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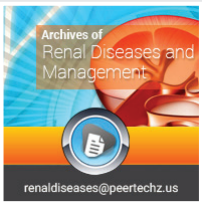

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Commentary

COVID-19 and end stage renal disease treatment modalities in the United States

John D Sullivan*

Chair and Associate Professor, Boston University, Metropolitan College, Finance & Health Care Policy Lecturer, BU School of Law, Health Care & Finance Law 1010 Commonwealth Ave, Boston, MA 02215 617 353 3016, USA

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***Corresponding author:** Dr. John D Sullivan, Ph.D, Chair and Associate Professor, Boston University, Metropolitan College, Finance & Health Care Policy Lecturer, BU School of Law, Health Care & Finance Law 1010 Commonwealth Ave, Boston, MA 02215 617 353 3016, USA, E-mail: jsulliva@bu.edu

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Introduction

From the establishment of nearly universal health coverage for end stage renal disease in 1972 to 2021, the primary treatment modality has been in-center hemodialysis despite significant advances in home therapies such as peritoneal dialysis and home hemodialysis. There are many theories as to why peritoneal and home hemodialysis lack so far behind in prescriptions with profitability and or a patient's compliance or support leading the logical explanations. But 2020 was a different year with the surge in COVID-19 cases. A likely forecast would be that treatment prescriptions for new patients would shift, at least modestly, from the traditional in-center regime to home therapies. This does not appear to be the case with very small numbers of new patients utilizing peritoneal and home hemodialysis. A simple high-level conclusion may be drawn assuming that the nephrology community simply followed the historical trends and continued to promote in-center treatments under the supervision of clinical support staff with in-direct services from dieticians and social workers.

Background

End Stage Renal Disease impacts more than three quarters of a million people and costs the government more than $42.2 billion in 2018 rising from $34.8 billion in 2009 with a per annum of roughly 2.1% negating the number of future patients that will require this therapy to sustain life going forward [1]. As always, the federal government, despite its good intentions, provides health care coverage for patients that could have sought treatment prior to the ESRD diagnosis rather than when the condition of the patient had deteriorated to the point whereby dialysis was the only option.

For those under the age of 65, or are not supported by Medicare, gain coverage through third-party payers or commercial insurance. These patients are the profit motive for providers as they pay more for each treatment as well as ancillary drugs such as Epogen. To run a clinic with all Medicare patients, at best, is a break-even venture. Utilization becomes the key variable as outpatient clinics strive to push to three shifts per day to maximize fixed asset leverage. While it doesn't seem financially plausible, this strategy can create an entity that despite its overhead of personnel and location costs, will be more profitable than a patient that is seeking treatment at home with someone to assist.

It may seem like a simple income statement analysis, but one must look at the expense equation and forecast as a stand-alone entity. By comparison, the expenses of having a patient treating themselves with peritoneal dialysis or home hemodialysis is far greater than a patient sitting in a chair in an outpatient dialysis unit. Going into details, home hemo dialysis patients require more artificial kidneys than their counterparts in a clinic and peritoneal dialysis patients need supplies that will dialyze them for more than a week.

Other treatment modalities had been a bit of a challenge over the past thirty years with the availability of peritoneal dialysis and home hemo dialysis increasing with advancements in medical technology, but never really gained traction with the lack of support by the general nephrology community.

The providers

In 2019, the top two dialysis providers, DaVita and Fresenius Medical Care, treated a combined 412,000 patients representing

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85% of the total patients under the top ten providers. To put this into perspective, Fresenius Medical Care treated 208,007 patients and the number three provider in the top ten, U.S. Renal Care, treated just 25,327 patients or 5% of the end stage renal disease patients within the top largest providers. Of the largest ten providers, the Centers for Dialysis Care at number ten supervised the dialysis of 1,526 or .03% [2].

The top largest providers treated 484,862 patients in 2019 in all three treatment modalities: In-Center Conventional Hemo Dialysis, Home Hemo Dialysis, and Peritoneal Dialysis. The allocation of patient treatment modalities is roughly the same for all providers with peritoneal dialysis being about 10% and home hemodialysis near 1%. One exception within the top ten is the non-profit Satellite Healthcare with 8,209 total patients with 18% utilizing home therapies.

