PATIENT-CENTERED
CHRONIC KIDNEY DISEASE CARE
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PATIENT-CENTERED CHRONIC KIDNEY DISEASE CARE

Chronic Kidney Disease (CKD) is a condition in which the kidneys gradually lose their ability to filter out waste from the blood. The loss of kidney function usually occurs due to prolonged high blood pressure or blood glucose levels that damage the blood vessels within the kidneys that are responsible for filtering the blood of waste. The blood vessel damage and subsequent inability of the kidneys to properly filter the blood causes dangerous levels of waste and toxins such as urea and creatinine to build up in the body. Buildup of this waste in the body can lead to conditions such as gout, anemia, heart disease, and other health complications. ¹

CKD affects 37M US adults in the US and costs Medicare $120B dollars to treat each year. ² There are five stages of CKD. The progression through the five stages of CKD can be delayed, but cannot be reversed. Additionally, each stage of CKD gets dramatically more expensive to treat. The final and most expensive stage of CKD is kidney failure, or end-stage renal disease (ESRD). ³

ESRD is a condition in which the kidneys cease to function on a permanent basis. ⁴ There are only two treatment options for patients with ESRD: kidney transplant and dialysis. Kidney transplants are surgical procedures in which a kidney is taken from a donor and transferred to a recipient patient. Dialysis is a treatment to artificially rid the body of waste and toxins in the blood. There are two types of dialysis: hemodialysis (HD) and peritoneal dialysis (PD). HD uses a machine that serves as an external artificial kidney to circulate and clean the blood outside the body and then returns the blood to the patient’s body. PD is a form of dialysis in which a patient’s own peritoneum is used as a filter to clean the blood of waste. Without treatment for ESRD, waste builds in the body and patients can die from complications within a few weeks. ⁵

There are about 750,000 people with ESRD in the US (Figure 1). Roughly 63% of ESRD patients are on HD, 7% are on PD, and 30% have received a kidney transplant. ⁶

Figure 2: There are five different types of BCIs currently being developed for health applications. ⁴
In total, ESRD patients make up 1% of the Medicare population but cost Medicare $36B, roughly 7% of the entire Medicare budget. While the costs for treating ESRD are high, outcomes are still poor for those on HD and waiting on transplants. About one in five on HD die within a year of starting HD. Additionally, nearly 5K people die each year waiting on a kidney transplant.

In order to improve outcomes and save on costs associated with CKD and ESRD, the below challenges must be addressed.

- Early detection of CKD
- Slowing the progression of CKD
- Making hemodialysis more Patient Centric
- Improving Organ Transplant Supply

Below is a brief overview of the main challenges leading to increased costs and poor outcomes for those with CKD. Next is an overview of the startups that are working to alleviate the challenges. Following is an investment recommendation for the CKD market.
SECTION 1: CHALLENGES
EARLY DETECTION OF CKD

In the majority of cases, CKD arises due to complications from diabetes or high blood pressure. Both diabetes and high blood pressure lead to damage of a patient’s blood vessels. When the blood vessel damage occurs in the kidneys, it prevents the kidneys from properly filtering the blood.

The early stages of CKD development often lack noticeable symptoms. Because of the silence of symptoms, experts recommend annual testing for CKD in at risk populations (such as those with high blood pressure or diabetes) to catch CKD development early.

There are two main tests for CKD. First is a blood test that checks to determine how well kidneys are filtering blood, by measuring the glomerular filtration rate (GFR). Second is a urine test to check for albumin, a protein found in urine when there is kidney damage. Unfortunately, adherence to annual testing is low in the at risk population. A study found only about 40% of American adults with diabetes receive an annual test for kidney disease. Due to the silence of the symptoms and the lack of screening, it is estimated that 90% of people with CKD are unaware they have it.

In order to detect CKD earlier, it needs to be easier for patients to get tested for the development of CKD. The below startups are working to improve access to testing.

- **Healthy.io**: Healthy.io has developed a way for consumers to take a picture of their urine dipstick to test for chronic kidney disease and have the results sent to their provider
- **Scanwell Health**: Scanwell Health is working on a urinalysis test to detect signs of chronic kidney disease.
- **Live Chair**: Live Chair is putting preventive care further into the community, enabling more screening for CKD.

SLOWING THE PROGRESSION OF CKD

As mentioned above, CKD has five stages, each getting dramatically more expensive to treat. According to the NIH, there are three main interventions that can be deployed to slow the progression of CKD:

- **Nutritional interventions**: The NIH recommends limiting sodium intake to control blood pressure. Additionally, it is recommended that patients consume adequate, not excessive, levels of protein to reduce albuminuria. Subsequently, patients should work with a dietitian to start Medical Nutrition Therapy (MNT).
- **Lifestyle interventions**: The NIH recommends that patients stop smoking. Additionally, the NIH recommends physical activity as it may improve glucose control in those with diabetes, which can slow the speed of damage to the kidneys.
- **Medical management**: Due to prolonged high blood pressure and blood glucose levels oftentimes leading to CKD development, the NIH recommends that medications to improve blood pressure and blood glucose levels in patients are appropriately used to delay CKD progression.
While these interventions are known to slow the progression of CKD, utilization of these interventions are often not taken advantage of. For example, it was found that even in those that get pre-ESRD nephrology care for over 12 months, nearly 87% did not receive any dietary care.\(^6\)

The below startups are making it easier for patients to access nutritional, lifestyle, and medical management resources to slow the progression of CKD.

