Spring 2020

Walking a Thin Line: Towards a Cautious Implementation of the Advancing American Kidney Health Initiative

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Walking a Thin Line: Towards a Cautious Implementation of the Advancing American Kidney Health Initiative

Senior Project Submitted to
The Division of Social Studies
of Bard College

by
Phoebe Schuyler Brand

Annandale-on-Hudson, New York
May 2020
This project is dedicated to my Uncle George, who passed away this month following a brave battle with cancer (and many skirmishes with the bureaucracy of the United States health care system).
Acknowledgements:

Thank you to my wonderful, intelligent, and caring mother. Your support both emotionally and grammatically is unmatched. I applaud you for not being too resentful of the fact that you had to write your Senior Project with a typewriter and write-out while I get to benefit from the wonders of editing and citation technology. I love you.

Thank you to my advisor, Helen Epstein, whose classes spurred me to pursue a path in the world of public health. Without your example, wisdom, and guidance I would not be where I am today.

Thank you to my board members, Gabriel Perron and Kathryn Tabb, for your support in this process and the knowledge and perspectives you bring to this project.

Thank you to my coworkers at the Rogosin Center for Health Action and Policy (Pamela Hoyt, Sally Girvin, Heather Murphy, Diane Morris, and Karen Meerabux) for all the experience I gained under your guidance. My work with you all and the lessons I learned in my time at Rogosin were fundamental to this project.

Thank you to the Health Ambassadors of Rogosin, for your strength and the example you set for fellow kidney patients and myself.

Thank you to my mentor and friend Bella Mazzetti, for setting such an impressive example in public health education and leadership. I am eternally grateful for your advice, guidance, and compassion in our work together at the Office of Gender Equity and beyond.

Thank you to my academic soulmate, Hannah Henry, for you enthusiasm in all matter public health, for being the best study buddy I could ask for, and for the kindness and compassion you have shown in our friendship.

Thank you to my dear friend Katy Carlson for taking the time to work through my messy editing stages, and for all your love and friendship over the years.

Thank you to my brother Harrison for providing me with distractions and entertainment and for always inspiring me with your talents. Here’s your first academic credit.

Thank you to my amazing friends (Kate, Olivia, Raphael, and Gemma) for listening to my rants about Medicare, kidney disease and public health. And for all our wonderful memories at Bard that had to end too soon.
Table of Contents:

Dedication ................................................................. ii
Acknowledgements ..................................................... iii
Table of Contents ........................................................ iv
Abstract ....................................................................... vi
Glossary ....................................................................... vii
Chapter 1: Introduction ................................................... 1

Chapter 2: Kidney Disease in the United States .................. 5

2.1 Introduction to Kidney Disease in the United States
2.2 Risk Factors and Diagnosis
   2.2.1 Risk Factors and their Role in Prevention and Diagnosis
   2.2.2 Lab Diagnosis
   2.2.3 Prevalence and Incidence
2.3 Medicare and ESRD
2.4 Cost of ESRD in the United States
   2.4.1 Out of Pocket Costs for Patients
2.5 Treatment Options for ESRD in the United States
   2.5.1 Dialysis
      2.5.1.1 In-Center Hemodialysis
      2.5.1.2 Home Hemodialysis
      2.5.1.3 Peritoneal Dialysis
   2.5.2 Palliative Care
   2.5.3 Transplantation
      2.5.3.1 Barriers to Transplantation in the United States
2.6 Discussion

Chapter 3: Literature Review of Global Models and Research .... 31

3.1 Introduction
   3.1.1 State of the Field
3.2 Global Burden of Kidney Disease
3.3 Treatments and Outcomes
   3.3.1 Dialysis Debates
      3.3.1.2 PD First Campaigns
   3.3.2 Transplantation
      3.3.2.1 Opt-in vs Opt-out Systems
3.3.2 Discard Rates
3.3.2.3 Living Donors
3.3.3 Overall ESRD Outcomes
3.3.3.1 Quality of Life

3.4 Costs
3.4.1 Overall Health Care Costs
3.4.2 ESRD Costs

3.5 Differentials in Access and Equity of Care

3.6 Lessons from Global Kidney Care

Chapter 4: Advancing American Kidney Health Initiative

4.1 Introduction to the AAKH
4.2 Initial Responses to the AAKH
4.3 End-Stage Renal Disease Treatment Choices Model (ETC Model)
   4.3.1 Introduction
   4.3.2 Identified Problems the ETC Model Aims to Address
   4.3.3 Methodology
   4.3.4 Components of the ETC Model
      4.3.4.1 HDPA
      4.3.4.2 PPA
   4.3.5 Recognized Limitations
   4.3.6 Projected Effects
4.4 Removing Financial Disincentives to Living Organ Donation
4.5 Reactions of the Kidney Community: Notice and Comment Period
   4.5.1 Clinical Comments
   4.5.2 Patients and Advocates
4.6 Discussion

Chapter 5: Conclusion

Work Cited
Abstract:

Across nearly all categories, the United States kidney care system ranks below its global counterparts. With a high prevalence of kidney disease, poor treatment outcomes, and high expenditures, there is no doubt that the U.S. kidney system needs revamping. In 2019, the Trump administration released the Advancing American Kidney Health Initiative, which, among other things, both restructures the Medicare payment systems for kidney care to incentivize new treatment practices and outcomes and alters the kidney transplant system in an effort to increase transplant rates. Alongside the goal of improving patient outcomes, the proposal seeks to reduce the expenditures of this Medicare entitlement program. While the proposal answers many of the major requests of the kidney community for improvements, the proposal must also be interrogated with the awareness of the Trump administration’s intentions of eliminating such entitlement programs and the general hostility of President Trump towards Medicare. Alongside this potential issue are several pitfalls in the proposal, including lack of transparency for patients, penalization of providers, absence of a safety net for poor and high-risk patients, and, some allege, a potentially risky living donor reimbursement program. This project aims to identify the promising aspects of the proposal alongside the potential risks of this new care model while drawing on the experiences of other industrialized countries in the realm of kidney care.
**Glossary:**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AAKH</td>
<td>Advancing American Kidney Health Initiative</td>
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<tr>
<td>ACA</td>
<td>Affordable Care Act</td>
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<tr>
<td>APD</td>
<td>Automated Peritoneal Dialysis</td>
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<tr>
<td>AV Fistula</td>
<td>Artificially connected artery in a vein, used for easier access to the veins for dialysis</td>
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<tr>
<td>CAPD</td>
<td>Continuous Ambulatory Peritoneal Dialysis</td>
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<tr>
<td>CKD</td>
<td>Chronic kidney disease, abnormality in kidney function</td>
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<tr>
<td>CMMI</td>
<td>Center for Medicare and Medicaid Innovation, otherwise known as the “Innovation Center”</td>
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<td>CMS</td>
<td>Center for Medicare and Medicaid Services</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td>Deceased donor</td>
<td>One whose organs are donated after death</td>
</tr>
<tr>
<td>Dialysis</td>
<td>Removal of wastes from the body, replicating kidney function. Includes peritoneal dialysis, or PD (removal of waste by adding fluid to the abdominal cavity) and hemodialysis, or HD (removal of waste from blood using a machine)</td>
</tr>
<tr>
<td>eGFR</td>
<td>Glomerular Filtration Rate, measures how well a patient’s kidneys are filtering blood by measuring how much of the waste product creatinine as compared to a patient’s age, race, sex and weight</td>
</tr>
<tr>
<td>ETC Model</td>
<td>Proposed End-Stage Renal Disease Treatment Choices Model</td>
</tr>
<tr>
<td>ESRD</td>
<td>End-stage renal disease, when a kidney ceases to function and the patient requires ongoing dialysis treatment</td>
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<tr>
<td>Forum of ESRD Networks</td>
<td>Non-profit organization of ESRD Networks to communicate the national quality agenda on kidney disease</td>
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<tr>
<td>HDPA</td>
<td>Home Dialysis Payment Adjustment, portion of ETC Model</td>
</tr>
<tr>
<td>HHS</td>
<td>Department of Health and Human Services</td>
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<td>HTN</td>
<td>Hypertension</td>
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</table>
LIS  Low-Income Subsidy for Medicare recipients
Living donor  One who consents to donate for transplantation to another person
MPS  Modality Performance Score, of the AAKH
Nephrologist  Doctor who specializes in kidney care
NESRDP  National End Stage Renal Disease Program, established the Medicare entitlement program for kidney disease in 1965
NKF  National Kidney Foundation
NOTA  National Organ Transplant Act of 1984
OPO  Organ Procurement Organization
Palliative care  End of life care that primarily aims to improve the quality of life and manage pain
PPA  Performance Payment Adjustment
PPS  ESRD Prospective Payment System that bundles Medicare payment for dialysis into a single per treatment payment amount
QoL  Quality of Life
UNOS  United Network for Organ Sharing
Urine albumin  Protein present in the urine when the kidneys are not filtering properly filtering, used as an indication of the filtering effectiveness of the kidney.
USRDS  United States Renal Data System
Chapter 1: Introduction

In the United States, one in three adults are at risk for Chronic Kidney Disease (CKD).\textsuperscript{1} The term “Chronic Kidney Disease” encompasses a range of issues with the kidneys, which, when left untreated, can lead to kidney failure, also known as End-Stage Renal Disease (ESRD). The two most common causes of kidney disease in this country are diabetes and high blood pressure, which make up 45\% and 29\% of newly diagnosed cases, respectively.\textsuperscript{2,3} Thirty-two percent of adults in the U.S. have hypertension; \textsuperscript{4} 9.5\% of adults have diabetes.\textsuperscript{5} As a direct result of these high prevalences, at least 37 million people in the U.S. have CKD, and more than 750,000 have ESRD.\textsuperscript{6} Otherwise known as the “Silent Killer,” kidney disease is difficult to detect in its early stages, with some researchers estimating that only half of all patients with CKD are aware of their condition.\textsuperscript{7}

While it is already striking that one in three adults are at risk in the general population, some populations are at even higher risks than others. Odds are already stacked against African Americans, Hispanics, and indigenous peoples to develop kidney disease, as they have both higher rates of diabetes and kidney disease and lower access to health care than their white

\textsuperscript{3} Alongside these two chronic conditions, other factors that can contribute to loss of kidney function are glomerulonephritis (an illness affecting kidney function), genetic diseases including polycystic kidney disease, birth defects, immune diseases, obstructions of kidney functions (i.e. kidney stones), and urinary tract infections.
\textsuperscript{4} “High Blood Pressure Fact Sheet|Data & Statistics|DHDSP|CDC.”
\textsuperscript{6} Ibid.
\textsuperscript{7} Ibid.
counterparts. As such, these groups represent much higher proportions of the kidney disease population than they do the general U.S. population. (African Americans, for instance, make up 35% of all kidney patients but only 13% of the general U.S. population.) Similarly, within the kidney patient population, 71% of individuals aged 18 to 64 on dialysis are unemployed, an exponentially higher proportion than in the general U.S. population.

Once they reach the stage of renal failure, patients must begin dialysis in order to survive. Dialysis works to filter a patient’s blood in absence of normal kidney functions, with the majority of U.S. kidney patients receiving dialysis in dialysis centers rather than at home. The two main categories of dialysis, peritoneal and hemodialysis, differ primarily in the way they filter the blood and the fact that peritoneal dialysis is usually utilized as an in-home dialysis treatment. Strikingly, the United States has one of the highest mortality rates for kidney dialysis patients in the world, at 21.7% in contrast to other industrialized regions such as Japan (6.6%) and Europe (average of 15.6%).

The gold standard for kidney disease treatment, associated with both the lowest long-term costs and best outcomes and quality of life, is the kidney transplant. Unfortunately, due to a combination of low rates of kidney donation from deceased and living donors and the growing

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ESRD population, the current waitlist for a kidney in the United States is five years. As a result, more than 4,500 people die while on the kidney transplant waitlist annually.  

Ninety percent of patients with ESRD are covered under the ESRD Medicare entitlement program created for kidney disease patients in the 1970’s. Today, 7% of total Medicare spending is used for ESRD, despite the fact that ESRD patients make up only 1% of the Medicare population. When combined with spending on CKD, kidney disease patients represent 23% of the total fee for service Medicare spending. As such, reducing expenditures to this program have consistently been a goal for the Centers for Medicare and Medicaid Services (CMS).

As a country with a comparatively high prevalence of, poor treatment outcomes for, and high expenditures on kidney disease, the United States kidney care system has several entry points for revision and improvement. The Advancing American Kidney Health Initiative put forth by the Trump administration in 2019 aims to address several of these goals through a variety of measures and payment models through the CMS. This Initiative will constitute the largest change to this U.S. kidney care entitlement program since its creation in the 1970’s. The two primary aspects of the initiative interrogated in this analysis are the End-Stage Renal Disease Treatment Choices Model (ETC Model) and the Removing Financial Disincentives to Living Organ Donation amendment to the National Organ Transplant Act.

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The primary goal of the ETC is to have 80% of all patients on home dialysis or have a kidney transplant by 2030, and mandatory incentive and penalization systems for providers are the primary mechanism used to accomplish this goal. These payment models also work towards the goal of reducing the expenditures of the Medicare ESRD program. The Removing Disincentives model reimburses living donors for costs such as lost wages, as well as the child care and elder care they may need while going through the transplant procedure to donate to a kidney patient. These reimbursements are meant to increase the number of living kidney donors and thus the number of kidney transplants.

The goals of both of these aspects of the AAKH are consistent with examples, recommendations, and research from other industrialized countries. However, especially in the case of the ETC Model, these recommendations are taken too far, with high benchmarks and extreme incentives that are unaccompanied by the education efforts and transitions needed both to prepare patients and providers for this shift in treatment priorities and avoid adverse outcomes (namely incentivizing treatments that may be inappropriate for many patients). In addition, the Trump administration’s accompanying goal of reduced Medicare expenditures is cause for suspicion. The CMS must walk a fine line between recognizing the dire need for drastic change and implementing such changes too abruptly and without the proper precautions. The following chapters will lay out the current circumstances of kidney disease in the United States and review literature and models of kidney care by our industrialized counterparts. The final chapter is a discussion of the extent to which the AAKH adequately and appropriately addresses the kidney crises in the United States, whether it incorporates the best practices of global models, and how it could best be improved.
Chapter 2: Kidney Disease in the United States

2.1 Introduction to Kidney Disease in the United States

Before embarking on an analysis of Trump’s proposal, a thorough understanding of the structure and make-up of the United States kidney care system is necessary. Within this system, the journey of a kidney patient is a complicated one, both in the nature of the disease and the means by which care is delivered and paid. This chapter aims to outline the larger context of kidney disease in the United States, as well as the experiences of the patients themselves, by illustrating the course and management of this disease.

