



Opinion Article

Assisted Home Hemodialysis Model, IT IS TIME,... NOT.... “Is it Time”?

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Citation: Rifai AO (2023) Assisted Home Hemodialysis Model, IT IS TIME,... NOT.... “Is it Time”? J Family Med Prim Care Open Acc 7: 226. DOI: 10.29011/2688-7460.100226

Received Date: 15 April, 2023; **Accepted Date:** 13 June, 2023; **Published Date:** 16 June, 2023

Introduction

The technology surrounding renal replacement therapy has not progressed as rapidly as in other areas of medicine, such as cardiology or surgery. The hemodialysis machine has remained largely the same for the past fifty years, as has peritoneal dialysis [1]. Although there are some visionary projects in development, such as the bioartificial implantable kidney [2] and pig kidney xenotransplantation [3], none have advanced to the same level as the technological advancements seen in cardiology [4], diabetes [5], or surgery [6] in recent decades.

Chronic kidney disease is a growing global health crisis, with diabetes and hypertension remaining the leading causes. The rates of these diseases, along with obesity and other urbanization-related conditions, continue to rise. Cardiovascular disease is the leading cause of death in adults with diabetes and hypertension, and advancements in cardiac-saving measures have improved outcomes for these patients [4]. However, these advances have also led to an increase in the incidence of chronic kidney disease, which is expected to result in a growing number of dialysis patients and the associated costs of managing them. This looming tsunami poses significant challenges to healthcare systems in the USA and worldwide [7].

Although there have been successful attempts to prevent or slow down the advancement of chronic kidney disease, a considerable number of patients will inevitably progress to End-Stage Renal Disease (ESRD) and need dialysis or kidney transplantation. Furthermore, with better survival rates among ESRD patients, the total number of dialysis patients is expected to rise. This presents significant difficulties in managing the cost of caring for ESRD patients and addressing their accompanying comorbidities.

Managing the growing population of dialysis patients has posed a significant challenge, as there is a shortage of healthcare manpower and financial resources [7].

Furthermore, the cost of dialysis is increasing at an unsustainable rate and is growing at a faster pace than the general population. To address these issues, in January 2021, the Centers for Medicare and Medicaid Services (CMS) introduced a new payment model, called ESRD Treatment Choices (ETC). The aim of the ETC model is to increase the percentage of patients who choose home dialysis (peritoneal or hemodialysis) or who are on the waiting list for a kidney transplant or receive a living donor kidney transplant. The primary objective of the ETC model is to improve patient outcomes and reduce the overall cost of care for ESRD patients [8].

The Drop in the Home Hemodialysis After 1972

In the 1960s, all dialysis treatments were conducted using hemodialysis machines, and these treatments were performed at home. There were no dialysis clinics, outpatient centers, or hospitals at that time to provide outpatient hemodialysis treatments.

However, in 1972, Medicare eligibility was extended to individuals with “irreversible kidney failure,” and Medicare coverage for dialysis treatments played a significant role in the growth of dialysis centers in the 1970s and 1980s. As a result, there was a significant shift from home-based hemodialysis to in-center hemodialysis. However, during this time, peritoneal dialysis emerged as a more popular home therapy option for patients.

Despite advances in medical technology, the basic design of hemodialysis machines has remained largely unchanged over the past few decades. Originally designed for in-center dialysis, these machines were large, sophisticated, and not user-friendly and they required a separate Reverse Osmosis (RO) system. While they were professional, safe, and reliable, there was little pressure to modify the machines for home use since there were no financial incentives for higher reimbursement or pressure to cut costs. As a result, the evolution of hemodialysis machines to meet the future needs of home dialysis was slow.

The Increasing Cost for Dialysis

In 1972, there were approximately 20,000 to 30,000 patients with ESRD on dialysis, and Medicare spending on ESRD was approximately 0.1% of the GDP [12]. Between 1990 and 2010, the majority of dialysis patients (90-95%) received in-center hemodialysis, while 5-10% received peritoneal dialysis. Home hemodialysis represented less than 1% of all dialysis modalities during this time period [10].

In response to the increasing cost of Medicare spending on dialysis, Medicare initiated the ESRD PPS (End-Stage Renal Disease Prospective Payment System) in 2011. The ESRD PPS is a bundled payment made to dialysis facilities on behalf of Medicare beneficiaries for their treatment, which includes dialysis treatment, laboratory tests, supplies, and certain drugs and services provided during the dialysis treatment. The aim was to control the cost of dialysis [11].