Unlike home therapies, in-center treatments require large investments in infrastructure that must meet both federal and state guidelines. Most providers, wanting flexibility, tend to lease property and invest via leasehold improvements to convert the space into a dialysis medical facility. Depending on the size, measured by the number of dialysis stations, and location of the clinic, building out space can cost between $1 million to $4 million per facility. Both Fresenius and DaVita have invested capital of billions into facilities over the years. Of the top ten providers, Fresenius operated the most In-Center units with 6,827 verses DaVita's 5,000. The third largest provider, U.S. Renal Care, by contrast, has only 510 in 2019 and the number ten on the list, Centers for Dialysis Care, operated 15 in-center units for 1,502 hemodialysis patients [3] .

The number of units in operation is obviously a reflection of the number of patients utilizing this modality option. This may be a cause-and-effect scenario based on patient need with the underlying idea that profitability may be a factor. As will be discussed below, the cost structure of providing dialysis treatment can be significantly lower in an in-center setting given the right financial and operational conditions.

It is difficult to predict why the United States allowed two providers to dominate the marketplace. One theory is that the budget for dialysis ballooned and was far more than it had been forecast. A complimentary belief is that while the market was expanding and adding cost to Medicare, the government simply looked away, allowed consolidation, and expected cost to come down at least on a per treatment basis [4]. Obviously, this wasn't the case as technology and drug therapies improved, it added to the cost of providing care to renal patients. Medicare, always reactionary, has always had a wait and test approach to managing the costs not really solving the expense problem, but rather trying to prevent further expenditures on the back end. In other words, in lieu of preventing renal failure as a goal, a relatively inexpensive proposition, Medicare attempts to limit the expense, which is significant annual expense for the basic treatment as well as hospitalizations.

To complicate matters, nephrologists have become integrated financially with dialysis chains. Serving as medical directors, physicians are paid based on a work-load system of patients within a given clinic. In some cases, physicians are partners with dialysis chains forming minority ownership positions in existing clinics and proposed de novo facilities. If it is true that volume and utilization can increase profitability, it is a possibility that patients may be prescribed in-center treatment over other options based on financial leverage and ongoing partnerships with large chains. The other possibility is that nephrologists just find it easier to put patients in a clinic based on their training and understandable concerns about a patient's ability to seek treatment in their home setting. It may also be complicated by a specific patient's home medical support despite an individual's qualifications and confidence to undergo peritoneal dialysis or home hemodialysis avoiding setting foot into a clinic. Many patients can't simply undergo the treatment without some clinical assistance, mostly provided by a family member, to conduct the treatment. This makes sense despite the advances in technology and the simplification of the preparation and undergoing treatment due to the simple fact that many things during the procedure can go wrong.

The largest two dialysis providers, beyond their leveraged size over the competition in patients, also hold another key advantage in the market. Fresenius Medical Care is a fully integrated company manufacturing dialyzers, arterial and venous lines, machines for both in-center and home use, peritoneal dialysis solution, a limited number of pharmaceuticals, and a significant lab testing business. By contrast, DaVita is not fully integrated although it does own a large lab business. Given the history of the companies, this makes perfect sense given that Fresenius started out as a manufacturer of dialysis equipment and subsequent medical supplies before its purchase of the largest service provider, at the time, National Medical Care in 1996. DaVita was formed as a company name change in 2000 from another provider, Total Renal Care, after an accounting scandal became public [5]. After changing the legal name of the company, DaVita concentrated, much like Fresenius, on the available acquisition targets left in the dialysis space rather than expand their business efforts, besides lab testing, into product development and machines.

In 2019, Fresenius Medical Care completed the acquisition of NxStage medical care [6]. While several providers, including Fresenius, worked on a machine that could provide hemodialysis in a home setting, nothing could come close to the NxStage machine. The machine was small and portable fitting comfortably into the trunk of even a small car. Most machines for home use are relatively large and not very flexible if they are needed to be moved and, in some cases, require significant plumbing to ensure proper treatment.

To add to the complexity of whether or not this for-profit model works is the lower rate of transplantation referral rates to transplantation than their non-profit centers. Over a four-year period, these key dialysis facilities were 16% less likely to be referred to nine transplant centers across the Southeastern United States [7]. While the study needs more attention, it draws questions as to the motivation of for-profit companies with regards to utilization of existing out-patient dialysis facilities.