**Nutritional Interventions:**
- **Nutrient:** Nutrient has built a platform that allows providers to quickly build meal plans for the patients, enabling them to adhere to diets that slow the progression of CKD.
- **Vidafuel:** Vidafuel has created a suite of healthy snack products that make it easier for patients to adhere to a diet that can slow the progression of CKD.
- **Platejoy:** Platejoy enables users to design personalized meal plans and makes it easy for the right ingredients to be seamlessly delivered to a user through an integration with Instacart.

**Lifestyle Interventions:**
- **2Morrow:** 2Morrow has built a digital platform to deliver Acceptance and Commitment Therapy (ACT) to patients in order to help them with behavior change associated with smoking cessation.
- **Quit Genius:** Quit Genius has created a platform that uses cognitive behavioral therapy (CBT) that enable the user to make the behavior changes necessary to stop smoking.

**Medical Management:**
- **PilloHealth:** PilloHealth has created a smart pill dispenser that keeps patients adherent to their medication regimen through daily alerts and reminders while keeping the patient’s care team in the loop.
- **HeroHealth:** HeroHealth has created a smart pill dispenser that enables users to program their pill dispenser schedule and receive notifications alerting them of when to take their medication.

**Making Hemodialysis More Patient Centric**

Currently, most HD is done in-center at a clinic operated by companies such as DaVita or Fresenius. For example, only about 10% of people who start dialysis initially utilize PD. For the 90% utilizing HD, only 2% begin receiving hemodialysis at home.\(^6\)

In-center HD can be extremely burdensome for patients. For example, a patient usually undergoes in-center hemodialysis for four hours, three times a week.\(^{14}\) The need to travel to an in-center facility exerts a large amount of control on a patient’s weekly schedule and can make it hard for them to hold down a job.\(^{15}\)

In order for more patient centric treatment modalities to be used such as home HD or PD, providers need to feel comfortable recommending modalities other than in-center HD. Unfortunately, providers often do not have the proper training to do this.
about 16% felt well trained and competent in the care of home HD patients. This lack of education is reflected in how providers educate their patients on treatment options. For example, a recent study showed that 67% of those on dialysis did not know they had a choice in their treatment modality.

Additionally, patients need to be able to make well informed decisions about their care. This is hard as 35% of ESRD patients “crash” into dialysis. “Crashing” into dialysis means the patient had little to no nephrology care before being unexpectedly admitted to a hospital due to kidney failure. Those that crash into dialysis are often left having to make rushed, life altering decisions, often without enough knowledge about each treatment modality. For example, a study indicated that over 60% of those on in-center dialysis did not know the disadvantages of choosing their modality.

Complicating the patient experience has been the CMS reimbursement model. While changing, it has traditionally been more profitable for dialysis providers to deliver in-center care. For example, Medicare’s monthly payments to physicians for managing the care of patients receiving dialysis at home has traditionally been lower than for managing in-center patients.

The below startups are working to increase patient education, prevent “crashing” into dialysis, and administer more patient-centric models of care such as home HD.

- **Monogram Health**: Monogram Health is focused on slowing the progression of kidney disease. They have created tools that allow for early chronic kidney disease detection. They then deploy care teams that allow for more planned dialysis, reducing the “crash” into dialysis.

- **Cricket Health**: Cricket Health is working to provide comprehensive kidney care. They have created a tool that allows for early detection of chronic kidney disease using claims data. Additionally, they have a focus on patient education to slow the progression of chronic kidney disease.

- **Somatus**: Somatus offers both inpatient and outpatient dialysis treatment. Additionally, they work to provide consumers the education they need to manage their condition.

- **Strive Health**: Strive Health utilizes care teams to reduce hospitalizations and deliver patient centered kidney care. Additionally, they offer both inpatient and outpatient dialysis treatment.

- **CVS/Satellite Healthcare**: CVS Kidney Care and Satellite Healthcare have formed a partnership to bring more comprehensive kidney care and in-home dialysis to patients. Additionally, CVS Kidney Care is working on a new home hemodialysis machine.

### Improving Organ Transplant Supply

Aside from dialysis, organ transplantation is the only other treatment for ESRD. In comparison to hemodialysis, transplants have been shown to lead to better outcomes for patients. For example, the five year survival rate for transplant recipients is 85%. The five year survival rate for hemodialysis patients is 42%.
Additionally, as shown below in Figure 2, transplants are more cost effective treatments than dialysis. For example, HD costs over $80K per patient per year. Transplants cost just under $40K per patient per year.