2.2 Risk Factors and Diagnosis

Ideally, to detect the early and preventable stages of kidney disease, a patient’s annual physicals with their primary physician would include lab tests that assess kidney function. Patients who already have recognized risk factors for developing kidney disease — such as diabetes, hypertension, family history of kidney disease, being older than 60 years, or being African American— should be tested regularly to monitor whether they are showing signs of early-stage CKD. (As discussed below, there are five stages of CKD.) Alternatively, patients may come to a physician with symptoms such as foamy urine, headaches, fatigue, and loss of appetite in order to be diagnosed. However, several factors prevent these opportunities for early diagnosis from occurring.

In symptomatic patients, for instance, many symptoms do not appear until the later and more severe stages of renal damage. Further, many symptoms, such as fatigue and headaches, are so ambiguous that a physician might not immediately relate them to kidney disease. Thus, the
best way to detect CKD is through routine diagnostic testing performed by primary care physicians. However, this oftentimes does not happen in the United States. Populations that do not have access to regular primary care check-ups, including uninsured, low-income, or those simply without the time or opportunities to see their physicians, often miss these essential tests. In 2016, the CDC estimated that only 54.6% of U.S. adults saw their primary care physician for an annual visit. Consequently, it can be assumed that this proportion of U.S. adults also lost the opportunity to be screened for symptoms of kidney disease, as well as for its risk factors, such as diabetes and hypertension. Race is also a primary risk factor for CKD. End-Stage Renal Disease prevalence is 3.7 times greater in African Americans, 1.4 times greater in Native Americans, and 1.5 times greater in Asian Americans than in whites.

2.2.1 Risk Factors and their Role in Prevention and Diagnosis

The two greatest risk factors for kidney disease are diabetes and hypertension. With 32% of U.S. adults suffering from hypertension, and 9.5% of adults suffering from diabetes, a high proportion of the United States adult population is already at risk for kidney disease. Both of these conditions disproportionately affect non-white populations, with diabetes affecting 15.1% of Native Americans and 12.7% of black populations compared to 7.4% of non-Hispanic whites. Hypertension affects 54% of non-Hispanic black adults compared to 46% of non-Hispanic white adults.

The theoretical model in Figure 2.1 portrays how the clinical factors interact with social determinants of health in the development of CKD. (In the figure, CVD stands for cardiovascular

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21 “High Blood Pressure Fact Sheet|Data & Statistics|DHDSP|CDC.”
disease, DM refers to diabetes mellitus, and HTN is hypertension.) This model, taken from the article “Social Determinants of Racial Disparities in CKD,” demonstrates the interactions between these risk factors, which must all be addressed in order for the kidney disease management to succeed.


2.2.2 Lab Diagnosis

Two tests are typically used to assess kidney disease: Glomerular Filtration Rate (eGFR) and Urine Albumin. eGFR measures how well a patient’s kidneys are filtering blood by measuring how much of the waste product creatinine is present as compared to the patient’s age, race, sex and weight. The Urine Albumin test assesses the presence of the albumin protein,
which only appears in urine when the kidneys are not properly filtering it. Both tests can indicate the filtering effectiveness of the kidney.

The five stages of kidney disease represent the severity of damage to the kidneys, with Stage 5 being complete renal failure. It is important to note that barring tests such as eGFR and Urine Albumin, patients usually do not develop noticeable symptoms of kidney disease until later stages, as the symptoms such as nausea, headaches, fatigue, limb swelling, and abnormal urination can easily be mistaken for other health issues.

At Stage 1, eGFR is 90 or greater, meaning that the kidneys are still functioning, but at a lower capacity than normal. At this stage, patients can make simple lifestyle changes to slow the progression of kidney disease, such as exercise and diet changes that benefit blood pressure and blood sugar levels. At Stage 2, eGFR drops to between 60 and 89, which means that the kidneys are still functioning but other signs of damage are likely appearing, such as albumin protein in the urine. By Stage 3, eGFR drops to between 30 and 59, meaning kidney function is decreasing, while other symptoms may also be appearing, such as swelling in appendages, back pain, and unusual urination. Since the kidneys at this stage are not doing their job of filtering wastes, other bodily responses, such as high blood pressure, anemia, and bone disease may occur. At this point, it is recommended that a patient see a nephrologist and dietician to take more drastic steps to prevent further development of the disease; in some cases, patients and doctors may also need to start planning for more advanced stages of the disease and care. Stage 4 occurs when eGFR is between 15 and 30, meaning the kidneys are moderately to severely damaged and are only one stage away from kidney failure. At this point, patients would ideally be meeting regularly with a nephrologist, getting their kidneys checked frequently, and taking angiotensin-converting enzyme (ACE) inhibitors to lower blood pressure and angiotensin receptor blockers (ARB) for
diabetes and high blood pressure management. Conversations with nephrologists will likely now lean towards preparation for kidney failure treatment and the lifestyle changes that come with such a transition.\textsuperscript{22}

Once a patient has progressed to Stage 5, their eGFR is less than 15, and their kidneys have failed. When a kidney has failed, it is no longer filtering waste out of blood, and a patient requires either dialysis to filter blood for them or a kidney transplant. In the vast majority of newly diagnosed cases in the United States, a patient’s kidney disease has already advanced to later stages. As displayed in the graph below, fewer than 10\% of patients diagnosed in 2012 were aware of their kidney disease at Stages 1, 2, and 3; forty-five percent became aware at Stage 4 or had progressed to Stage 4 and were rapidly approaching kidney failure. (Information in that graph was based on data from the National Health and Nutrition Examination Survey.)

![Graph showing percentages of NHANES Participants with CKD aware of their kidney disease, 2001-2012.](https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease)

2.2.3 Prevalence and Incidence

According to the United States Renal Data System (USRDS) report for 2018, there were 124,675 newly reported cases of End-Stage Renal Disease (ESRD) in 2016 and a total of 726,331 prevalent cases of ESRD in the U.S (crude prevalence of 2,160.7/million).\(^2^3\) Since 2011, crude incidence has nearly plateaued, but the age-sex-race-standardized prevalence has risen by 20,000 cases per year, a trend that has continued since 2006. The USRDS attributes this upward trend at least partly to the longer survival of ESRD patients in recent years, which has increased the total population of living kidney disease patients. Other possibilities include the indirect effects of the diabetes and obesity epidemics in the United States. (39.8% of adults in the U.S. suffer from obesity,\(^2^4\) which is also a risk factor for CKD.)

Because so many people do not know they have kidney disease until the final stages, the most common experience for patients is to discover their kidney disease status at the point of late stage kidney failure, either from hospitalization for kidney failure or severe symptoms. Those whose kidneys are no longer functioning (or may soon fail) receive a dialysis care plan, and they are usually enrolled in Medicare for coverage of this costly treatment.

2.3 Medicare and ESRD

Ninety percent of patients with ESRD are enrolled in Medicare.\(^2^5\) In 1972, seven years after the establishment of the Medicare program for the elderly in 1965, the National End-Stage

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Renal Disease Program was established via Section 299I of Public Law 92-603.\textsuperscript{26} The creation of this program was a result of requests from professionals and providers in the field to create a coordinated system for ESRD patients, as well as a response to the discriminatory practices that were being used to decide who could receive dialysis (see footnote).\textsuperscript{27, 28} This Medicare entitlement program functions to cover the high-cost treatments required to keep ESRD patients alive, and as an entitlement program is a guaranteed right for anyone diagnosed with ESRD.

In addition to offering coverage for ESRD patients, this program also serves to coordinate care across the country among the various kidney disease service providers, including nephrologists, dialysis companies, and hospitals. The Forum of ESRD Networks, a non-profit organization that includes all ESRD Networks and was also established in the 1970’s, “facilitates the flow of information and advances a national quality agenda with Centers for Medicare and Medicaid Services (CMS) and other renal organizations,” while also providing services such as quality oversight, data collection, and technical assistance to ESRD providers.\textsuperscript{29} The care and coordination of kidney disease in the United States is shared and organized across and among these various programs.

Since the enactment of the National ESRD Program, the number of eligible patients has grown from 10,000 patients in 1972 to 511,270 patients in 2016.\textsuperscript{30} At the same time, the


\textsuperscript{27} Prior to the creation of this program, in Seattle committees of physicians, nurses and community leaders (later dubbed “God Panels”) were in charge of deciding who would get access to the limited dialysis machines available. They would make this decision based subjectively off of the patient’s anticipated contribution to society, a practice later deemed unethical, spurring the creation of this entitlement program to guarantee treatment to all kidney patients.


Medicare ESRD coverage program expanded to include the 2011 CMS-implemented ESRD Prospective Payment System (PPS), which “bundled Medicare’s payment for renal dialysis services together with separately billable ESRD-related supplies ... into a single, per-treatment payment amount.” This includes coverage for three or fewer dialysis treatments per week and payment adjustments according to geographic area for “health care wages and facility sizes.” It also reduced overall fees by 2%. No other major changes have been made to the system since its establishment. As such, the proposed revisions to the kidney care system put forth by the Trump administration will be the largest revamp of this system since its establishment.

### 2.4 Cost of ESRD in the United States

Seven percent of total Medicare spending is used for ESRD, despite ESRD patients making up only 1% of the Medicare population. When combined with spending on CKD, kidney patients account for 23% of the total fee for service Medicare spending. Put another way, CKD spending in 2016 exceeded $79 billion, and ESRD spending exceeded $35 billion, for a total of $114 billion in 2016. ESRD spending has been rising at a steady rate since 2004, at a rate of about 4% most years, including 2016. In contrast, CKD spending increased by 23% since 2015, which “has primarily been driven by an increase in the number of identified cases, particularly those in the earlier stages (CKD Stages 1-3)” according to the US Renal Disease Data System (USRDS).

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31 Ibid.
32 Ibid.
33 “V2 CH9 Healthcare Expenditures for Persons with ESRD,” 2.
35 Ibid.
The cost of kidney disease care and management varies by treatment type. Peritoneal dialysis is the cheapest treatment, at $76,177 per year per patient. Hemodialysis, in contrast, is $90,971 per year per patient. The treatment with the lowest cost, and the one associated with the best outcomes and quality of life, is the kidney transplant, at $34,780. This is the most cost-effective treatment, as most patients do not need to continue any form of treatment following the procedure. It is for this reason that Medicare eligibility ends for patients that have received a transplant and discontinued dialysis (36 months after the transplant).36

Overall, across the board government spending on kidney disease has increased in recent years. Between 2011 and 2016, transplantation costs increased by 51%, while hemodialysis cost increased by 78% for ESRD patients, in contrast to the 16% increase per capita in that same period for general Medicare beneficiaries. One cause of this sharper increase in kidney disease spending is pharmaceutical costs, with per patient per year pharmaceutical spending for kidney beneficiaries being 4.1 times higher than for the general Medicare population.37 According to the US Renal Data System, who published these findings, “the reasons for this disparity in drug cost growth are unexplained.”38

2.4.1 Out of Pocket Costs for Patients

Under Medicare, approximately 80% of the costs for kidney disease treatment are covered. More specifically, Medicare coverage for kidney disease is divided into three parts, two of which are mandatory and one of which is voluntary. Part A of Medicare covers in-patient care, such as that occurring in a hospital, nursing home, or hospice facility. Part B covers the majority

37 Ibid, Figure 10.5a.
of medical services for kidney patients, including dialysis and the necessary immuno-suppressants required for transplantation. Parts A and B are mandatory when enrolled in Medicare; Part D covers pharmaceuticals and is the only voluntary aspect of Medicare ESRD coverage (i.e., patients may choose to opt-out of Part D if their employer-based insurance covers pharmaceuticals already). For kidney patients, out-of-pocket costs for pharmaceuticals are lower as a proportion of total spending than their general Medicare population counterparts, but because ESRD total costs are so much higher than other diseases, the actual amount spent by ESRD patients is higher.

In terms of actual out-of-pocket costs incurred by ESRD patients, under Medicare coverage, Part A covers the cost of kidney transplants or dialysis once the deductible of $1,408 is met. Part B covers hospital fees for transplant surgeons, with a monthly premium of $134 in 2017, an annual deductible of $183, and a coinsurance of 20%. Similarly, outpatient dialysis and home dialysis are covered under Part B, again with a 20% coinsurance.

Medicare beneficiaries with kidney disease also qualify for the Low-Income Subsidy (LIS), with a higher proportion of kidney patients receiving LIS (50.3%) than in the general Medicare population (30.2%). The LIS significantly drops the price of pharmaceuticals under Part D, with annual medication costs for non-LIS patients averaging at $1,091 versus $135 for LIS patients.

40 A note on the Medicare Donut Hole Coverage Gap: Kidney patients are vulnerable to the Donut Hole Coverage gap, in which they may have to pay up to 50% of prescription drug costs. The Affordable Care Act brought this coverage gap down from previous situations where patients were sometimes responsible for 100% of prescription drugs costs.
41 “ESRD Medicare Costs and Coverage - Medicare Interactive.”
42 Ibid.
2.5 Treatment Options for ESRD in the United States

Once enrolled in Medicare, a kidney patient must decide which treatment option to choose. In order to survive without a functioning kidney, they must begin a form of dialysis, and if they wish, they can enroll for the kidney transplantation waitlist. Trends in distributions of modality choices have remained relatively stable since 1980, as shown in Figure 2.4 from the USRDS database, paralleling the overall increase in total treated ESRD cases. There have been no significant changes in the suggested or preferred treatments in the U.S. over the past 40 years. Outcomes of the three main forms of treatment (hemodialysis, peritoneal dialysis, and transplant) have improved slightly since 1997. For hemodialysis, five-year survival rates have improved from 0.30 to 0.35, with a more rapid gain witnessed for peritoneal dialysis at 0.29 to 0.41. Transplantation survival rates have risen from 0.65 to 0.73. ^43


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2.5.1 Dialysis

Patients can choose from two general types of dialysis — hemodialysis and peritoneal dialysis — with options to perform the dialysis either in home or in a clinic setting. When faced with the task of choosing which dialysis to embark on, patients have several factors to consider, including price, lifestyle, proximity to dialysis centers, accessibility, support systems at home, time, and more. Some patients weigh the expected life expectancy on the various forms of dialysis against the option of receiving palliative care off dialysis as they make decisions about care. According to the NKF, depending on a patient’s overall health, age, and medical conditions, average life expectancy is 5-10 years on dialysis, although many patients can live up to 20-30 years.\[^{44}\] Mortality rates differ between modalities, as do quality of life measures. On top of this, professionals in the field will have opinions, and in some cases incentives, that affect how they promote certain treatments over others.\[^{45}\]

Whether a patient is primarily undergoing in-center dialysis or home dialysis, the dialysis center is oftentimes the hub for the patient’s kidney care team, as it houses nephrologists, nurses, renal dieticians, technicians, and social workers, especially if it is a hospital-based setting. If a patient is conducting home dialysis, they are required to visit their care team at the center at least once a month for lab work and general check-ins.


\[^{45}\] Reasons for physicians to suggest certain modalities include professional opinions, as well as incentive programs offered by governing agencies for certain modalities, such as those put forth by CMS.
2.5.1.1 In Center Hemodialysis

In hemodialysis, a patient’s blood is filtered to remove waste and water with the support of a machine called a dialyzer. While filtering, the system also controls blood pressure and imports necessary minerals such as potassium, sodium, and calcium. Oftentimes, when beginning hemodialysis, a patient also gets an arteriovenous fistula, which is an artificial connection between an artery and a vein, implanted through a minor surgical procedure. This allows for easier access to the veins for dialysis. Patients receiving dialysis in a dialysis center generally need to go three times per week to remain comfortable and avoid kidney failure. Each visit lasts approximately four hours, thus taking up approximately 12 hours of a patient’s schedule each week, not including travel. When choosing a dialysis center, patients need to

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consider accessibility, proximity, transportation, and dialyzing shift schedules that work with the patients’ schedules.


