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Valuation of Dialysis Centers: Technological Environment

As in other industries, there are continuous technological innovations and developments in healthcare. Technology has helped to change the patient experience and has had a significant impact on medical processes. Clinical dialysis methods, such as hemodialysis, peritoneal dialysis, etc., all require machines that are technologically evolved and are heavily dependent on technological innovations.[1] This fifth installment in the five-part series regarding dialysis centers will review the *technological environment* in which these enterprises operate, including some recent technological advancements.

Since the emergence of clinical dialysis over 60 years ago, the provision of dialysis care has evolved significantly, due to advances in clinical technologies.[2] While many early challenges prevented dialysis therapies from becoming a viable treatment for end-stage renal disease (ESRD) patients, such as ultrafiltration control systems and accurate dialysis fluid modules,[3] significant problems with the provision of dialysis therapy remains, notably, the creation and maintenance of safe and functional vascular access pathways.[4] However, advances in vascular access, along with the utilization of *health information technology* (HIT), may help dialysis centers overcome these challenges and provide high-quality care for patients with increased efficiency. The ability of dialysis centers and their affiliated providers to leverage these technologies while simultaneously providing high-quality care may serve as a defining feature of the successful dialysis center in the era of healthcare reform.

Advances in Vascular Access

The technological environment related to vascular access (e.g., *autogenous arteriovenous* [AV] fistula, AV graft, or central venous catheter) for dialysis patients is developing, in part, as a response to problems associated with this central feature of the hemodialysis technique, such as higher risks of death, infection, and cardiovascular events.[5] For example, the percentage of hemodialysis patients with an AV fistula (i.e., "an abnormal connection between an artery and a vein"[6]) has increased from 28.9% to 32.8% between 2005 and 2016.[7] In response, new therapies and devices have developed to decrease vascular access complications, including:

(1) Devices developed as an alternative to surgical fistula creation, to offer a less-invasive vascular access option to patients requiring hemodialysis;[8]

(2) Bioengineered blood vessels built from stem cells, which allow patients with AV fistula complications to continue to receive dialysis treatments;[9] and,

(3) Drug-coated balloons to treat *stenosis* (i.e., narrowing) of AV fistulas before the condition devolves into full *thrombosis* (i.e., formation of a clot inside a blood vessel).[10]

Further, it may be possible to develop specific devices to measure vascular access blood flow rates, a significant step toward the prediction of the development of thrombosis of AV fistulas and AV grafts, by using technologies similar to those utilized with cardiovascular patients.[11]

Home-Based Dialysis Treatment

In the past decade, advances in dialysis techniques and machinery have allowed increasing numbers of ESRD patients to receive, or personally perform, home-based services. *Peritoneal dialysis*, which uses the lining of the patient's abdomen as a filter to clear wastes and extra fluids,[12] allows the ESRD beneficiary the luxury of receiving dialysis treatments at home or at work, without visiting an outpatient dialysis center.[13] Similarly, *hemodialysis* machines have evolved such that patients may receive this form of treatment in their homes through a machine similar to that found in outpatient dialysis centers, but the machine is smaller and portable.[14]

Although portable hemodialysis and peritoneal dialysis technology has existed since the 1970s,[15] only recently have more patients begun to rely on home-based dialysis treatments. From 2007 to 2016, the incidence, i.e., the occurrence of new instances, of ESRD patients using home dialysis therapies increased from 6,700 to 12,500 new ESRD patients, with the large majority of patients in 2016 (12,100) opting for peritoneal dialysis treatments.[16] The sudden increase in the number of patients using home dialysis led to the *U.S. Food and Drug Administration* (FDA) declaring a shortage in *dialysates*, i.e., peritoneal dialysis solutions, for *Automated Peritoneal Dialysis* (APD) and *Continuous Ambulatory Peritoneal Dialysis* (CAPD), due to increasing demand

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and limited supply from the primary supplier, *Baxter International, Inc.* (Baxter), in 2014.[17] The shortage may have subsided by 2016, but was not completely eradicated;[18] this could have a negative effect on the growth of new peritoneal dialysis treatment regimens.

TELEHEALTH TECHNOLOGY IN DIALYSIS

Telehealth is used to provide healthcare services remotely via electronic information and telecommunication technologies, such as computers and mobile devices.[19] In case of kidney diseases, telemedicine is used as a means of remote patient monitoring, e.g., monitoring blood pressure levels at home.[20] Telehealth is also useful in the provision of services to patients in rural areas. Since, approximately 25% of the U.S. population lives in areas considered to be rural, and rural locations generally have increased incidence of ESRD, telemedicine provides an opportunity to service the rural population.[21]

HEALTH INFORMATION TECHNOLOGY IN DIALYSIS

Incorporation of HIT into dialysis care may improve retention and analysis of vital patient information relevant to the treatment of ESRD.[22] In light of the highly consolidated and integrated nature of the dominant companies operating dialysis centers, proper HIT utilization is essential to maintain patient volumes, coordinate patient care, and make informed care decisions.[23] In particular, proper documentation of *Chronic Kidney Diseases* (CKD) and ESRD on *electronic health records* (EHR) utilized by providers led to improved outcomes for dialysis patients, including better coordination of care between primary care providers and specialists and better control of risk factors.[24] Although a 2014 *American Journal of Nephrology* study found that proper notation of CKD by primary and specialty care physicians in a patient's EHR did not reduce the number of ESRD patients, the study also found that proper notation of CKD in an EHR did lead to increased incorporation of CKD treatment guidelines, such as review of Vitamin D and phosphorous levels.[25]

FUTURE OF DIALYSIS TECHNOLOGY

Technological innovations in stem cell and bioengineering techniques are laying the path for new sources of autologous tissues for *regenerative therapies* (i.e., replacement or regeneration of human cells, tissue, or organs, to restore or establish normal function)[26] and *precision medicine* (i.e., disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person).[27] Researchers and companies are following this path and introducing solutions that could completely transform the dialysis industry. Scientists at Manchester University, with the help of embryonic stem cells, are successfully growing human kidney tissue within a living organism, replicating the function of a kidney (e.g., producing urine), which would effectively reduce the need for dialysis.[28] Researchers have also been trying to develop a wearable artificial kidney for a number of decades. A Canadian startup, *Qidini Labs*, is working to develop an artificial kidney with wearable technology, made from nano-filters, which work like a tiny dialysis machine.[29] These types of technological developments could help patients bypass the need for dialysis altogether.

CONCLUSION

The future developments discussed above may significantly change how kidney disease is diagnosed and treated. It may serve to greatly reduce the need for these services, at least in dialysis facilities, in the face of increasing demand and decreasing supply. Dialysis providers must continually adjust to deal with pressures related to changes in the utilization levels, stagnant reimbursement levels, increasing regulatory scrutiny, and technological developments in the dialysis industry.

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