![Figure 2: Kidney transplants are a more cost effective treatment option in comparison to dialysis.](image)

While transplants are more cost effective and produce better outcomes than dialysis, the organ transplant market suffers from a lack of appropriate supply and misaligned incentives. For example, there were 125K new ESRD patients in 2017, yet there were less than 20K transplants performed. 6

Misaligned incentives of the players in the space have kept more patients than necessary on dialysis. There are four main players in the market:

- **Donor Hospitals**: Donor Hospitals refer patient deaths to organ procurement organizations (OPOs) for possible collection of deceased patient organs.
- **Organ Procurement Organizations (OPOs)**: OPOs are nonprofits who have the responsibility to recover the organs from donor hospitals for transplantation. There are 58 OPOs in the US.
- **Transplant Centers**: Transplant Centers are the institutions that perform the transplant surgery.
- **Living Donors**: Living Donors are patients who voluntarily decide to donate a kidney.

Below is a high level overview of their incentives:

**Donor Hospitals**: Donor Hospitals are responsible for communicating with OPOs about all imminent death candidates. They lack any incentives that would lead them to do more than the required minimum amount of communication with OPOs.

**OPOs**: OPOs are evaluated by CMS every four years on two main criteria, “Donation Rate” and “Organ Yield Rate”. OPOs risk losing their certification if these numbers fall below a certain threshold. 22
• **Donation Rate**: The ratio of actual organ donors / number of “eligible deaths”.
  + This ratio has a few complications, with the largest being that OPOs get to self-report the number of “eligible deaths” and can manipulate the number to hold standing with CMS.

• **Organ Yield Rate**: The ratio of number of organs transplanted / number of actual donors.
  + The ratio of organ yield rate disincentivizes OPOs to pursue every organ donor as older donors have less organs that meet transplant criteria. Obtaining only one organ could potentially draw their ratio number down.

**Transplant centers:** Transplant Centers have traditionally been compensated based on how well transplanted patients recover. This results in many viable kidneys not being transplanted because the transplant center does not want to take a risk on an organ not working well in the recipient. Additionally, there is not a penalty for leaving people on the waiting list.

**Living Donors:** Living donors have traditionally not been compensated well enough for the services they provide. Generally, a donor can have their initial consultation, donation surgery, and post-op care covered by the kidney recipient’s insurance. Yet the donor is not compensated for travel costs or wages lost during the recovery period. This has kept many from donating.

Due to these misaligned incentives, the transplant rates are lower than they could be. For example, it is estimated that there are 17,000 additional viable kidneys that do not get transplanted each year.

In mid 2019, an executive order by Trump set out to align the incentives by putting pressure on OPOs to more accurately report their data. Additionally, the order allows for more flexibility in removing financial burden from living donors. The order also increased funding for efforts to develop artificial kidneys to supplement the donor supply.

The below startups are working to optimize the living and deceased organ supply and create artificial kidneys.

- **OmniLife**: OmniLife is enabling Transplant Centers and Organ Procurement Organizations to seamlessly communicate in order to increase the access of organ transplantation for patients with ESRD.
- **Vascular Perfusion Solutions**: Vascular Perfusion Solutions is working on devices that enable transplantable organs to stay viable outside the donor for longer periods of time.
- **Qidni Labs**: Qidni Labs is building an implantable artificial kidney for those with CKD that enables patients to skip receiving dialysis or waiting for transplantation.
- **US Kidney Research Corporation**: US Kidney Research Corporation is working on an artificial kidney. Unlike traditional dialysis, the team’s technology does not require water or dialysate solutions in order to filter a person’s blood.
SECTION 2:

INVESTMENT RECOMMENDATION
There is opportunity in addressing all of the above challenges (Early detection of CKD, Slowing the progression of CKD, Making hemodialysis more Patient Centric, Improving Organ Transplant Supply). Additionally, an overlooked investment opportunity is in coordinating financial and nonclinical support for patients burdened by CKD.

Patients with ESRD have to deal with a huge shift in their life. As mentioned above, the time commitment of dialysis and side effects make it hard for people to continue to work. This puts many in a difficult financial situation. This difficult financial situation makes it harder for the patients to prioritize their health, which can ultimately lead to worse outcomes.

While government programs exist to help patients if they are unable to work or need additional financial assistance, they are oftentimes burdensome to enroll in. First, understanding what programs are out there can be difficult for a patient to find. Additionally, applying for the benefits can be complicated. For example, when applying for a benefit such as Social Security Disability, a patient first has to determine if they potentially qualify for the benefit. Second, applying requires a patient to gather an extensive list of hard to obtain medical documents that indicate they have kidney failure. Additionally, this work often needs to be replicated in order to apply for more assistance from other programs such as SNAP.

There is opportunity in streamlining the enrollment in government benefits. Startup Uno Health is beginning to work on this opportunity. Easy enrollment in government benefits allows patients to get additional financial support. This support allows patients to have additional resources, which enables them to more easily focus on their care. Focusing on care should improve outcomes and save payers money.
27. United States Social Security Administration https://www.ssa.gov/hlp/isba/10/hlp-isba100-medev.htm