In the U.S., the majority of ESRD patients (63.1%) use hemodialysis. Ninety-eight percent of these hemodialysis patients receive their treatment in a dialysis center rather than at home. In 2015 there were 6,592 dialysis centers of varying categories in the U.S., including private for-profit, non-profit, religiously affiliated, and government affiliated, some being located in hospitals but many in individual locations. The two largest dialysis companies are Davita and Fresenius. Together they control more than 80% of the dialysis market; most of their

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revenues come from the clinics.\textsuperscript{49} The monopolies held by these companies, and the incentive to profit from in-center dialysis, has been identified as a primary issue within the kidney care system in the U.S.

2.5.1.2 \textit{Home Hemodialysis}

A patient may also perform hemodialysis in their home. In order for this to be possible, several factors are necessary. Before even starting this process, a patient must undergo training to learn how to dialyze outside of a clinic and how to identify common problems such as infection. In addition, patients need to set up a space in the home that is dedicated to the dialyzing process, that can be kept sanitary to store supplies, and that has a water source for the machine. In some cases, special electrical and plumbing systems also may be needed.

Such requirements can create a number of barriers for patients. Low-income patients, for instance, may not be able to set up a dedicated space in their house or even have a stable housing situation to begin with. In addition, it is highly recommended that the patient have a caregiver in the home who is also trained to help with the process, referred to as a “care partner.” This figure is not always present for many patients. Because there are no medical professionals involved with in-home dialysis, anxieties over infection and error are a common barrier to choosing and implementing this treatment. In addition to the barriers noted above, some patients remain on in-center dialysis due to the “friendship and camaraderie” developed in the in-clinic dialysis setting.\textsuperscript{50}


\textsuperscript{50} “Choosing Dialysis: Which Type Is Right for Me?,” National Kidney Foundation, August 8, 2019, https://www.kidney.org/atoz/content/choosing-dialysis-which-type-right-me.
If a patient is trained and the proper accommodations are made in their home, however, there are many aspects of in-home dialysis that may be preferable to in-center treatment. Patients can dialyze more often when at home, for instance, as many as five to seven times a week, which is associated with better outcomes and general quality of life. Many patients also feel more comfortable receiving the treatment in their home. This is especially true for patients who have mobility handicaps and would require transportation to in-center dialysis. Time constraints are also alleviated, because the patient chooses the time of day they are dialyzing.

2.5.1.3 Peritoneal Dialysis

The third option for patients is peritoneal dialysis, performed outside of a clinic. Through a minor surgery, peritoneal dialysis patients have a small catheter placed in their abdomen, through which a sterile cleansing fluid is pumped into the belly. This fluid collects toxins and wastes and is then drained. This can either be done through Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD). CAPD is machine free (as shown in Figure 2.7), and the actual detoxifying process occurs throughout the day, with the fluid being drained periodically. The draining process is done four to five times in a 24-hour period, each exchange taking about 30 to 40 minutes.

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Alternatively, the APD method uses a dialyzing machine that delivers and drains the fluid automatically. Many patients opt to do this while they are sleeping, as shown in Figure 2.8.

Peritoneal dialysis is preferred for some patients due to the clear benefits for mobility and travel, improved quality of life from frequent dialyzing, absence of needles, and the fact that the process generally takes less total time than in-center hemodialysis. Some drawbacks of peritoneal dialysis include that: it must be done every day; it may trigger body image issues related to the catheter and fluid retention; it can cause difficulties in controlling blood glucose if the patient has diabetes; it requires storage space and training time; and there is potential for an infection at the entrance site of the catheter if it is not monitored properly.\textsuperscript{52, 53}

\textsuperscript{53} “Choosing Dialysis.”
2.5.2 Palliative Care

With the mean age of the United States kidney disease population being 64.6, a significant portion of kidney patients are considered elderly. Considering the comorbidities that come with age and the progression of kidney disease, such as cardiovascular disease and congestive heart failure, elderly patients tend to have less successful experiences with dialysis. Additionally, the quality of life accompanying a rigorous dialysis treatment plan has proven to be less favorable than a hospice style of care where palliative care is enacted. As defined by the World Health Organization (WHO), palliative care is an “approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and...assessment and treatment of pain and other problems, physical, psychosocial and spiritual.”

Symptom management in this case can include treating the effects of high blood pressure, heart disease,

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diabetes, depression, and anxiety, so that patients remain physically and emotionally comfortable. Both hospice care and palliative care are covered under Medicare.

As cited in the 2015 study, “Palliative and end-of-life care issues in chronic kidney disease,” research has found that for older and frailer patients, dialysis is not beneficial. Instead, the authors found, conservative management of these patients’ symptoms allows for “better preservation of function and quality of life and with fewer acute care admissions,” with many of these patients actually living as long as those who did opt for dialysis. Such findings that dialysis may in fact worsen the symptoms for older patients make a strong argument for the inclusion of hospice and palliative care in more discussions of care options.

2.5.3 Transplantations

For many patients, the gold standard for kidney disease treatment is a kidney transplant. Patients who receive kidney transplants are more likely to live longer than those who remain on dialysis (see Figure 2.9) and also are able in many ways to return to what life was like before their diagnosis of kidney disease (as long as they maintained a healthy lifestyle to support the new kidney, of course). Patients may receive a kidney from a deceased donor or from a living donor with whom they are matched. Currently, 215,061 people are living in the United States with a kidney transplant, making up 29.6% of all prevalent ESRD patients.

Although transplantation is considered the optimal treatment, the process for receiving a kidney transplant is long and complicated. In 2018, 21,167 kidney transplants were performed.

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However, as of December 4, 2019, 103,392 patients were on the United Network for Organ Sharing (UNOS) kidney waitlist, with an average wait time of five years.

UNOS is a private, non-profit organization contracted by the federal government to manage organ donation and transplantation in the United States.\(^{58}\) The organization’s responsibilities include maintaining the database of organ transplant data, monitoring organ matching, and educating and providing assistance to transplant professionals on allocation policies and procedures. When a patient is referred by their doctor for a kidney transplant and passes the required physical, mental, and financial assessments, they can be added to this national waitlist.\(^{59}\)

\(^{58}\) Notably, the United States operates under an “opt-in” organ donor program, in which people are automatically not organ donors and must choose to be one in their registration process. Other countries, such as Spain, have “opt-out” systems, where everyone is automatically registered as a donor, and in order to not be listed one must opt-out.

Organ Procurement Organizations (OPO’s) are non-profit organizations that help coordinate the procurement, matching, and distribution of deceased donor organs in their geographic regions. There are 58 OPO’s in the United States, all of which are administered by UNOS. In order to increase their chances of receiving an organ, many patients list themselves within multiple OPOs, not just the one in which they reside. Other patients are unable to access multiple OPOs due to financial and other barriers, however, including not having the time to travel to do consultations with transplant teams in other geographic regions. Patients listed in distant OPOs must also have both the flexibility to travel there in a short period of time in the event an organ becomes available and the means to leave at a moment’s notice.

When a deceased organ becomes available, the OPO must first determine the quality of the donated kidney. Factors taken into account include age, blood type, cause of death, and history of hypertension or diabetes. Once the kidney is deemed usable, the OPOs use their database to determine who on the kidney transplant waitlist is a) a match with the donor and b) scores the highest based on a series of factors regarding who needs the kidney first. Those factors include age, how long they have been on the waitlist, and how long they have been on dialysis. Essentially, a standard of medical urgency is used to allocate the organ to the sickest patient first.

The living donor matching system also occurs through UNOS. Several regulations govern the allocation of living organs. One critical piece of legislation to this research is the National Organ Transplant Act (NOTA) of 1984, which, alongside a ban on the sale of organ parts,
forbids the exchange of organs for “valuable consideration.”\textsuperscript{62} NOTA, which also governs OPO’s and UNOS, does not include in its definition of valuable consideration “the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.” For this reason, grant programs in the United States such as the National Living Donor Assistance Center (NLDAC) have provided reimbursements to a small number of living donors who require assistance in order to mitigate the financial barriers associated with living donation. (This is further discussed in the following section.)

Many patients conduct their own informal campaigns to find living donors, as seen below in Figures 2.10 and 2.11. These campaigns urge family, friends, and community members to become registered so that the patient may create a network of potential matches. The desperation present in many of these campaigns stems from the long wait times for kidneys. While it varies greatly by OPO, the current average wait time for a kidney is five years, although that wait time may be shorter or longer depending on the locations in which the patient is registered.\textsuperscript{63} In 2014, 4,761 patients died while waiting for a kidney transplant, and 3,668 patients lost their places on the waitlist after becoming too sick for a transplant.\textsuperscript{64}

\textsuperscript{62} National Academies of Sciences et al.

Some patients are lucky enough to find a living donor who is both willing and able to undergo the surgery. Twenty-eight percent of kidneys transplanted in 2016 came from living donors, which are correlated with higher graft survival rates (and thus successful transplants) than kidneys transplanted from deceased donors (98% and 93%, respectively). Kidney transplantation surgeries are covered by the recipient’s insurance. In the case of Medicare, 80% of the costs of kidney transplantation for the recipient are covered. While the living donor does not incur any of the costs associated with the surgery itself, other costs naturally accrue, such as lost time from work, child care, and general recovery time. This is a primary barrier to a larger pool of living donors, and, as will be discussed in the following section, adversely affects certain socioeconomic groups more than others.

2.5.3.1 Barriers to Transplantation in the United States

The United States currently operates under an “opt-in” organ donor system, meaning that all people are presumed to not be organ donors, and therefore must register to become a donor. This is opposed to “opt-out” systems that other countries use, where all residents are considered donors unless they decide they do not want to be registered as such. Many see this as a primary barrier to decreasing wait times and increasing kidney transplantations in the United States, although transitions to such a system would be a large undertaking. Global models for this transition are discussed in Chapter 3.

In the United States, lower-income populations face more barriers both to being living donors and to finding living donors. If an ESRD patient is in a lower-income group, it can be assumed that a significant portion of their family and friends will be in the same or similar income group. Low-income groups are more at risk for diabetes, hypertension, tobacco use, and

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substance abuse, which are risk factors for kidney disease and also disqualifying factors for becoming donors.

Because living donors are largely friends and family members, economic barriers are particularly poignant for low-income patients’ potential living donor pool. Barriers such as lost work hours and wages, as well as child care or elderly care costs incurred during the surgery and recovery period, may prevent lower-income people from becoming living donors even if they want to. Uninsured individuals also have more cause for concern as donors, due to the fact that consequential post-donation complications may be deemed unrelated (and thus not covered under the recipient’s insurance). This puts them in danger of incurring large medical bills. The intricacies of this conundrum, as well as the possible solutions, will be analyzed in Chapters 3 and 4.

2.6 Discussion

In recent years, analysts, policy makers, and advocates have highlighted several aspects of the kidney disease system that are in need of advancement and innovation. Issues in diagnostic and prevention practices include the lack of community-specific interventions for at-risk communities, as well as proper education initiatives that promote awareness of the disease. At the treatment level, home peritoneal dialysis is considered to be underutilized, and transplantation is a lengthy and complicated process that is not accessible to all patients. Palliative care is also underutilized, especially given the large number of kidney patients who are elderly, and the comfort palliative care can provide while maintaining similar mortality rates to dialysis for many patients.
But how do our global counterparts fare when it comes to the management and treatment of kidney care? Notably, the United States has one of the highest mortality rates for kidney dialysis patients in the world, at 21.7% in contrast to other industrialized countries and regions such as Japan (6.6% mortality rate) and Europe (average of 15.6%). Studies have identified several areas where the United States is particularly behind its global counterparts, including compliance with treatment regimen, nutritional practices, staffing, care, and patient education, despite our higher prevalence of kidney disease and higher government expenditures on kidney disease. The following chapter will examine how comparable industrialized countries deliver kidney care, and thus what may be learned from their care models.

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Chapter 3: Literature Review of Global Models and Research

3.1 Introduction

Worldwide, it is estimated that nearly two million people have End-Stage Renal Disease (ESRD). However, the causes of this disease, the experiences of the patients, the treatments, and the outcomes of the treatments vary widely globally. Diagnosis, prevention, and detection are largely dependent on the health care and care coordination systems of each country, and some countries face even larger barriers to successfully treating ESRD due to the genetic makeup of their populations or broader ongoing health crises. Prevalence of ESRD varies 30 fold among reporting countries, and the range of treatment options and preferences is equally wide. Certain regions emphasize home dialysis, for instance, (especially peritoneal dialysis) at much higher rates than the United States. In addition, some countries have succeeded in providing kidney transplants to more of their kidney population than the US does, largely through revisions to the organ donation system itself.

While the contrasts and ranges of experiences worldwide are complex, the circumstances of ESRD in the United States are striking when compared to its global counterparts. Patients with ESRD from the United States make up 29% of total prevalent cases worldwide, despite making up only 4.25% of the world population. What is it that other industrialized countries are doing to achieve lower rates of kidney disease, attain better outcomes, provide more transplants, and manage care in more cost-effective ways?

Analysis of ESRD prevalence, treatment, and outcomes in the chapter consistently focuses on three countries: Australia, Japan, and Canada. This is due to several factors, including

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the abundance of research from those three countries, their positions as models of efficacy in the
global kidney community, and their usefulness — as industrialized countries — in producing
comparative data for analyzing the United States’ own efficacy. Some analyses also incorporate
data from unique projects or circumstances in other countries, as well as relevant international
comparisons and research conducted in the United States.