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The cost of treatment options

The cost of treatment for a patient on dialysis isn't a simple calculation as the providers and government predicts. There happens to be multiple moving variables that impact the profitability of an outpatient clinic. The key is the utilization of the outpatient unit combined with a favorable commercial mix of patients that reimburse the clinic at a much higher rate than Medicare or Medicaid. With a high utilization of the clinic, fixed costs such as personnel and overhead can be reduced significantly with variable costs such as lines and dialyzers fixed at a low rate given that they are only used three times per week. This also happens to work in reverse creating an incentive to keep utilization as high as possible within an outpatient unit. Low numbers of patients and empty shifts can cripple a clinic with treated patient reimbursement not able to cover the high fixed costs of the facility not including the investment in the leasehold improvements and equipment.

Many jump to the conclusion that therapies such as peritoneal dialysis are far more profitable are incorrect. The reason why they appear so profitable is that many peritoneal dialysis patients are younger and seeking dialysis for the first time. As a result, they typically have commercial insurance that reimburses the treatment for an amount far greater than the Medicare and Medicaid rate. Therefore, it is more prudent to look specifically at the expenses associated with the treatment modality. If the revenue structure were reversed between peritoneal dialysis and in-center hemodialysis, the profitability, without the benefit of utilization, would certainly favor the preferred hemo modality. Since peritoneal and home hemodialysis have patients undergoing treatment seven and six days a week versus the standard three times per week in the clinic, a cost comparison as well as the preparation is required to make an accurate assessment of the underlying cost.

For a peritoneal dialysis regime, these patients undergo a surgical procedure that inserts a catheter into their lower abdomen for treatment. While the treatment for renal failure seems like a better option for these patients, there are significant risks that come with this option for treatment. With careful precautions, patients can avoid contracting peritonitis, an infection of the lower abdomen that would require patients to temporarily switch to hemodialysis while their infection is being treated.

This is similar for patients that choose to have treatment in their homes with home hemo dialysis treatment with the assistance of a machine as the one created by NxStage. In this venue, patients dialyze typically every day for six days although with shorter treatment times that run about an hour and a half as compared with the three day a week three and a half hours within an outpatient dialysis setting. Although the cost of treatment for this modality appears to be less expensive than the traditional in-center out-patient expenditures with staff and facility overhead, supply costs tend to run more than double for obvious reasons related to the number of weekly treatments.

Profitability for different treatment options looks somewhat skewed as home therapies have significantly higher margins than those treated in an outpatient setting. This is misleading because finance professionals only look at the bottom line. This tends to be a simplistic look at the modalities. It is true that if a provider looks at either peritoneal dialysis or home hemodialysis that as a stand-alone venture it generates a far greater profit margin than the typical in-center hemodialysis unit. Unfortunately, the financial data is misleading in that most patients that start this treatment are still covered by a higher paying third-party payor commercial insurer. A true cost analysis would only focus on the direct and indirect expenses associated with the treatment.

This is only a first step. It is true that the variable costs of providing peritoneal dialysis and home hemodialysis are more than what would it cost in an out-patient setting. It is equally arguable that the cost of the overhead including staff, rent, utilities, etc. add significant cost to treating patients within a clinic. This is true, but it is also a fixed cost that does not fluctuate. In other words, on a cost per treatment basis, this expense will be reduced by each treatment as the volume of treatments within the clinic rises. As a result, with the right number of patients that still hang onto commercial insurance, say 20%, a stand-alone dialysis unit can be more profitable than home therapy with the same patient insurance coverage ratios.

This is not to say that patient treatment is directed by profitability. One might conclude that patients during a pandemic should be directed towards home therapies rather than environments such as "tight fitted" dialysis clinics with patients that are already immunosuppressive compromised.

COVID-19

The COVID-19 virus was a tough impact to the dialysis community with their immune deficiencies and subsequent treatment regimes. Given the disease and its ability to jump from patient to patient, it can be assumed that nephrologists would direct patients to outpatient care that would remove them from the in-center clinic and back to the home setting. But a look at the data from the early days of the pandemic would suggest otherwise. While it is difficult to move a patient from in-center to a home treatment, new prescriptions for dialysis could be driven towards peritoneal dialysis or home hemodialysis if the patient is in an environment is complimentary to this modality. The raw data reflects no significant change in the number of new patients utilizing home therapy over traditional in-center dialysis [8]. However, this is purely a reflection of a one-time snapshot of incidence and treatment modalities. Underlying factors may have skewed the numbers to reflect a wrong assessment of prescriptions.