As of 2018, Medicare spending accounts for 18% of the GDP, while dialysis services for the 500,000 dialysis patients represent 1% of the Medicare recipients, with the cost being approximately 7.2% of Medicare Fee-for-Service spending.

According to recent data, the number of dialysis patients covered by Medicare is now 20 times larger than it was when Medicare started covering dialysis and ESRD. The cost of treating ESRD patients is also significantly higher, at 7.2 times more than the average Medicare recipient. Additionally, from 2010 to 2020, there was an increase in the percentage of incident dialysis patients performing home dialysis, from 6.8% to 13.3% [17].

For the first year in more than a decade, and according to the Centers for Medicare & Medicaid Services (CMS), the inflation-adjusted total Medicare expenditures increased by 10.9% to \$672.7 billion in 2020, while ESRD expenditures decreased by 4.1% to \$38.1 billion. The ESRD population accounted for about 5.7% of total Medicare expenditures in 2020 [17].

The COVID-19 pandemic has had a significant impact on dialysis care and its associated costs. Healthcare providers have had to adapt to new protocols and policies to ensure the safety of patients and staff, and the pandemic has highlighted the importance of home-based therapies such as home hemodialysis. As the world continues to navigate the pandemic, it remains to be seen how dialysis care will continue to be impacted in the future.

Renewed Interest in Home Hemodialysis

The development of newer hemodialysis machines such as the Fresenius “Baby K” and NxStage has made home hemodialysis a more feasible option for patients. The NxStage machine is currently the most widely used machine for home hemodialysis.

Nephrologists have recognized the potential to improve the quality of life for their patients, especially those in rural areas. Studies have demonstrated that home hemodialysis can offer clinical benefits over in-center hemodialysis, including reduced cardiovascular morbidity and mortality, as well as decreased

medication utilization for hypertension, phosphorus, Parathyroid Hormone (PTH), and Erythropoiesis Stimulating Agents (ESA). Additionally, home hemodialysis has been associated with lower overall costs, fewer hospitalizations, and improved quality of life, as well as reduced mortality rates.

Despite the potential benefits of home hemodialysis, there are still significant barriers to its adoption. The current system for home hemodialysis therapies has not been functioning optimally, and efforts to enroll more patients in the existing system have not yielded the desired clinical or financial outcomes. Two significant barriers to the adoption of home hemodialysis are the lack of confidence of patients or their partners to master hemodialysis, especially the cannulation process, as well as the fear of vulnerability in the event of a medical emergency. These barriers must be addressed to improve access to home hemodialysis and optimize patient outcomes [14].

In 2020, the American Heart Association (AHA) released a position paper that endorsed home hemodialysis as a preferred and viable option for suitable patients with end-stage kidney disease. The paper emphasized the growing body of evidence indicating that home hemodialysis is linked to better cardiovascular outcomes, enhanced quality of life, and reduced healthcare costs when compared to in-center hemodialysis. The AHA also called for an increase in education and training for nephrologists and healthcare professionals to enhance access to home hemodialysis and improve patient outcomes [15].

There are all valid barriers to home hemodialysis. In addition to the psycho-social and medical barriers, there are also logistical barriers that can impact the choice of home hemodialysis.

Psycho-Social Barriers

Performing hemodialysis at home can be intimidating and a significant adjustment for patients and their loved ones, given the level of responsibility and time commitment involved. Home hemodialysis requires multiple sessions per week, with each session taking several hours, which can be challenging for patients and their families to manage. In fact, 83% of home hemodialysis patients perform 4-5.9 sessions per week. Additionally, patients need a dedicated area for the equipment and supplies, which can be a concern for those living in smaller homes or apartments with limited physical space.

Medical Barriers

The fear of technological complexity may be the most important barrier for HHD and the fear of an emergency or vulnerability and being alone is also a serious concern and barrier to HHD. Visual or cognitive impairment or medically unstable patients can be barriers as well. But a partner can help with all these factors.

Dialysis Clinic Barriers

Patients and families may face various barriers when considering home hemodialysis or other home therapies at dialysis

clinics. One of the major challenges is the complexity of information and education provided to them. Lumping both hemodialysis and peritoneal dialysis as “home therapies” can be confusing and overwhelming. It is crucial to offer clear and concise information about the options available, along with the benefits and potential challenges of each modality. Moreover, the continuous nature of home hemodialysis can be overwhelming and may cause burnout for patients and their partners. Therefore, it is essential to provide resources and support to patients and partners, such as scheduled breaks or respite care, to prevent burnout and offer much-needed rest and recovery time. This can also enhance patient and partner satisfaction with the therapy and improve overall outcomes.