3.1.1 State of the Field

For industrialized countries with solid health care systems, there remain a few universally
recognized priorities for improving kidney care. In developed countries, the growth of the
population aged 65 and older is an imminent issue in regards to the capacity of the healthcare
systems to manage their care. In addition, lack of routine testing for kidney disease has led to a
large population of undiagnosed people living with the disease worldwide. Lastly, kidney disease
is consistently incredibly costly, with high-income countries spending an average of 2-3% of
their health care budgets on the disease, despite the kidney disease populations representing on
average only 0.03% of their populations.69

Inconsistencies in data collection and the transparency of health care systems within
different countries pose challenges to international comparative research, but several
organizations and research teams have managed to make such comparisons a priority. For
example, the International Society of Nephrology is working to compile an ongoing Kidney
Health Atlas, a cross-sectional survey of 160 participating countries aimed at estimating the
“global burden of ESKD and capacity for care delivery across countries and regions.”70

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69 “WHO | The Global Burden of Kidney Disease and the Sustainable Development Goals,” WHO (World Health
70 Bello AK, Levin A, Lunney M, Osman MA, Ye F, Ashuntantang G, Bellorin-Font E, Benghanem Gharbi M,
the International Society of Nephrology on the Global Burden of End-Stage Kidney Disease and Capacity for
Kidney Replacement Therapy and Conservative Care across World Countries and Regions” (International Society of
organization aims to provide international guidance and recommendations by synthesizing these findings, while also providing crucial information to the kidney community at large. Thus far, the ISN has published two summaries of their findings: the 2017 and 2019 Global Kidney Health Atlases, which provide key findings on the current and predicted burdens of kidney disease worldwide, as well as recommendations for both global leaders in kidney care and national priorities in regards to kidney disease management. These recommendations include: increased financing for ESRD prevention and management; increased multidisciplinary collaboration to address workforce shortages; collection of quality indicators; expansion of health information systems; and promotion of ESRD prevention and treatment by “implementing policies, strategies, and advocacy and mitigating barriers.”

All industrialized countries share these issues. In stark contrast to the United States, however, other industrial countries have managed to reduce the prevalence of ESRD while improving the management of the disease and both the quality of life and outcomes for its patients. Whether these successes stem from superior health care structure and delivery, utilization of different treatments, or some combination of the two, the United States stands to learn much from other countries if it wants to improve conditions around kidney disease for its citizens.

3.2 Global Burden of Kidney Disease

Incidence and prevalence rates of kidney disease are predictably varied across the world, but the United States consistently ranks high in both categories. The United States ranks second in incidence rate of treated ESRD (meaning newly diagnosed cases of ESRD), at 378 cases per

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71 Ibid, 121.
million population, second only to Taiwan. At 2,196 ESRD cases per million population, the United States’ prevalence rate (meaning the proportion of people who have the disease) ranks third behind Taiwan and Japan. By comparison, 13% of countries have prevalence rates of <500 per million population, although analysis of such low rates must always take into consideration the possibility of underreporting.

*Growth* in kidney disease incidence rates over recent years must also be considered in analyzing the global burden of kidney disease. While nearly half of all countries contributing to the USRDS International Comparisons have reported relatively stable incidence rates of ESRD since 2003, roughly 30% of countries had incidence rates that rose by two to four percent per year, including the United States. The United States had a 2% increase in ESRD prevalence from 2003 to 2016.

For some countries, increases can be attributed to aging populations and higher rates of diagnosis, which are often the result of awareness campaigns and screening projects. Thus, these increases may be reflecting an increase in diagnosis and reporting, rather than an actual increase in people suffering from kidney disease. This is considered to be the case in the United States. Notably, the United States also ranks 4th in incidences of treated ESRD attributed to diabetes as the primary cause, with 176 cases per million population.

It is clear that the United States is outranking its global counterparts when it comes to prevalence, while also being in the highest category of countries in terms of the rates of increase of ESRD. The answer to these high rates lies partially in the upstream causes of kidney disease in the United States.

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3.2.1 Causes of Kidney Disease

The number one cause of chronic kidney disease worldwide is diabetes mellitus, with the other leading causes being hypertension and obesity. Worldwide, the prevalence of diabetes rose from 4.7% in 1980 to 8.5% in 2014. The United States witnessed a more drastic increase; its CKD prevalence grew from 2.54% in 1980 to 7.4% in 2014. The United States ranks third in prevalence of diabetes and 4th in incidence of treated ESRD due to diabetes as the primary cause. These numbers reflect the reality that the United States faces greater pressure due to the connection between the diabetes epidemic and kidney disease rates than other countries.

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75 “Chapter 11: International Comparisons,” 11.
How does the cause of kidney disease differ in other countries? In the case of Japan, the answer lies in a genetic predisposition of people of Japanese descent to have fewer nephrons (the filtering agent of the kidney).\(^77\) It is for this reason that Japan consistently ranks above the United States in incidence and prevalence. As Japanese Americans make up only 5.6% of the U.S. population, their genetic predisposition can only partially explain the high rates in the United States, although it is a reality to take into consideration.\(^78\)

Also important to the U.S. context is the fact that those of African descent are both genetically at risk and more susceptible to ESRD. A 2011 study found that a particularly high percentage of African Americans with non-diabetic ESRD have genes related to renal failure susceptibilities.\(^79\) On top of this genetic foundation of susceptibility, African Americans are disproportionately vulnerable to diabetes (11.7% of blacks have diabetes compared to 7.5% of non-Hispanic whites).\(^80\) African Americans comprise 13.4% of the United States population, but 35% of all patients receiving dialysis in the United States, clearly showing that, the effects of the diabetes epidemic, compounded with the presence of genetic predispositions, contributes to the high prevalence rates of ESRD of the United States.\(^81,82\) Rates in African countries are significantly lower than in the United States. This can be largely attributed to underreporting, but

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it remains the case that the disproportionate burden of diabetes, hypertension, and kidney disease on African Americans cannot be solely explain by genetics.

As the industrialized country with the highest prevalence and incidence rates in diabetes and second highest in ESRD, it is clear that the United States does not have a higher burden of kidney disease merely due to underlying genetic reasons (as is the case with Japan). Rather, the U.S. bears a greater burden of the worldwide diabetes crisis and, thus, also a greater burden of the global ESRD crisis. The genetic susceptibility of certain population groups also contribute to a smaller degree to this higher rate of ESRD (albeit on a smaller scale) as do disproportionate rates of other comorbidities — such as diabetes and hypertension — in minority populations.

But once patients in the United States are diagnosed with ESRD, how do their experiences in treatment differ from those in other industrialized countries?
3.3 Treatments and Outcomes

Figure 3.2 “Percentage distribution of type of renal replacement therapy modality used by ESRD patients, by country, in 2016”, USRDS “Chapter 11: International Comparisons” 2 (2018): 11.
One of the starkest points of contrast in global experiences of kidney disease is that of preferred treatment modalities. The above table displays the range of distributions of treatments for kidney patients, from Japan with almost 90% of their population receiving in-center hemodialysis to Norway having more than half their patients receive transplants. The United States places in the middle range for most treatment options, contrasting with other countries that rely heavily on one treatment or another in their national kidney agendas and consequently their treatment distributions. While to a certain extent a range of treatment distributions is to be expected, considering each treatment's merits for different patient populations\(^83\) such stark differences should be seen primarily as a result of national kidney policies. As will be revealed in this section, the distribution of treatments can be heavily altered by national agendas and incentive programs.

In this next section, the individual merits of the treatments utilized by different countries will be investigated along with the reasons for differing outcomes across treatments for kidney patients by country. It will prove, once again, that the United States is an outlier when it comes to utilization of several treatment options.

### 3.3.1 Dialysis Debates

According to the 2018 USRDS report, the most common ESRD treatment for 80% of all countries was in-center hemodialysis, as it is in the United States.\(^84\) While variation in treatment modalities is evident around the world, the variation in dialysis utilization worldwide is particularly pronounced. This is especially the case with in-home versus in-center dialysis, with


\(^84\) "Chapter 11: International Comparisons", 11.
regions like the U.S. having low rates of home dialysis (12%) and others having rates as high as 74%, as is the case in Hong Kong.\textsuperscript{85}

There are a variety of factors that can contribute to this range of dialysis distributions. One primary factor is the cost of each dialysis, which itself varies across countries depending on the cost of equipment (i.e., whether the equipment is manufactured in the country or imported). In addition, with research constantly revealing the differing outcomes of the various dialysis treatments, countries may push to adopt other dialysis treatments to improve patient outcomes (or to reduce the costs associated with poor outcomes). Depending on these factors, governments and health care systems can influence the utilization of their preferred treatment choices through publicity campaigns and incentive systems, as the United States is attempting to do in the ETC Model.

3.3.1.2 PD First Campaigns

One prime example of government campaigns to promote a single dialysis modality is the string of “PD First” (meaning “peritoneal dialysis first”) campaigns seen across the Asian Pacific, including in Hong Kong and Australia. In these campaigns, peritoneal dialysis is promoted as the first suggestion to patients, with health care providers and government agencies supporting this method of home dialysis collaboratively, largely for its merits as a “more convenient and resource-conscious option” and, by extension, a cost-saver.\textsuperscript{86} In the case of Hong Kong, their pioneering PD First campaign, which started in 1985, has led them to attain 74% home dialysis utilization. This is a stark contrast to the United States.


How do patient outcomes compare for in-home peritoneal dialysis compared to the in-center hemodialysis on which the United States most relies? In their 2013 article “Peritoneal Dialysis First Policy Made Successful: Perspectives and Actions,” Philip Kam-tao Li and Kai Ming Chow analyzed the ever-increasing number of countries pushing peritoneal dialysis as the preferred modality of choice. The authors found that PD First campaigns led to improvements including “patient survival, retain(ed) residual kidney function, lower infection risk, and increase(d) patient satisfaction while reducing financial stress on governments.”\(^87\) In regards to Quality of Life indicators, peritoneal dialysis patients reported “less illness intrusion, better renal care, higher satisfaction, and the ability to travel.”\(^88\)

In conclusion, the merits of peritoneal dialysis shine through especially in the realm of cost savings and patient quality of life and autonomy. PD First campaigns are slowly spreading across the world, and notably the Trump ETC Plan, while not explicitly calling itself a “PD First” campaign, is based on similar goals.


\(^{88}\) Liu et al., “A Global Overview of the Impact of Peritoneal Dialysis First or Favored Policies.”
3.3.2 Transplantation

Figure 3.4. “Distribution of the percentage of kidney transplantations by kidney donor type and country, 2016”, USRDS “Chapter 11: International Comparisons,” 11.
Differences in transplantation rates, sources, and allocation systems are widespread across the world, with the United States ranking on the lower end of the spectrum at 39 out of 61 reporting countries in 2016. While transplantation will always be limited by the sheer constraints on supply, in 25% of the countries included in the US Renal Data Survey’s International Report 50% to 70% of treated ESRD patients are living with a kidney transplant.

The United States’ transplantation system differs from that of other countries in several ways. As described in Chapter 2, the United States requires residents to opt-in to become a deceased donor. Other countries, such as Spain, automatically register all residents to be organ donors, and residents who do not want to be deceased donors must actively opt-out. The United States also has what is considered a more cautious approach to organ harvesting. As discussed later in this chapter, 18% of deceased kidneys processed in the U.S. were discarded in 2016, whereas in the European Union the average discard rate was only 10%. To put these numbers in perspective, this means that 3,500 donated kidneys are discarded every year in the United States.

Of relevance when discussing global models for transplantation is the illegal and unregulated international organ market and the issue of transplant tourism. Unfortunately, the United States’ paucity of organs is not an issue isolated to our geographic boundaries, with kidney patients constituting the largest proportion of those seeking transplants elsewhere. For example, nearly two-thirds of kidney transplants performed in Pakistan were for foreigners.

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90 “V2 CH6 Transplantation,” 6.
This must be considered a direct consequence of the lack of organs in countries like the United States, and the desperation of kidney patients that drives them to seek organs through illegal and unethical routes. Thus, increases in available organs and reductions in waitlist times here could result in benefits to those exploited and unfairly compensated in unsafe and unregulated settings abroad.

The nuances of the organ harvesting systems and associated legislation are detailed in the following sections, outlining the three main ways that other countries alter their transplant systems to achieve higher transplant rates and reduce wait list times.

3.3.2.1 Opt-in vs. Opt-out Systems

While many countries in Europe, including France, Italy, and Spain, are opt-out organ donation systems, the United States has remained in an opt-in system, despite several state-led attempts to make changes. Legislators in New York, Delaware, and Colorado have failed in passing opt-out legislation, due largely to protests from religious groups, such as the Orthodox Jewish population of New York, or fears of encroachments on constitutional and personal rights. Interestingly, the two prominent legislators who have pushed for presumed consent policies either had kidney disease or had close family members with kidney disease in need of transplants.93

Consistently, countries with opt-out systems have higher rates of transplantation than the United States.94 In terms of the potential of an opt-out system to increase available organs and thus organ transplant rates in the United States, predictions are varied. A recent study by the University of Michigan found that the waiting list in the United States would only be marginally

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decreased if the country transitioned to an opt-out program. However, the secondary effects of this waitlist reduction would be an exponential increase in the longevity of transplant recipients, with kidney transplant candidates gaining the most life years out of any patient group.95

Another article from Stanford argues that countries with “no religious or cultural beliefs that discourage organ donation” would be the prime candidates for transitions to opt-out systems as a means of reducing waitlist times. As has been proven in the state-led attempts to transition to presumed consent policies, following this recommendation the United States is not currently in a place to make the transition due to the underlying beliefs of religious and political groups.96

3.3.2.2 Discard Rates

One contested subject in the realm of kidney transplantation is that of the criteria and standard held for deceased donor kidneys. As mentioned earlier, the United States has a high standard for donated kidneys and thus a higher discard rate than countries in the EU (18% versus 10%, respectively). The types of criteria that some countries are more lenient on than the United States include factors such as the age of the donor. Transplantation specialists in Norway, which has the highest transplant rate in Europe, argue that while the transplant success rates may be lower with suboptimal donations, those organs still may be adequate fits for older patients.97, 98

The risks of transplanting a suboptimal kidney are also seen as lower than the risks of remaining on dialysis, especially for elderly patients. As Dr. Díez Nicolás notes, key to the legislation of such changes in organ standards is the fact that these “extended criteria” oftentimes “require
additional consideration and specific consent by the recipient.” Yet as in the case of opt-out systems and incentivization strategies, the details of such policies are what can make the difference between ineffective and dangerous policies and those which are effective and life-saving.

3.3.2.3 Living Donors

Some countries have attempted to increase overall transplants by increasing the number of living donors. This has primarily been successful through reimbursement strategies and other reward systems for the living donors. Living donor pools are seen by some as an underutilized resource for U.S. kidney patients, and indisputably the short-term and long-term outcomes are better with living donor kidneys than deceased donor kidneys.100,101

As the United States prepares to implement similar changes in the Trump ETC plan, both the benefits and dangers of such programs must be weighed. Key to that analysis are the circumstances of living donations. First, the recognized issue these programs aim to address is that there are people that would be willing to be living organ donors if they were not experiencing certain “disincentives.” These disincentives include but are not limited to: fear of death or disability; fear of lost opportunity (to donate to others who might need an organ in the future, like their children); and financial disincentives (about matters ranging from lost work hours to child care).102 Another important consideration is the motivations guiding most living donors. These types of donations today most often come from family, friends, or the patient’s immediate community, for the obvious reasons that those close to the patient want them to live

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99 Díez Nicolás et al.
102 “Incentives for Organ Donation.”
and live well. In the more rare circumstances where a patient manages to find a stranger willing to be a kidney donor, the motivation is currently altruistic rather than financial.

