-screen interface and purifies tap water and makes dialysate in real time.

“Tablo really obviates the need for infrastructure,” Trigg explained. “It’s like a mini rolling dialysis clinic. You don't need anything else with Tablo, except for an electrical outlet and some source of tap water.”

Tablo also incorporates both Wi-Fi and cellular data communication capabilities, uploading vital signs and other data from a session, which “takes the administrative part of dialysis out of the patient's hands,” Trigg said. In addition, Tablo is able to receive wireless software updates and patient prescriptions.

“Tablo is currently the only hemodialysis system cleared for two-way data transmission,” Trigg added.

Tablo was originally designed for home hemodialysis. But the company is now also aiming at in-hospital and in-center self-care.

With in-center self-care, patients dialyze themselves within a traditional dialysis center as they would at home. Better known in Europe than in the US, the option offers extra support to patients while allowing them more independence and flexibility and keeping labor costs low. In both care settings, Trigg said, Tablo's simplicity, automation, and all-in-one design offers cost advantages for providers.

Tablo has been cleared for use in acute and chronic care settings, and is used in several hospital ICUs and regular floors, according to Trigg, as well as some centers offering it for in-center self-care. Trigg declined to name the health care settings.

Outset isn't forsaking HHD. The company is currently enrolling patients for an IDE study to expand Tablo's label indication for home use.

"We have been very happy with the results so far, and are continuing to move forward," Trigg says. She didn't want to speculate on a timeline for HHD approval, but anticipates a full market release in 2018, initially for in-center and in-hospital indications.

"Patient independence is the future, and our vision is different insofar as we don't believe independence has to mean your only option is home," Trigg said.

Reimbursement

Reimbursement for HHD remains a challenge in the United States.

Private insurers pay the first 30 months of a patient's dialysis, which is the only time companies like DaVita can make a profit, according to an article that appeared in *NEJM Catalyst*.

Once Medicare kicks in, service providers lose money.

Bundled Medicare payments, that took effect in 2011, support three weekly in-center sessions at $240 each; service providers were paid the same whether the patient is dialyzed in-center or at home. Suddenly, centers had to find cost savings.

With medical justification, doctors can sometimes get a fourth or fifth day of dialysis paid for—most HHD is done five days a week—but Medicare doesn't offer specific HHD incentives other than for training.

"[CMS hasn't] put in place any firm guidelines or rules for paying for more frequent dialysis—it still sort of exists in that grey area," Denhoy said. "I think Medicare also knows that two major

providers control 60-70% of the dialysis market in the US, that those entities are very much profit-driven, and if you start creating incentives to do more frequent dialysis and you're paying for more frequent dialysis, your bill is going to go up."

But Milad believes that economics will start to favor HHD.

"The provider is going to need to care more about not just what is the cost of an individual therapy, but what is the cost of managing the patient," he said. "To the extent that there are therapeutic options available like HHD, which can simultaneously lower the cost of the therapy while at the same time generating better health outcomes, which will reduce the cost of the total patient burden for managing them, market forces will naturally push providers more towards home therapies —even if the reimbursement per se doesn't change to benefit HHD."