Time for a New Model as there are New Technologies on the Market

The latest advancements in technology for the hemodialysis machines have enabled healthcare professionals to discuss the barriers to home hemodialysis. With the next-generation machines, patients can now perform hemodialysis at home with greater confidence and ease. Moreover, advanced tele and remote diagnosis methods, treatment, and monitoring using Artificial Intelligence (AI) algorithms can help mitigate the fear of vulnerability in an emergency.

Proposal: The New Home Hemodialysis Model, the “Assisted Home Hemodialysis”

The latest generation of hemodialysis machines, such as NxStage (<https://www.nxstage.com/>), Tablo (<https://www.outsetmedical.com/>), Quanta SC+ (<https://www.quantadt.com/>), or Diality (<https://www.diality.com/>), are vastly different from

conventional hemodialysis machines. In fact, today, the NxStage machine is currently the most used machine in home hemodialysis.

The latest generation hemodialysis machines boast a more convenient design, with increased portability, compactness, and reduced maintenance requirements, making them highly suitable for home-based use. Moreover, they incorporate more automated functions and remote monitoring capabilities, which enhance patient safety and provide valuable support. These technological advancements hold the potential to make home hemodialysis a more feasible and attractive model.

The newer hemodialysis machines, including Tablo, Quanta SC+, and Diality, are bicarbonate-based and use tap water and a regular electrical plug, making them easier to set up and use at home. In contrast, the NxStage machine uses a lactate-based dialysate that requires at least 5 hours to prepare and mix the dialysate, unless an emergency pack is used, which is bicarbonate-based. Additionally, the newer machines have higher maximum dialysate flow rates, which may improve treatment efficiency and reduce treatment time. Tablo has a maximum dialysate flow rate of 300 ml/min, not significantly different from NxStage. Whereas Quanta SC+ can reach up to 500 ml/min, and Diality up to 600 ml/min.

Tablo has gained significant market share in acute hospital care space and is now being used in the home hemodialysis space as well. Quanta SC+ has performed well during the COVID-19 pandemic in the UK’s National Health Services and is currently undergoing final regulatory approvals in the USA. Diality, on the other hand, needs to go through safety and effectiveness trials before seeking FDA approval, which could take up to few years (Figure 1).

	NxStage	Tablo	Quanta SC	Diality
COMPLEXITY for user	+	+	+	Unknown
Separate RO	NO	NO	YES	YES
Modular (RO and machine)	YES	NO	YES	YES
Plug and Go	5-6 hours	YES	YES	Unknown
Lactate dialysate	YES	NO	NO	NO
Bicarbonate dialysate	NO	YES	YES	YES
Remote Monitoring	YES	YES	YES	unknown
Dialysate Qd max	280 ml/min	300 ml/min	500 ml/min	600 ml/min
Portable for travel	YES	NO	NO	unknown
Currently in use in USA	YES	YES	ONLY in UK	NO

Figure 1: New Hemodialysis Machines.

The Neokidney by Nextkidney, <https://nextkidney.com/>, a Dutch European model, utilizes sorbent technology, which is currently awaiting approval in the European Union. It is expected to take at least five more years before this technology becomes available in the USA.

However, if a new model of delivering hemodialysis that prioritizes home-based treatment is embraced, patients may be more likely to choose home hemodialysis as a viable option for their treatment, given that the advanced technology is highly compatible with home-based care.

There is a need for Assisted Home Hemodialysis OPTIONS, to help increase enrollment in the home hemodialysis therapies:

AHHD OPTION 1, “The Diamond option”

A patient care technician, PCT, visits to initiate set up, cannulate, perform and completes, then disconnects the hemodialysis treatment. The monitoring is done via a central audiovisual capability, by a remote RN and that RN can monitor more than one patient at a time from a central station. Artificial intelligence can assist in predictions of “trouble”. Patients may choose to pay extra fee out of pocket for this option, or the insurers will bear the cost for that.

AHHD OPTION 2

A Patient Care Technician (PCT) visits the homes of patients who require hemodialysis and cannulates their AV access to initiate treatment before leaving. The treatment is then monitored via a central audiovisual system. However, a significant number of patients may be interested in performing home hemodialysis if they receive professional assistance in cannulating their AV access and have access to user-friendly machines.

This could involve PCT visits to perform cannulation, followed by remote monitoring or even completing the entire treatment. Additionally, artificial intelligence can assist in predicting potential issues that may arise during treatment.