Considering the above circumstances, strategies to increase the number of living donors could work in three ways. The first would be to increase the number of purely altruistic donations, by somehow inciting selfless and philanthropic urges in the population. The second would be to limit the disincentives to donating, thereby expanding the population that would donate if they could, such as by reimbursing lost wages. The third would be an outright incentive — i.e., a monetary or alternative reward that goes beyond reimbursement — so as to “improve the donor’s circumstances” (i.e., tax credits, tuition or job training, or payments). This option is limited under the National Organ Transplant Act (NOTA) of 1984, which prohibits the transfer of a “valuable consideration” to the living donor (see footnote 103). If NOTA were to be amended, such programs would function to expand the portion of the population that would not donate unless they were not only reimbursed but rewarded.104 However, despite the presence of the valuable consideration clause, reimbursement programs hold the potential to border on coercion for those in poor economic conditions.

Israel is one country that attempted to increase living donations through reimbursement strategies. In 2008, Israel implemented a policy where registered donors were given priority if they later were in need of an organ themselves (this was informally dubbed a “don’t give, don’t get” policy). This can be considered an incentivizing (reward) system, although in this case the incentive is not monetary and only really constitutes a reward if the donor ends up needing an

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103 Recall that valuable consideration is defined to not include “reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ” according to 42 U.S. Code § 274e - Prohibition of Organ Purchases
104 “Incentives for Organ Donation.”
organ later in life. This policy also included reimbursement measures and social support services for living donors. The results of this initiative were deemed successful, with the organ donation rates increasing from 7.8 to 11.4 donors per million by 2011.\textsuperscript{105}

The American Society of Transplantation (AST) and American Society of Transplant Surgeons (ASTS) convened a workshop in 2014 to address the above issues. In their final statement, upon review of relevant research, workshop organizers stated:

“We believe it important not to conflate the illegal market for organs, which we reject in the strongest possible terms, with the potential in the United States for concerted action to remove all remaining financial disincentives for donors and critically consider testing the impact and acceptability of incentives to increase organ availability in the United States.”\textsuperscript{106}

The workshop participants also concluded that it remains committed against valuable consideration and that they do not support “any trials of direct payments or valuable considerations to donors or families based on a process of market-assigned values of organs.”

Some researchers have made the argument for the amendment of NOTA’s valuable consideration clause, claiming that it would be to the benefit of those on organ waitlists to legalize payments to living organ donors, while also mitigating the effects of the U.S.’s organ shortage on developing countries. In her article “Payment for living organ donation should be legalised,” Amy Friedman argues that considering the toll of the illegal organ harvesting market in the developing world, drastic amendments to the acquisition of consensually obtained organs in the United States must be taken.\textsuperscript{107} She claims that “it is appropriate that living donors, indigent or wealthy, share in the tangible benefits of their ethical concern for others.”

\textsuperscript{105} Lavee et al., “Preliminary Marked Increase in the National Organ Donation Rate in Israel Following Implementation of a New Organ Transplantation Law.”


economists also make claims to the argument for altering the valuable consideration ban. Authors of the 2018 study “Would Government Compensation of Living Kidney Donors Exploit the Poor?” conducted an empirical analysis of the consequences of a government incentive of $75,000 for living donors. They argue that the primary argument against incentive systems, that it would exploit poor populations, “overlooks the fact that many poor patients desperately need a kidney transplant and would greatly benefit from an increased supply of kidneys.”

To this point, they find that the net benefit from kidney transplantation to low-income populations would increase from $1 billion to $12 billion per year. They argue that at $75,000 for a kidney, the donor would be receiving the “fair market value of their kidney, and hence would not be exploited.”

To address the potential of exploitation or negative consequence on low-income living donors, The Working Group on Incentives for Living Donors emphasizes the reality of the demographics of both kidney patients and donors in the U.S. in their article “Incentives for Organ Donation: Proposed Standards for an Internationally Acceptable System.”

The authors explain that because U.S. kidney patients are already from lower economic groups, their low-income friends and family donors would constitute a larger portion of the overall living donor population. This raises the question of whether low-income status should be a contraindication to living organ donation. However, the authors argue that the selection process of organ donation is already very cautious in order to avoid complications or poor outcomes for donors. As such, those who are not in sufficient health are not selected to be donors. Low-income people have higher rates of diabetes and obesity, they continue, so we can assume potential low-income


109 “Incentives for Organ Donation.”
donors are often rejected due to diabetes and obesity. In this complicated intersection of factors, the authors conclude that unless disproportionate poor outcomes started to present themselves in the low-income donors that are in a healthy enough state to donate, the potential for creating a coercive market for organs from poor populations is not high. In addition, because a reimbursement system would mostly work to utilize those willing (family and friends) but unable (lost wages) to donate, it would not drastically change the makeup and motives of low-income living donor populations. Lastly, they conclude, removing disincentives could result in net positive changes to these populations, as was also cited by the authors of “Would Government Compensation of Living Kidney Donors Exploit the Poor?”

In other cases, altruism is seen as a triumphing strategy over financial incentives as well as a means to mitigate the dangers of coercive incentivization strategies. For instance, in his book The Gift Relationship: From Human Blood to Social Policy, Richard Titmus argues that altruism (the blood donation model used in the UK) is not only more economically efficient for inspiring blood donation than financial incentives, but also less likely to induce unwanted effects.\textsuperscript{110} His argument provides an interesting theoretical model for considering altruism versus incentives, but the comparison is not entirely apt, as blood donation, unlike kidney donations, does not involve for-profit entities, and kidney transplantation involves much more invasive surgical processes than giving blood.

In sum, the case for reimbursements and incentives schemes as tactics to inspire living donations is mixed. Since examples from our global counterparts are limited, speculative analysis remains the primary resource for weighing their potential benefits and drawbacks. As

such, case by case scrutiny of the motives, means, and execution of such legislation is prudent, as will be done in the case of the Trump model in the following chapter.

3.3.3 Overall ESRD Outcomes

The United States consistently ranks lower than its global counterparts in measures of outcomes of kidney disease. Mortality rates and outcomes differ for all treatments, just as overall patient mortality differs across countries. The Dialysis Outcomes and Practice Patterns Study found that crude one-year mortality rates were 6.6% in Japan, 15.6% in Europe, and 21.7% in the United States. Even with adjustments for age, gender, race, and 25 comorbid conditions, the relative risk (RR) for mortality was 2.84 for Europe compared with Japan and 3.78 for the United States compared with Japan.111

The reasons behind the United States’ poor performance when it comes to outcomes has previously been explained by lower dialysis rates, but recent research consistently highlights the role of the comorbidities to which US. patients are prone.112 According to the 2007 article, “Why Is the Mortality of Dialysis Patients in the United States Much Higher than the Rest of the World?”113 differences between outcomes for facilities within the United States vary greatly and the lack of uniform patterns of practice may be to blame. When comparing clinical practices of vascular access initiation, compliance with treatment regimen, nutritional practices, staffing, care, and patient education, the level of care in the United States was far below that of other countries. The paper concluded that such inconsistencies in practice patterns in the United States could also account for such drastic differences in mortality rates globally. It can also be assumed

that because the rates of kidney transplants are lower in the United States than in other industrialized countries, U.S. patients are missing out on the significantly higher outcomes associated with transplantation.

3.3.3.1 Quality of Life

Just as outcome factors such as mortality rates are drastically different between countries, so too does the perceived burden of kidney disease by patients themselves vary globally. Unfortunately, research focused on the global differences in the perception of the disease by the patients themselves is sparse, and studies of the relationship between patients’ perceptions and their actual physical functioning tend to be contradictory.

In one Japanese study, for instance, hemodialysis patients reported a greater burden of kidney disease than did patients in the United States or Europe. However, while the perceived burden was higher, actual physical functioning using the Kidney Disease Quality of Life (KDQOL) scale\textsuperscript{114} for Japanese patients was higher than patients in the United States and Europe.\textsuperscript{115} The reason for this difference was not identified in this paper, but future studies may reveal why there are such stark differences in patient perception versus physical outcomes.

In contrast, an Australian study using the Australian diabetes, obesity, and lifestyle longitudinal study explored the relationships between progression of CKD, quality of life, and outcomes (including physical component summary scores and mental component summary scores).\textsuperscript{116} These researchers found that physical but not mental quality of life is “significantly

\textsuperscript{114} 1776 Main Street Santa Monica and California 90401-3208, “Kidney Disease Quality of Life Instrument (KDQOL),” accessed December 9, 2019, https://www.rand.org/health-care/surveys_tools/kdqol.html. Expand upon as an indicator in spring semester


\textsuperscript{116} Melanie L. R. Wyld et al., “The Impact of Progressive Chronic Kidney Disease on Health-Related Quality-of-Life: A 12-Year Community Cohort Study,” Quality of Life Research: An International Journal of Quality of Life
impaired” in chronic kidney disease and worsens with the progression of the disease. This is nearly the opposite in Japan, where mental well-being and subjective quality of life measures were low even when physical functioning was high and mortality rates were low. No such quality of life data exists for American kidney patients compared with kidney patients in other countries. This sparsity of data, combined with contradictory findings within the data that does exist, make clear the need for an international analysis of quality of life measures related to kidney disease so as to better identify the aspects of care systems that improve (or worsen) the mental effects of kidney disease.

3.4 Costs

3.4.1 Overall Health Care Costs

The United States government currently outspends all other high-income countries when it comes to health care (see Figure 3.5), but still underperforms when it comes to quality and access of care. In their 2018 article, “Health Care Spending in the United States and Other High-Income Countries,” Irene Papnicolas et al used OECD data to interrogate these discrepancies in both cost and quality as compared to other high-income countries.

The study authors found that the United States spends almost double per capita on health care than other countries, spends more than any other country on pharmaceuticals, and has the lowest insured population. Some aspects of that high spending stand out especially from our counterparts, such as the fact that 8% of this country’s total spending goes to governance and administration, as compared to the mean of 3% in other countries. The U.S. also has high rates of specialists compared to the low availability of primary care physicians, as well as relatively high levels of administrative burden on these physicians — despite the already high proportion of spending allocated to administration.

Given the exorbitant amount of money spent on health care, one might expect that care to be more readily available and of a higher quality than in other countries. Instead, according to the 2018 study “Health Care Spending in the United States and Other High Income Countries,”

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the United States again ranks below its counterparts. The study found that United States survey participants experienced the lowest satisfaction with the health care system (19% compared to a mean of 45%), for instance. The study also found that a greater percentage of U.S. participants thought the entire health care system needed to be rebuilt than in any other country surveyed (23% compared to a mean of 8%). In terms of access and equity, the U.S. also had the highest proportion of unmet need in the population, and the highest out of pocket spending as a percentage of total national health spending.

That same 2018 study concluded that prices of physician and hospital services, pharmaceuticals, and diagnostic tests were the main drivers of high health spending in the U.S., affecting not only the cost of health care but also access to care. The authors found that the most efficient places to target spending adjustments would be to reduce pharmaceutical prices and administrative costs. A subsequent study published in 2019 found that waste in health care spending could account for 25% of total health care spending, with these reductions coming mostly from the realm of care coordination and “administrative complexity.”

3.4.2 ESRD Costs

The economics of kidney disease, which includes health care expenditures and costs borne by patients, differ across industrialized countries. The average proportion of total health care spending by high-income countries on kidney disease is 2% to 3%. Kidney disease constitutes 23% of Medicare spending in the United States, with all of Medicare spending constituting 20% of national health care spending. With the United States spending almost

119 “WHO | The Global Burden of Kidney Disease and the Sustainable Development Goals.”
double that of its global counterparts on overall healthcare, the United States outsends on kidney disease both in terms of the proportion of spending on kidney disease and total spending per capita on kidney disease.

Within each country, the relative costs of each treatment varies due, in turn, to differences in factors such as pharmaceutical prices, hospitalization costs, import costs for foreign materials, and prices of equipment. For example, the “Perspectives” article found that in many countries peritoneal dialysis was 10% to 30% less expensive than hemodialysis (specifically, in China PD was 10% cheaper, in Nepal it was 30% cheaper, and in South Korea, Taiwan, and Thailand it was 20% cheaper). The Trump ETC model predicts that an increase in peritoneal dialysis would lead to cost savings such as those observed in the former countries, due to its lower comparative cost per patient.

As stated in previous sections, and as witnessed in all realms of public health, prevention and detection of kidney disease at early stages is one of the most effective ways to reduce total expenditures on CKD and ESRD. By catching the disease early and eliminating the need for expensive treatments, costs for both patients and the health care system go down.

### 3.5 Differentials in Access and Equity of Care

The one area where these industrialized countries universally struggle and require improvement, including the United States, is in the differentials in access and equity of care. Around the world, minorities and disadvantaged populations consistently have higher rates of ESRD, lower transplant rates, and poorer outcomes. In Canada, Australia, and New Zealand this is particularly true of indigenous populations (Canadian indigenous populations, for

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instance, are three times as likely to develop ESRD as white populations).\textsuperscript{122} Similarly, in the United States, African American populations are 3.4 times as likely to develop ESRD and Native Americans are 0.5\% times more likely to develop the disease than white populations.\textsuperscript{123}

Reasons for such disparities stem largely from differentials in comorbidities, lack of access to primary care (and, therefore, early diagnosis), and myriad other socioeconomic factors, although each country’s populations also experience unique barriers. One Australian article, for instance, also identifies the “ongoing reality of colonisation, and silence about its implications” as a fundamental cause.\textsuperscript{124} Such implications include persistent structural violence against minority groups, which negatively impacts their access to and quality of health care.

The task of addressing structural health care inequities is a daunting one for many countries, but must be seen as a priority. Although research into variable outcomes and initiatives to address them exist around the world, effective and real change remains a consistent need, one that will take a concerted effort. How the Trump ETC Model recognizes and addresses this issue will be discussed in the following chapter.

3.6 Lessons from Global Kidney Care

In sum, the United States underperforms in nearly all areas of kidney care compared to other industrialized countries and in some cases to non-industrialized countries. Currently, United States ESRD patients make up 29\% of total prevalent cases worldwide, despite making up only 4.25\% of the world population, due largely to the high rates of diabetes in this country.