Even in patients that have received a transplant with a functioning graft have been particularly vulnerable to COVID-19 with their immune system repressed to keep their new kidney from being rejected. Mortality rates, once concentrated on those finding the right immunosuppressive drug regime, realized that COVID-19 had turned into the main factor for mortality. What would have been a normal analysis of how to keep patients with a functioning graft alive with good

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clearance was more complicated by the growing spikes and lack of a vaccination of those that needed it most [9].

On the surface, it appears that nothing had changed from past prescriptions and the simple question is why would nephrologists continue to place patients in an outpatient setting whereby COVID-19 could be present? Two possible answers are that it is purely easier to place patients into a clinic where they can be supervised by qualified clinicians or based on the assumption that utilization of a clinic is key to a higher profit margin, more patient shifts on a specific machine translates into higher profitability.

Data also suggests that patients were significantly at lower risk by undergoing treatment at home. One study from the Ontario Renal Network at Western University in London, Ontario found that not only dialysis patients were at nearly 4 times the risk for COVID death due to hypertension, diabetes, and cardiovascular disease, but 88.8% of deaths occurred undergoing dialysis at a clinic verses at home. That said, patients within the clinic tended to be older and may have had underlying immunosuppressive issues or been seeking treatment in a long-term care facility [10].

It is logical to assume that with utilization down due to COVID-19 deaths, dialysis providers would suffer financially. DaVita announced that their first quarter earnings improved in 2021 despite lower treatment volumes as COVID-19 related costs diminished. For the first quarter of 2021, margins were 15.7% regardless of the higher mortality rates with 7,000 patients linked to COVID deaths in 2020 compared to 600 deaths reported in March 2021. The company also reported that it received an additional $2.72 in additional revenue per treatment compared to the prior year due to increases in the Medicare payment and favorable changes in their commercial mix and increased hospital inpatient revenue [11].

Assessments

While the overall numbers of new patients entering the system would suggest that nephrologists did not deviate from historical prescriptions despite an upcoming pandemic, other variables are a factor in the analysis. Indeed, physicians did suggest and encourage patients to dialyze at home to prevent a possible exposure to COVID-19. The issue did not settle with the prescription, but rather the support in the home setting [12]. Since patients are truly on their own, but need someone to assist in the treatment, many patients simply returned to in-center dialysis due to lack of support or an uneasiness of conducting peritoneal or home hemodialysis outside of a clinic. As a result, numbers reflected are not a complete accounting of what physicians were prescribing. Rather, the shifting patients from one modality to another presents a clearer picture of how the treatment regime is either a benefit or hinderance to a patient. Even the best of intentions may fail without the proper patient treatment environment.

Conclusions

It had always been thought that the reason why home therapies were lagging in patient numbers was a lack of support from the nephrology community. This is partially true with medical training for home therapies relatively limited for young nephrologists. However, if home therapies are an important component to the patient population, more effort needs to be concentrated on both the nephrologist as well as the support network required by every patient.

It is not an understatement that home therapies have been lacking in the United States over the past forty years. While the technology has improved significantly during this timeframe making machines more user friendly, what is lacking is a basic understanding of the patient and their respective environment. Of all times to be tested, a global pandemic, the treatment option was available, but without the support, failed to protect both the patient and diminish the spread of the disease within the renal community.

Reports on an annual basis often quote significant increases in home therapies, but these are small number of patients divided into a small patient base. Overall, peritoneal and home hemo still remain a very small percentage of the total renal population hovering at the same levels for more than three decades. Medicare in controlling the cost of dialysis patients must do so through prevention. For home hemodialysis and peritoneal dialysis to work, support needs to be provided to ensure both patient safety and keeping the option available to renal patients. Transplant recipients, also need support for those that can no longer afford their immunosuppressive drugs resulting into transplant failure requiring in-center treatment after an expensive transplant procedure had been conducted.

Lastly, an evaluation into the entire industry needs to be conducted given the pure size of the two controlling entities providing treatments. Does the oligopoly benefit patients for the cost paid by taxpayers? Given the benefits that patients may receive under an underutilized home therapy be controlled by two companies when some small providers have fully used these treatment modalities.

As a challenging time has thrown the globe into a crisis situation with the treatment of patients, the one upside is that these issues have come to the surface and require immediate attention to keep quality high and prevent patients from undergoing this life saving treatment if it can certainly be delayed.

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