AHHD OPTION 2A: “The Gold Option”

After the treatment is completed, the Patient Care Technician (PCT) returns to disconnect the patient. Throughout the treatment process, remote monitoring is conducted by a Registered Nurse (RN).

AHHD OPTION 2B: “The Silver option”

Since the disconnection process is simpler, patients or their

partners can disconnect themselves from the dialysis machine.

AHHD OPTION 3: “the Bronze option”

The current model of self-cannulation, self-treatment, and self-disconnection can be intimidating for patients and their families, and is not gaining the desired traction for growth. To improve this model, remote monitoring by a registered nurse and AI-assisted management of alarms and potential problems should be added.

AHHD OPTION 3: (the current model-yet without real time monitoring)

The current model of self-cannulation, completing the treatment, and self-disconnection can be intimidating for patients and their families. However, this model is not gaining traction as much as we would like it to grow.

AHHD OPTION 4:

The mobile hemodialysis van, with a PCT on board, offers a full treatment and includes remote monitoring by a remote RN who can monitor more than one patient. Artificial intelligence can be utilized to assist in predicting potential issues during treatment.

AHHD OPTION 5:

A hybrid model could be implemented where patients have the option to receive dialysis at home for an additional premium, which could be set by CMS, the LDO, or a dialysis staffing company providing PCTs.

Conclusion

There are distinct differences between Peritoneal Dialysis and Home Hemodialysis, and grouping them together as “home therapies” can be confusing for patients trying to choose a modality. Fear of vulnerability in a medical emergency and lack of confidence in mastering hemodialysis are the two major obstacles to the growth of home hemodialysis. However, new dialysis machines equipped with artificial intelligence and connectivity to remote monitoring experts, such as hemodialysis nurses, can help alleviate anxiety and provide real-time support and solutions.

Offering a range of options for assisted home hemodialysis may encourage more patients to enroll in this modality, which has been proven to have numerous benefits over in-center hemodialysis. A shift towards a more patient-centered approach to dialysis care is needed to enhance the quality of life and outcomes for this vulnerable population (Figure 2).

	PCT	Monitoring	Extra Cost	Amount
AHHD Option 1 Diamond Option	PCT to set up, cannulates, completes treatment, Disconnects	Remote monitoring by RN via audiovisual with artificial intelligence algorithms to predict potential complications	Paid by patient OR For additional premium by insurance	\$\$\$\$ amount set
AHHD Option 2 A Gold Option	PCT cannulates, then leaves, and returns to disconnect.	Remote monitoring by RN via audiovisual with artificial intelligence algorithms to predict potential complications	Paid by patient OR For additional premium by insurance	\$\$\$ amount set
AHHD Option 2 B Silver Option	PCT cannulates only	Remote monitoring by RN via audiovisual with artificial intelligence algorithms to predict potential complications	Paid by patient OR For additional premium by insurance	\$\$ amount set
AHHD Option 3 A Bronze Option	The patient or partner completes all the treatment. It is the current model, without remote monitoring	Remote monitoring by RN via audiovisual with artificial intelligence algorithms to predict potential complications	SHOULD be a part of the current bundle payment (Creates comfort and reduces anxiety for patients)	\$ amount set
AHHD Option 3 Current Model	The Patient or partner completes all the treatment. The current model, without remote monitoring	No remote monitoring, only trouble shooting help if needed	NO EXTRA COST to patient and paid completely by carriers	0
AHHD OPTION 4 MOBILE OPTION	PCT sets up, cannulates, completes treatment, Disconnects In a MOBILE VAN	Remote monitoring by RN via audiovisual with artificial intelligence algorithms to predict potential complications	Paid by patient OR For additional premium by insurance	\$\$\$\$ amount set Open market

Figure 2: Assisted Home Hemodialysis (AHHD) Options.

To expand the use of home hemodialysis, it may be necessary to redefine the term “home therapies” and to establish new Large Dialysis Organizations (LDO) exclusively dedicated to home therapies, specifically home hemodialysis. Dialysis providers that fail to adapt to the changing healthcare landscape and technological advancements may be left behind.

While a new home hemodialysis model may not be cheaper as a stand-alone option compared to in-center hemodialysis or current home hemodialysis, it could ultimately lead to lower costs for the entire ESRD bill. Home hemodialysis has been shown to provide better clinical outcomes, better quality of life, and lower rates of hospitalization and mortality. Therefore, exploring and considering it as a practical solution to the challenges facing the dialysis population is worthwhile.

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