\textsuperscript{124} Dwyer et al., “Equitable Care for Indigenous People.”
In regards to treatment, in-home peritoneal dialysis is underutilized compared to other countries that have made large strides in transitioning to it as a means for reducing costs and improving patient outcomes. The United States also falls behind when it comes to transplant rates, as a country with an already small donor pool due to our opt-in system, high discard rates, and low utilization of living donation. Outcomes of dialysis treatment are also worse than other industrial countries, at 21.7% one year mortality compared to 15.6% in Europe. Moreover, the United States underperforms in all the above categories despite high expenditures in both overall health care costs and kidney care costs.

Faced with the reality that the United States is underperforming compared to other industrialized countries in essentially all aspects of prevention, treatment, and outcomes of ESRD, the Trump administration has released a proposal to alter the current U.S. kidney care system, discussed in the following chapter.
Chapter 4: Advancing American Kidney Health Initiative

By this point, one should need no convincing that the United States kidney care system is in need of improvement and revision. This chapter will analyze two primary components of the American Kidney Health Initiative launched by the Trump administration this past year, the End Stage Renal Disease Treatment Choices Model (ETC Model) and the Removing Financial Disincentives to Living Organ Donation proposal, both of which aim to make such improvements.

In both cases, the final version of the proposed rules have yet to be released. Indeed, in the case of the ETC model, the final rule is four months late. As such, this analysis is based off of the proposed rule documents released on the Federal Registrar page for the notice and comment period.

4.1 Introduction to the AAKH

On July 10, 2019, President Donald Trump and his administration launched the Advancing American Kidney Health Initiative (AAKH) via an executive order signed by the president that same day. The initiative, originally set to begin in January of 2020, outlines a multifaceted approach to addressing the kidney disease crisis in the U.S. and includes a range of strategies, including prevention programs, artificial kidney research, and several payment models aimed at incentivizing shifts in care practices.

The release of this initiative was announced in a special event hosted by the U.S. Department of Health and Human Resources Services (HHS), with introductory remarks by Secretary of the HHS, Alex Azar. Secretary Azar, whose father suffered from kidney disease, stated, “President Trump is tackling the toughest issues in American healthcare, and few areas
need reform more than the way we treat kidney disease”\textsuperscript{125} Following his speech, President Trump discussed the motivations and sentiment behind the administration's focus on kidney disease. Standing in front of a dozen advocates and patients of the kidney disease community, the President outlined the plan and the immediate steps to be taken by the administration in the following months and years.\textsuperscript{126}

The initiative has three primary goals, each of which, in turn, has objectives that serve as benchmarks. The goals and objectives are enumerated in the \textit{Advancing American Kidney Health} paper released alongside the announcement by the HHS, which provides an executive summary, goals, and objectives for the initiative, along with a list of the strategies set forth by HHS.\textsuperscript{127} Some goals build off previous initiatives and projects of the HHS. These will serve as either models or will be broadened within AAKH.

The first goal of the executive order is to “reduce the risk of kidney failure.” This goal encompasses all initiatives involving prevention and detection, as well as educational programs that target high-risk populations. The two objectives within the section are 1) “advance public health surveillance capabilities and research to improve identification of populations at risk and those in early stages of kidney disease” and 2) “encourage adoption of evidence-based interventions to delay or stop progression to kidney failure.”\textsuperscript{128} As a benchmark, the AAKH aims to reduce the number of Americans developing ESRD by 25% by the year 2030.

The second goal of the AAKH is to “improve access to and quality of person-centered treatment options.” This encompasses efforts to provide more treatment options for patients,

\textsuperscript{125} \textit{Advancing American Kidney Health}, accessed December 6, 2019, https://www.youtube.com/watch?v=8BbZqt8Tum4.

\textsuperscript{126} Include names of kidney advocates and patients present


\textsuperscript{128} Ibid, 7.
including encouraging home dialysis and transplantation and promoting artificial kidney research.

The first objective of this goal is to “improve care coordination and patient education for people living with kidney disease and their caregivers, enabling more person-centric transitions to safe and effective treatments for kidney failure.” The second objective is to “introduce new value-based kidney disease payment models that align health care provider incentives with patient preferences and improve the quality of life.” The initiative lays out four voluntary payment models and one mandatory payment model, released by the CMMI (the Center for Medicare and Medicaid Innovation created under the Affordable Care Act) as a proposal to the Federal Registrar on July 11. Mandatory payment models are ones that physicians and facilities can opt to participate in, whereas the mandatory model is required of half of all facilities in the United States. As is the case with most CMS voluntary payment models, these voluntary models include more favorable incentives and allow for more flexibility in where providers choose to implement redesigns to care. In contrast, the mandatory payment model requires providers to participate, and includes more negative payment incentives. The four voluntary payment models are the: Kidney Care First (KCF), Comprehensive Kidney Care Contracting (CKCC), CKCC Professional, and CKCC Global programs, all meant to incentivize the goals of the AAKH through more streamlined management of the kidney disease system. The only mandatory payment model is the End-Stage Renal Disease Treatment model, which will be discussed further in Section 2.3 and will be the primary payment model analyzed in this work.

The final objective under this goal is to “catalyze the development of innovative therapies including wearable or implantable artificial kidneys with funding from government, philanthropic and private entities through KidneyX, and coordinating regulatory and payment
policies to incentivize innovative product development,” as well as easing access to home-based forms of care and transplants.  As a benchmark for this goal, by 2030 the HHS aims to have 80% of ESRD patients receiving home dialysis or a transplant, a goal that would be primarily achieved through the mandatory payment model.

The third and final goal of the initiative is to increase access to kidney transplants. The two objectives under this goal are to “increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate” and to “increase the number of living donors by removing disincentives to donation and ensuring appropriate financial support.” Within the AAKH, the proposed Removing Financial Incentives to Living Organ Donation initiative addresses these objectives, as discussed further in section 2.3.8.

4.2 Initial Responses to the AAKH

Upon the announcement of the executive order, news outlets, kidney organizations, and government agencies released their summaries and initial reactions. Reactions were largely positive, with many professionals and reporters surprisingly impressed with the scope of the plan released by the Trump administration. This surprise stemmed in part from the hostility of the administration toward the Affordable Care Act (ACA), some aspects of which (e.g., the CMMI) are necessary for the AAKH to function. However, many of these positive reactions were tempered with doubt, due primarily to the immensity of the plan and questions as to whether the benchmarks were realistic.

The HHS press release summarized the executive order and also noted the department's immediate action items following the order. Agency officials stated in this press release that in

129 Ibid, 8.
130 Ibid, 8.
the following week they would be commencing several “immediate actions,” which included the release of the payment models by the CMMI. These models would include “new incentives for preventing kidney disease and managing kidney patients’ health in a more comprehensive and person-centered way.” The incentives would largely be monetary, and in the case of the mandatory payment model would include both rewards and penalties. These payment models, including the mandatory model released by the CMS on the Federal Registrar, would comprise the largest and most immediate changes of the AAKH. As of the time of this press release, they were set to begin in January of 2020. However, in the case of the mandatory ETC Model, final legislation has yet to be released (as of April 2020).

Among news outlets that initially covered the order were NPR and The New York Times. Both outlets’ coverage included responses from experts and researchers in the field of kidney health, as well as members of previous administrations’ health departments. NPR’s Selena Simmons-Duffin and Carmel Worth interviewed Dr. Holly Mattix-Kramer, who commended the intentions of the AAKH, speaking for other members of the kidney community by saying, “‘We're extremely excited...for so long we felt like no one was paying attention to this epidemic of kidney disease.’” Dr. Mattix-Kramer also targeted the previous payment structures as one part of the problem, asserting that while there were payment structures in place once a patient reached kidney failure, previously there had been no incentivizing payment structures for prevention. President Obama’s previous head of CMS, Andy Slavitt, was also quoted in the article, affirming the recognized need for such legislation in stating that the “care of kidney

patients has been broken in the US for a long time, plagued with a corporate duopoly [and] a lower income minority population losing out.”

The sentiment of these two was echoed by those interviewed in a *New York Times* article written by Reed Ableson and Katie Thomas. Dr. John Sedor, a doctor at the Cleveland Clinic and consultant for several federal programs, noted, “‘dialysis has been a wonderful technology, but it has suffered from little innovation.’” In the article, Tonya Saffer of the National Kidney Foundation (NKF) also remarked that “‘We are very optimistic and excited that there is great attention at the presidential level,’” then added, “‘it’s really been four decades since anybody has paid attention to this space in a very meaningful way.’”

While many key figures in the kidney community commended the announcement, however, several were wary of the immensity of the undertaking. Both Dr. Mattix-Kramer and Slavitt expressed qualms about the order’s viability. Dr. Mattix-Kramer was especially worried about the program’s ambitious benchmark of having 80% of patients on home dialysis or transplanted by 2030, which she thought to be overambitious. For many of her patients, she said, socioeconomic circumstances have and could continue to make the transition to home dialysis difficult or impossible, for such basic reasons as, “‘you need social support and you need a clean house and you need someplace to have equipment.’” Slavitt worried especially about a misalignment between this proposal and other objectives of the Trump administration. In a tweet quoted in the NPR article, he noted:

"There is one law that makes this new change possible. The same law that requires people with [preexisting] conditions get coverage. The ACA, without it, there is no authority to do this.”

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134 Andy Slavitt on Twitter: “There Is One Law That Makes This New Change Possible. The Same Law That Requires People with Pre-Ex Conditions Get Coverage. The ACA. Without It, There Is No Authority to Do This.”
Many large kidney organizations released responses to the DHHS press release and President Trump’s executive order. The National Kidney Foundation (NKF), for instance, one of the leading organizations in kidney patient support, advocacy, and research, announced their support of the initiative, especially due to the “alignment of the initiative with NKF’s public policy priorities in areas of improving kidney disease awareness.”

The two largest for-profit dialysis companies, DaVita and Fresenius, also remarked on the announcement. Notably, both companies have historically profited off the large portion of ESRD patients that dialyze in their centers. In DaVita’s press release, company officials stated that they were “encouraged” and “excited” about the changes to come with the AAKH. (They also noted their own position in the market for home dialysis.) As the largest provider of home dialysis equipment in the U.S., Fresenius’s press release stated that “the company's execution of its home strategy is additionally supported by the Executive Order on Advancing Kidney Health.”

Notably, the announcement of the AAKH also spurred changes to investment in dialysis companies, especially DaVita and Fresenius. Prior to the announcement, fears of negative repercussions on the two companies caused investors to withdraw, with a resultant 5% drop in stock prices for both companies on the day of the announcement. Both rebounded by the following day, however, as the order was not as severe as had been feared by the companies and their investors, especially considering their burgeoning home dialysis equipment production.

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programs. Indeed, in a statement to CNBC, health policy research analyst Chris Meekens stated that “the encouragement to build out home [dialysis] and the penalty for not building out is not as great as we thought would be necessary to spur that to quickly change behavior.”

4.3 End Stage Renal Disease Treatment Choices Model (ETC Model)

In recognition of the issues stated in the previous two chapters, especially that of the underutilization of in-home dialysis and transplantation in this country, the mandatory payment model (ETC Model) included in the AAKH aims to improve increased utilization of both treatment options. The model also addresses the issue of the high costs of kidney disease treatment, by incentivizing the cheaper treatment options of home dialysis and transplantation through incentive strategies for physicians in an effort to reduce Medicare expenditures on kidney disease.

4.3.1 Introduction

The AAKH’s mandatory payment model was released as a proposed rule by CMS and HHS on July 18th, 2019 on the Federal Registrar entitled “Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures” (otherwise known as the ETC Model). The notice and comment period were set to remain open until September 16, 2019, and the final model was set to begin in January 2020.

The proposal included two payment adjustments: the Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA). The HDPA is a positive

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138 Coombs, “Kidney Dialysis Stocks Soar as Investors See Trump Executive Order as Good News.”
140 Alongside the ETC model was included a Radiation Oncology Model which is unrelated to the ETC model other than the shared goals of reducing expenditures and improving quality of care.
payment adjustment for participating facilities; the PPA is a combination of positive payments adjustments and negative penalizations of facility reimbursements under Medicare. The ultimate goal of the proposal is to have 80% of kidney patients on either home dialysis or to have a kidney transplant. More specifically, in the words of CMS, “the proposed ETC Model would be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants, in order to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures.”\textsuperscript{141} Importantly, as the model stands right now, participating ESRD facilities and managing clinicians would not have the option to opt out.

The model utilizes the pre-existing structures of the ESRD Prospective Payment System (PPS) and the Medicare Physician Fee Schedule (PFS). The PPS is a required payment system under Medicare that bundles services at a patient and facility level to pay ESRD facilities for renal dialysis services. The PFS operates as the vehicle for adjusting physician Medicare reimbursements in this model, with reimbursements being less or more according to whether the physicians accomplish the model’s goals. In other words, the model does not necessarily create any new structures within the CMS, but rather extends previous avenues for payment adjustments in order in order to enact both monetary incentives and monetary penalties.

All payment adjustments would be within the Medicare Shared Savings Programs (MSSP), a payment model that allows providers to become an Accountable Care Organization (ACO), defined as an organization that “agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare fee-for-service (FFS) beneficiary population.”\textsuperscript{142}

\textsuperscript{141} Ibid, 1.
\textsuperscript{142} “About the Program | CMS,” accessed April 15, 2020, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/about.
who bill the Monthly Capitation Payment (MCP) for managing ESRD Beneficiaries) are either increased or decreased in this payment model according to their enactment of its objectives. All savings and expenditures for the program would be listed under the Medicare Shared Savings Program budget. Ultimately, the goal of the program is to reduce Medicare expenditures associated with kidney disease.

4.3.2 Identified Problems the ETC Model Aims to Address

In the introductory sections of the ETC, the CMS recognizes the current challenges for kidney patients in the U.S., as well as the research that undergirds the goals of the proposal. Authors of the initiative note that home dialysis and transplantation, the primary treatment models supported in the proposal, are recognized “among health care providers and patients as preferable alternatives to in-center hemodialysis (HD), but the utilization rate of these services in the United States (U.S.) has been below such rates in other developed nations.’’\(^{143}\) The authors also recognize, in reference to the goal of reducing expenditures, the current situation in which “ESRD beneficiaries have accounted for about 1 percent of the Medicare population and accounted for approximately 7 percent of total Medicare spending,’’\(^{144}\) and that this disproportionate spending must be remedied.

The proposal describes ESRD patients as one of the “most medically fragile and high-cost populations served by the Medicare program.’’\(^{145}\) Drawing on 2018 data from the United States Renal Data System (USRDS), the proposal also acknowledges ESRD patients as Medicare beneficiaries with a mortality ‘‘greatly exceeding that of the general Medicare population.’’\(^{146}\)

\(^{143}\) Ibid, 196.
\(^{144}\) Ibid, 197.
\(^{146}\) Ibid, 197.
sum, the proposal recognizes ESRD beneficiaries as a section of the Medicare population “with poor clinical outcomes and potentially avoidable expenditures,” and thus prime targets for care adjustments and budget reassessment. This sentiment echoes that of most American and global kidney care researchers.

These care adjustments include increased utilization of home dialysis and transplantation. Citing several studies, the authors claim that home dialysis has the potential to improve patient outcomes and reduce costs (due to “lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between PD and HD services and supplies, and lower operating costs for dialysis providers for providing home dialysis”)

These studies also jointly emphasize the need for bolstered education to offset misconceptions about home dialysis, the importance of strong support systems for patients transitioning to home dialysis, and the potential of peritoneal dialysis to be a safer modality with lower mortality rates and comorbidities. It is important to note, however, that while this is quoted in the proposal, such details are not actually included in the model.

The proposal recognizes that barriers to home dialysis utilization exist in the United States, including “ease of initiation, physician experience and training, misinformation around other modalities, inadequate education for CKD beneficiaries, built-up capacity at ESRD facilities, and a lack of infrastructure to support home dialysis,” in addition to “the monthly visit

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148 Ghaffari et al., “PD First.”
151 Ibid, 203.
requirement..., the need for home care partner support, as well as philosophies and business practices of dialysis providers...lack of independence for home dialysis clinics, and business-oriented restrictions that lead to inefficient supply distribution.”

The low rates of kidney transplantation in the U.S. is another primary target of the proposal. As detailed in Chapter 3, the proposal echoes the sentiment of many in the field that transplant rates have ample room for improvement. The proposal cites a 2011 study, “Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes,” which found lower mortality rates, lower rates of comorbidities, and higher quality of life for patients who received a transplant rather than dialysis. The lower cost of transplantation is largely undisputed, as there is for the most part no need for longer-term care costs other than check-ups once a patient has had their kidney transplanted successfully.

In short, the ultimate goals of this model rest on the intersection between the recognized issues of underutilization of transplantation and home dialysis and their status as cheaper treatment options, an intersection that has long been recognized by kidney experts around the world.

4.3.3 Methodology

The ETC Model is the first-ever mandatory payment model for ESRD facilities and managing clinicians. The model will be tested on approximately 50% of all ESRD

153 Ibid.
beneficiaries. This large sample size is cited as necessary in order to approximate accurate and statistically significant results regarding the effectiveness of the proposal, especially for transplants, which currently occur in fairly low numbers. The initiative authors also note that a large sample size allows for a more accurate capture of the wide range of circumstances experienced by kidney patients and that its mandatory nature helps avoid self-selection bias.158

In order to select which facilities and clinicians will participate in the sample group and which will be in the comparator group, CMS is using the Dartmouth Atlas Project HRR geographic unit (hospital referral regions). There are 306 HRR’s in the U.S., and within each geographic region the DAP will randomly select 50% of ESRD beneficiaries.159 This selection method was chosen over Core Based Statistical Areas (CBSAs), Metropolitan Statistical Areas (MSAs), or states as geographic units due to either inappropriate sizes for the analysis or due to their exclusion of certain groups.

4.3.4 Components of the ETC Model

4.3.4.1 HDPA

The Home Dialysis Payment Adjustment (HDPA) is a positive payment adjustment that would incentivize transitions to home dialysis and higher rates of transplantation in facilities. Neither this nor the PPA would impact beneficiaries’ out of pocket costs. Within the HDPA there are proposed Clinician HDPAs (which would be monthly capitated payments included in the Managing Clinician's dialysis claims) and Facility HDPAs (which would be adjusted within the facility’s ESRD PPS per treatment base rate). All model participants (50% of all facilities in the United States) must be included in the HDPA. The HDPA is categorized as a process-based initiative that will slowly be phased out as the outcomes-based PPA is phased in. The HDPA will

158 Ibid, 204.
159 Each facility has to have at least 11 patients.
only run for the first three years, 2020 to 2022, by which time the PPA will take its place. Figure 3.1 shows the scoring for the HDPA from CY 2020 to CY 2026, with it being phased out by CY 2023 following decreasing magnitudes of payment adjustments.\textsuperscript{160}


\textit{4.3.4.2 PPA}

The Performance Payment Adjustment (PPA) model includes both positive and negative payment adjustments, the magnitude of which are both set to slowly increase over time. The PPA is staggered to begin on July 1, 2021, and would run through 2026, with the brunt of the negative payment adjustments being carried by facilities rather than individual clinicians.

In order to determine the PPA payment adjustments for facilities, the Modality Performance Score (MPS) will be used to assess changes in rates of home dialysis and transplantation. Home dialysis scores count for two thirds of the MPS, while the transplant score only counts for one third.\textsuperscript{161} To calculate home dialysis rates, home dialysis treatment

\textsuperscript{160} National Kidney Foundation, “Launch of Advancing American Kidney Health Initiative.”

\textsuperscript{161} Ibid, 323.
beneficiary years will be divided by total dialysis treatment beneficiary years that Measurement Year (MY). Transplant rates will be determined by dividing the total number of transplanted beneficiaries by total dialysis treatment beneficiary years. In other words, these measure the rate of change to home dialysis and transplantation over time. This data will come from “Medicare claims data, Medicare administrative data, and data from the SRTR in order to reduce the reporting burden on Model participants.”

Two benchmarks are used to determine the MPS. The first benchmark is the “achievement score,” which is the past year of historical rates in the comparator geographic areas. The second benchmark is the “improvement score,” or the Model participant’s increase in home dialysis and transplant rates compared to that participant’s scores in the past. The achievement score tracks how well individual facilities are improving compared to facilities with similar populations and circumstances, while the improvement score measures progress toward the ETC goals. The Model participants cannot achieve the highest performance score through the improvement benchmark alone, meaning they must show achievements compared to their geographic comparator region as well. The highest benchmark possible would be the achievement of 80% of patients being on home dialysis or transplantation.

The MPS will be calculated annually as a Measurement Year (MY), with payments adjusting every six months. Figure 4.2 shows the scoring for both benchmarks for MY 1 and MY 2. Figures 4.3 and 4.4 show the facility and clinician PPA amounts and schedules. Put another way, these figures are essentially rubrics for how well participants improved their achievement and improvement scores.

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162 Ibid, 249.
Figure 4.2. Benchmark year Scoring, National Kidney Foundation, “Launch of Advancing American Kidney Health Initiative”.

<table>
<thead>
<tr>
<th>Achievement Score Scale for MYs 1 and 2 (1/1/2020 through 6/30/2021)</th>
<th>Points</th>
<th>Improvement Score Scale for MYs 1 and 2 (1/1/2020 through 6/30/2021)</th>
</tr>
</thead>
<tbody>
<tr>
<td>90th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year</td>
<td>2</td>
<td>Not a scoring option</td>
</tr>
<tr>
<td>75th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year</td>
<td>1.5</td>
<td>Greater than 10% improvement relative to benchmark year rate</td>
</tr>
<tr>
<td>50th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year</td>
<td>1</td>
<td>Greater than 5% improvement relative to benchmark year rate</td>
</tr>
<tr>
<td>30th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year</td>
<td>.5</td>
<td>Greater than 0% improvement relative to benchmark year rate</td>
</tr>
<tr>
<td>&lt;30th Percentile of benchmark rates for</td>
<td>0</td>
<td>Less than or equal to benchmark year rate</td>
</tr>
</tbody>
</table>

Table 4.3. Proposed Facility Performance Payment Adjustments Amounts and Schedule, National Kidney Foundation.

<table>
<thead>
<tr>
<th>MPS</th>
<th>Performance Payment Adjustment Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 and 2 (7/1/2021 through 6/30/2022)</td>
</tr>
<tr>
<td>Facility Performance Payment Adjustment</td>
<td>≤ 6</td>
</tr>
<tr>
<td></td>
<td>≤ 5</td>
</tr>
<tr>
<td></td>
<td>≤ 3.5</td>
</tr>
<tr>
<td></td>
<td>≤ 2</td>
</tr>
<tr>
<td></td>
<td>≤ .5</td>
</tr>
</tbody>
</table>

Figure 4.4. Proposed Clinician Performance Payment Adjustment and Schedule, National Kidney Foundation.
4.3.5 Recognized Limitations

The ETC Model authors recognize several limitations that may affect the outcomes and results of the model. One of the primary limitations is the potential for physicians cherry picking (selectively picking healthier patients), and lemon dropping (selectively avoiding high-risk patients) in order to meet benchmarks and receive their payments. The proposal aims to avoid such practices and explicitly prohibits model participants from either a) “taking action to avoid treating beneficiaries with chronic conditions such as obesity or diabetes, or who are entitled to Medicaid because of disability;” and b) “taking any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant’s or downstream participant’s financial or quality performance.”\(^{164}\) Beyond these sentiments, however, the model includes no other tangible guidelines or measures to protect patients from these possible biases.

In the summary submitted to the Federal Registrar, CMS notes the overlap of the ETC with other CMS programs and initiatives. While the authors acknowledge that any overlap with other programs would have shared interests and priorities, and thus would be compatible in intention, they also admit this could result in “repetitive services or duplicative payments and commit to avoiding them.”\(^{165}\)

4.3.6 Projected Effects

The CMS modelled the possible financial impacts of the ETC proposal through a stochastic simulation run 500 times. The simulation used data from 2016 and 2017 Managing Clinician’s Medicare claims for dialysis and transplants. With the HDPA constituting an upward payment adjustment, and the PPA constituting both an upward and downward payment

\(^{164}\) Centers for Medicare Medicaid Services, 26.
\(^{165}\) Ibid, 18.
adjustment, the model was run and found an estimated net savings to Medicare of $185 million dollars between January 1, 2020 and June 30, 2026. The model also projected a $15 million increase in expenditures implementation. This resulted in a net impact of $169 million dollars in savings (total Medicare ESRD Spending was $35 billion in 2016).\footnote{Ibid.} Figure 4.5 shows the modelled financial impacts on expenditures for the entirety of the ETC model via the simulations conducted by the CMS.

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>2025</th>
<th>2026</th>
<th>6.5 Year Total*</th>
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</thead>
<tbody>
<tr>
<td>Net Impact to Medicare Spending</td>
<td>20</td>
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<td>-22</td>
<td>-36</td>
<td>-49</td>
<td>-57</td>
<td>-26</td>
<td>-169</td>
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<tr>
<td>Overall PPA Net &amp; HDPA</td>
<td>19</td>
<td>-1</td>
<td>-24</td>
<td>-38</td>
<td>-52</td>
<td>-60</td>
<td>-29</td>
<td>-185</td>
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<tr>
<td>Clinician PPA Downward Adjustment</td>
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<td>-6</td>
<td>-7</td>
<td>-8</td>
<td>-10</td>
<td>-6</td>
<td>-38</td>
<td></td>
</tr>
<tr>
<td>Clinician PPA Upward Adjustment</td>
<td>2</td>
<td>5</td>
<td>6</td>
<td>6</td>
<td>8</td>
<td>4</td>
<td>31</td>
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<tr>
<td>Clinician PPA Net</td>
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<td>-1</td>
<td>-1</td>
<td>-2</td>
<td>-2</td>
<td>-1</td>
<td>-8</td>
<td></td>
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<tr>
<td>Clinician HDPA</td>
<td>2</td>
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<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
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<tr>
<td>Facility Downward Adjustment</td>
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<td>-93</td>
<td>-114</td>
<td>-137</td>
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<td>Facility Upward Adjustment</td>
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<td>45</td>
<td>56</td>
<td>64</td>
<td>80</td>
<td>45</td>
<td>307</td>
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<tr>
<td>Facility HDPA</td>
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<td>14</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Total PPA Downward Adjustment</td>
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<td>-82</td>
<td>-100</td>
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<td>-79</td>
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<tr>
<td>Total PPA Upward Adjustment</td>
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<td>49</td>
<td>61</td>
<td>70</td>
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<td>49</td>
<td>338</td>
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<tr>
<td>Total PPA Net</td>
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<td>-32</td>
<td>-38</td>
<td>-52</td>
<td>-60</td>
<td>-29</td>
<td>-228</td>
<td></td>
</tr>
<tr>
<td>Total HDPA</td>
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<td></td>
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<td>KDE Benefit Costs</td>
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<tr>
<td>HD Training Costs</td>
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<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>10</td>
</tr>
</tbody>
</table>

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending.


In terms of the projected success of the ETC at attaining its benchmarks, the model found that home dialysis would ultimately represent “approximately 19 percent of overall maintenance
dialysis in selected geographic areas by 2026.” The model did not reach an official assumption for how attainable the transplantation benchmarks were. Clearly, while projections past 2026 are not available, this is nowhere near the goal of 80% on both modalities.

4.4 Removing Financial Disincentives to Living Organ Donation

Another important portion of the AAKH deals with the living organ donor system. The “Removing Disincentives to Living Organ Donation” model was released on December 20, 2019, with the notice and comment period ending on February 18. This aspect of the AAKH holds potential for addressing issues with the U.S. kidney transplantation system, but as the final proposal has not been released yet, only the preliminary proposal models can be analyzed in this project.

The proposal plans to amend the National Organ Transplant Act (NOTA) of 1984 so as to address aspects of the current system that make living organ donation very difficult for the donors. Recall that within the current system, although the procedure itself is covered for the donor under the recipient’s health insurance plan, extraneous costs such as child care and lost wages are not covered or reimbursed. These financial and time-based barriers are primary disincentives for those who would otherwise be willing candidates to be living donors in the United States. The ETC proposal builds off protocols executed by The National Living Donor Assistance Center (NLDAC), an HRSA-funded grant program that has handled the living donor network since 2006. Through the NLDAC grant, some living donors have been able to apply for reimbursements, although it has been limited to a small portion of low-income living donors.

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Under the new proposal, lost wages (including loss of income from missing work during the transplant process, evaluation, surgery, recovery period, and follow-up visits) would be reimbursed for many more living donors than the current NLDAC grant currently covers, as well as any expenses incurred to the donor for child care or elder care. While the average reimbursement for grant recipients is currently $1,934, the new proposal would cover wages at $28/hour for 40 hours per week (averaging $1,120 per week), child care at $420 per week, and elder care at $504 per week. The current NLDAC system prioritizes lower-income donors, but with the new proposal, the upper threshold of the income would be raised to include more donors. The reimbursement will be tailored to the circumstances and repercussions experienced by each donor following the surgery, meaning some donors will not be reimbursed, including those above the income threshold.

This aspect of the proposal is based on the successes of previous adjustments to the U.S. system (such as the NLDAC grants) as well as similar programs in other countries (such as the programs implemented by Israel discussed in Chapter 3). One U.S. survey found that 75% of current donors would not have donated without reimbursements. With a predicted 20% increase in rates of living donors for a year, this proposal could make possible 500 new kidney transplants annually. This, in turn, is predicted by CMS to translate into $68 million in Medicare savings over 10 years if the program is successful. The proposal retains the clause in the NOTA

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168 “NLDAC limits donors to a maximum of $6,000 for reimbursement of solely travel and subsistence; a correlating demonstration project, on lost wages, limits reimbursement of solely lost wages to a maximum of $5,000; donors receiving reimbursements from both programs are capped at receiving a combined maximum of $8,000”


that bans the transfer to living donors of valuable considerations that go beyond reimbursements for the reasonable payments involved with the procedure.

### 4.5 Reactions of the Kidney Community: Notice and Comment Period

Notice and Comment for the Proposed ETC Model opened on September 18, 2019. Three hundred and twenty-nine comments were submitted in total. These comments came from a range of stakeholders in the kidney community, including those in the clinical realm, such as nephrologist organizations and researchers, and advocacy and patient groups.

#### 4.5.1 Clinical Comments

On the clinical side, organizations such as the Mayo Clinic, the Society of Nephrology, National Kidney Foundation, and various dialysis and kidney care networks submitted their concerns about the model. The comments primarily addressed the negative repercussions the proposal could have on clinics and the feasibility of such a quick transition into the model. The comments also highlighted the possible negative effects the proposal could have on their patients. As stakeholders familiar with the lives and choices of kidney patients, these commenters also brought up concerns that the model does not recognize the diversity of experiences among kidney patients and that the proposal was trying to provide home dialysis and transplantation to more patients than could actually benefit from these treatments. Nearly all of these commenters argued that the 80% goal for transplantation and home dialysis was an overcorrection.  \(^{171,172,173}\)

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173 Ibid, 1.
Clinical groups also argued that the negative impacts on facilities would be too great, with small dialysis facilities or networks being put at even greater risk. Several groups noted that the risks outweigh the positive payment bonuses, especially in the early years of the model. Rogosin (a NYC-based network of dialysis clinics) argued that the transitions to home dialysis for smaller-scale centers like themselves would be made more difficult by their disconnect from the home dialysis supply chain as compared to the large companies that also control manufacturing. One of the monopolies in dialysis, DaVita, actually argued similar points, noting concern for small scale providers. DaVita went on to raise concern that patients could be negatively affected by lemon dropping, and facilities that tend to serve-low income and high-risk groups may also be penalized if they choose not to prescribe the treatments incentivized by the payment model. DaVita, alongside many other clinical entities, argued that these facilities must be better protected or removed from the model.

In regards to the validity of the payment model methodology, Rogosin argued that the models do not account for vast variations in baseline rates of home dialysis utilization. Such variations can arise from a multitude of factors; they described:

“wide variations in rates of home dialysis and transplantation based on patient age (4X and 100X difference), race (2X and 15X difference), and primary cause of ESRD (3X and 23X difference) for incident patients (Figure 3.) and age (2X and 6X difference), race (1.5X and 2X difference) and primary cause of ESRD (2X and 4X difference) for prevalent patients (see Figure 4)”

176 Ibid, 4.
Thus, within the payment model calculation the patient population denominator needs to be better risk adjusted, especially for geographic regions that have high rates of high-risk patients.

4.5.2 Patients and Advocates

From the perspective of patients and patient advocates, the main flaws in the proposal again lie in the over adjustment to transplantation and home dialysis, echoing the sentiments of the comments from the clinical realm. In addition, patients and patient advocates warned in their comments, the protections against cherry picking and lemon dropping are not nearly strong enough to buffer patients against adverse selection. Patient commenters also called for more transparency on models such as this in order to empower patients to engage their care planning. The Coalition for Supportive Care of Kidney Patients suggested that rather than emphasizing length of life, multiple studies have shown patients prioritize quality of life. These stakeholders also argued that the care coordination and priorities of the kidney care community should reflect this reality, and that palliative care should be included as a positively rewarded treatment option.

Many groups argued that certain adjustments and clarifications are necessary in order for the model to achieve its’ goals without harming patients' choices and outcomes. The pressure towards home dialysis, combined with a lack of education and transparency for the patients, worries these groups. Like the clinical groups, they urge vigorous oversight on the part of CMS

to avoid cherry picking and lemon dropping, and they request specific measures rather than vague commitments to those issues.

4.6 Discussion

The ETC Model and Removing Disincentives proposal both address primary issues with the kidney disease care system in the United States. However, with 63% of kidney patients receiving in center dialysis, and 29% of prevalent patients having transplants currently, the shift to 80% on home dialysis and transplantation would constitute a massive transition in care practices. With such a dramatic transition, adverse patient outcomes are almost guaranteed, especially considering the lack of educational opportunities presented in the model and the harsh penalties model participants will receive if they fail to meet benchmarks. Considering the advice of global researchers, and the current state of the U.S. kidney care system, a less drastic and more cautious model is advised, as is discussed in the conclusion chapter.

Chapter 5: Conclusion

This research aimed to identify both the primary issues within the United States kidney disease care system and the extent to which these problems were adequately addressed in two key portions of the Advancing American Kidney Health Initiative. Those two portions are: the Proposed End-Stage Renal Disease Treatment Choices Model (or ETC Model) and the Removing Financial Disincentives to Living Organ Donation Model. Insights and examples from global researchers, clinicians, and policy makers (especially fellow industrialized countries) were essential in this analysis in order to identify alternative models that the United States could utilize. Limitations to this research included the dearth of international comparisons, as well as the fact that as of April 29, 2020 the proposal’s final version has yet to be released. As a result, the author could analyze only the proposed version.

This research found that in certain ways, the ETC Model succeeded in addressing the major requests of the kidney community and did so by taking into account examples from global models and research. However, issues remain in the realm of patient protection and the viability of the model’s goals. In particular, it bears repeating that enthusiasm about the Trump administration’s attempts to alter an entitlement program that serves such a vulnerable patient population must be tempered with a certain degree of caution and a willingness to continue to push for meaningful reform. The proposal as it stands remains in a grey area, walking a thin line between enthusiastically and productively addressing the very real issues of the U.S. kidney care system, and making these changes too swiftly and drastically for them to be safe and effective.

From the time of diagnosis to treatment, a kidney patient’s care in the United States is more expensive and less successful than the care kidney patients receive in other industrialized countries. Missed opportunities for early intervention and prevention of kidney disease, and the
prevalence of its upstream risk factors (such as diabetes and hypertension), contribute to the high rates of late stage ESRD. This burden is especially heavy for low-income, African American, Hispanic, and Indigenous populations, who are disproportionately affected by all three diseases.

When it comes to treatment, the two most successful and cost-efficient treatment modalities — transplantation and in-home peritoneal dialysis — are underutilized in the United States. Barriers to higher rates of transplantation include the opt-in structure of the U.S. organ donation system, high discard rates of kidneys, and the shortage of living donors. In addition, many researchers believe that palliative and end-of-life care are not prescribed often enough for elderly patients. Strikingly, mortality rates for kidney patients in the U.S. are much higher than in other industrial countries, which some researchers blame on inconsistent practice patterns and treatment regimens.\(^{180}\)

The Medicare entitlement program that governs kidney care has not had a major revision since its creation in the 1970’s, and it is obvious that major change is necessary to address the above issues. Taken together, the ETC Model and Removing Financial Disincentives to Living Organ Donation Model, which are the two most substantive pieces of legislation released under the Advancing American Kidney Health Initiative, constitute the first major change to kidney care in decades. The extent to which these two models effectively recognize and address the existing issues in U.S. kidney care is largely dependent on the details currently missing from the proposals, such as transparency to patients, risk adjustments for high-risk patients, education and collaboration with the providers executing the changes, and the feasibility of the benchmarks

themselves. Of particular relevance here is the means by which these goals are to be achieved, as will be analyzed below.

One area where the ETC Model succeeds in using models from global research and policy to address an issue is in its promotion of in-home peritoneal dialysis. The potential of peritoneal dialysis for achieving cost savings and improving patient outcomes is readily apparent in recent literature. Yet, the logistics of a major shift from current treatments to peritoneal dialysis are essential to the success of such campaigns. In their article “Peritoneal Dialysis First Policy Made Successful,” Philip Kam-tao Li and Kai Ming Chow found that the three most important factors for a successful PD First campaign were “nephrologist experience and expertise, peritoneal dialysis catheter access, and psychosocial support for PD patients.” While the Trump proposal succeeds in recognizing the need and merit for shifting to peritoneal dialysis, the crucial educational elements are absent. Instead, the initiative counts on mandatory positive and negative payment models to force physicians’ behavior while neglecting to set up the necessary support systems for such massive transitions.

Because it is a cheaper alternative to in-center dialysis, and one that improves patient autonomy, a push to increase utilization of PD is prudent. However, caution must be taken to avoid over implementing the suggestions, especially if one takes into consideration for what proportion of patients this treatment could, realistically, actually work. The choice of treatment must be made primarily according to what works best for the patient’s lifestyle, priorities, and comfort. The ETC’s 80% benchmark for a shift to home dialysis and transplantation sounds promising. Yet it risks pushing physicians to pressure patients to try these treatments when it may, in fact, not be appropriate. Patients who live in unstable housing situations, for instance, or who have no viable “care partners” would have trouble complying with the rigors of a PD
regimen. (This is not just idle speculation. Even the simulations run by the CMS to project the financial impact of the proposal found that it would be unlikely to achieve the 80% benchmark.)

The topic of patient protections is a particularly important aspect that is missing from the ETC Model. The model, for instance, does not include any section that discusses making information about the initiative transparent to patients. As the model would encompass 50% of all facilities in the U.S., it would be prudent to ensure that patients are: a) informed of their facility’s participation in the model; and b) continue to be given agency in the selection of their treatment modality according to their personal resource and situations.

Paralleling this issue is the potential pitfall of adverse patient selection under this model. Facilities may lemon drop or cherry pick patients (i.e., drop high-risk patients and/or select low-risk patients so as to more readily reach the benchmarks and benefit from the positive incentives). Second, this same lack of protections against adverse patient selection may also disadvantage providers practicing in communities composed primarily of high-risk patients. That is because it will become particularly difficult for those providers to reach the benchmarks (due to underlying social and health issues their patients experience), which would make them vulnerable to the disproportionate negative payment penalties. As such, facilities such as these should either not be included in the model or have different benchmarks that take into consideration their patients’ more difficult circumstances.

The home dialysis requirements of the proposal also puts small dialysis centers at risk. While large companies such as DaVita and Fresenius manufacture their own dialysis equipment, small facilities or networks would have a more difficult time getting up to speed on the necessary home dialysis training and equipment preparation. (Had the model launched in January 2020 as originally proposed, small facilities would most certainly not have had adequate time to prepare
for such drastic shifts.) These negative impacts on smaller dialysis centers and those in communities with high-risk patients only serves to enhance the unfair power dynamic created by monopolies in dialysis centers, with 80% of the market already controlled by these two companies.

In the realm of transplantation, the Removing Financial Disincentives to Living Organ Donation Model works to increase the pool of living donors and reimburse them for accrued costs surrounding the procedure. While the current system allows for a small number of grants to be distributed to low-income living donors, this new model widens the scope of people eligible for receiving reimbursement for lost wages, child care, and elder care. The system works to remove the disincentives to living organ donors, primarily those cited above, in order to make it more viable for more people to join the living organ donor pool.

The merits and ethics of such patient payment strategies have been contested, in part due to concerns about the possibility of low-income people being coerced into organ donation. However, exploitation of low-income groups is of more concern for incentive models (currently banned under the valuable consideration clause of the NOTA) rather than reimbursement models. As described in Chapter 4, the AAKH’s reimbursement system does not trespass into “valuable consideration” territory, as it is a payment associated with the cost of the procedure rather than an unrelated large sum of money. As such, the proposed model directly addresses the financial disincentives disproportionately faced by low-income patients and donors without being coercive. In addition, the potential for exploitative effects of reimbursement strategies on low-income donors is mitigated by the strict health standards used for assessing living donor candidates. If anything, the best strategy for expanding the pool of living organ donors would be to put more emphasis and funding into prevention programs targeting such contributing diseases
as diabetes and hypertension (which are disqualifying factors for living donation and thus constitute a large barrier to living donation eligibility for low-income populations). This strategy, of course, would simultaneously lower kidney disease rates and the consequent need for transplantation in the first place.

Unfortunately, the model was unable to incorporate what would potentially be the most effective change: transitioning to an opt-out system. Such a task is vastly larger than the scope of the AAKH and one that has failed when attempted at state-wide levels, as described in Chapter 2, largely due to political and religious concerns. Still, the potential remains to increase transplantation rates in the future if policy makers can succeed in educating the public on the merits of deceased organ donation.

The high discard rates of kidneys also continues to be an issue in the United States, with other countries, such as Norway, illustrating the viability of a transplantation program based on lower standards for organ allocation. While the AAKH cited lower standards as a primary objective of the original proposal, specific legislation has yet to be released. This issue of the CMS failing to meet its self-imposed deadlines extends to many aspects of the AAKH. Most notably, the final version of the ETC Model following the notice and comment period was supposed to be released in January of 2020. As of April 29, 2020, the day this project was submitted, the CMS had yet to release the final version of the model, and it seemed likely its release would be further delayed by the ongoing burden of the COVID-19 crisis on the health care sector.

One especially important element that is missing from these proposals is that of prevention. While the larger AAKH does include goals and objectives relating to upstream prevention and detection efforts, actual action plans have yet to be released. In absence of
educational programs and screening initiatives that address not only kidney disease but its upstream contributors (such as diabetes and hypertension), the issues experienced by the growing U.S. kidney disease population will only continue to be perpetuated. The author hopes the prevention elements promised in the AAKH’s initial release will soon be detailed and implemented.

It is surprising that a proposal whose very foundation is hinged on the Affordable Care Act’s Center for Medicare and Medicaid Innovation could come from an administration that has consistently exerted efforts to dismantle that same structure. It is equally surprising that Trump’s administration, which has consistently ignored scientific evidence related to numerous environmental, medical, and social issues, released a proposal that cohered to the recommendations of global researchers, clinicians, and policy makers. Credit is due to those in the CMS who succeeded in addressing the primary actions requested by those in the kidney community for years. This does not change the fact that these innovations are paired with reductions in expenditures and drastic care changes to an entitlement program that serves over 500,000 U.S. citizens, however. Nor does it change the fact that these reductions in expenditure are achieved via mandatory monetary incentives and penalizations to physicians to spur drastic changes in patients’ treatments, without providing for educational programs to ease such a transition. Based on these factors, policy makers should consider revisions to the proposed model that would incorporate patient protection strategies, lower benchmarks, and a foundational emphasis on prevention and detection so as to alleviate the burden of ESRD in the United States in the first place. Further research and legislation is needed to make large-scale revisions to the U.S. transplant system in order to effectively cut down wait list times and ensure access to the best treatment for kidney disease patients, the transplant.
Worked Cited:


