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PREDICTORS OF KIDNEY TRANSPLANT RECEIPT AND MEDICARE COSTS FOR PATIENTS

PARISA ASGARISABET

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PREDICTORS OF KIDNEY TRANSPLANT RECEIPT AND MEDICARE COSTS FOR PATIENTS
WITH END STAGE RENAL DISEASE

by

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by
Parisa Asgarisabet, BS, MS, PhD
2020

DEDICATION

To
Beitollah Asgarisabet and Roghayieh Asgarvand
Masoomeh, Rana, Mahsa,
and
Jan

PREDICTORS OF KIDNEY TRANSPLANT RECEIPT AND MEDICARE COSTS FOR
PATIENTS WITH END STAGE RENAL DISEASE

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PREDICTORS OF KIDNEY TRANSPLANT RECEIPT AND MEDICARE COSTS FOR PATIENTS WITH END STAGE RENAL DISEASE

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Background: The objectives of this study were to first understand whether a dialysis center's ownership status modified the association between informing end-stage renal disease (ESRD) patients about transplantation options and patients' transplantation status; and second, to understand whether Medicare's Prospective Payment System (PPS) implementation affected the cost of care for ESRD patients from Medicare's perspective.

Method: This study used the United States Renal Data System (USRDS) data containing information on all ESRD patients in the US, linked to Medicare claims. To address the first objective, a multi-level analysis using mixed effect multinomial logistic regression model was conducted with patients aged 18 to 64, having an ESRD onset during 2006 to 2016. To address the second objective, an interrupted time series analysis (ITSA) was used to estimate the effect of Medicare's PPS implementation on cost of care from Medicare's perspective. The second aim examined patients 18 years and above with ESRD onset from 2005 to 2015. Total cost was further categorized into total outpatient, outpatient dialysis, outpatient non-dialysis, and inpatient costs, and analyzed using ITSA.

Results: The study showed that informing patients about transplantation options was associated with increased odds of enrolling in kidney transplant wait list (WL) or receiving a live donor kidney transplant (LDKT) at both for-profit and non-profit dialysis centers. However, this effect was less pronounced at for-profit as compared with non-profit dialysis centers (Non-profit dialysis centers: Enrolling in WL OR: 2.23 [95% CI, 2.07-2.40] and Receiving an LDKT OR: 3.35 [95% CI, 2.65-4.25]; For-profit dialysis centers: Enrolling in WL OR: 1.73 [95% CI, 1.66-1.79] and Receiving an LDKT OR: 2.35 [95% CI, 2.08-2.66]). The results also showed that the odds of informing patients was higher for for-profit as compared with non-profit dialysis centers, and characteristics of patients informed were similar between for-profit and non-profit dialysis centers.

With respect to costs, the study showed that PPS was significantly associated with decreased total cost; total cost remained steady before PPS, but cost declined over time after PPS (-0.88% [95% CI: (-0.96, -0.79)]). However, the effect of the PPS was not the same across cost categories. Although, total outpatient and outpatient dialysis costs were decreasing over time before PPS, these cost categories significantly increased immediately after PPS but continued to decline afterward. Outpatient non-dialysis cost was steady before PPS, and after a significant decline after PPS, continued to increase over time. Inpatient costs, which were increasing before PPS, had an immediate decline after PPS and showed a declining pattern over time after PPS. **Conclusion:** The first part of the study found that the beneficial effect of informing patients on transplantation status differs by the ownership status of the informing facility. Information provided by for-profit dialysis centers was less effective and potentially lower quality than that provided by non-profit dialysis centers. The study highlights the need for

developing guidelines to standardize transplantation information provided, in order to ensure similar informational quality across centers. The study also found that the PPS was associated with decreasing total cost of care, however, the effect was not the same for all cost subcategories. Nevertheless, PPS seems to have achieved the cost containment goal that it set out to achieve.

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BACKGROUND

Introduction

End-Stage Renal Disease (ESRD) occurs when kidneys fail to effectively filter waste products from blood, leading to physiological toxicity and consequent morbidity and mortality.¹ Prevalence and incidence of ESRD is increasing worldwide, and the US is no exception. Prevalence of ESRD in the US has been increasing at a stable rate since 1996 and has more than doubled since 1996.² In 2017, 124,500 patients developed ESRD resulting in 746,557 prevalent cases of ESRD at the end of 2017 in the US.²

Treatment options for ESRD patients are hemodialysis, peritoneal dialysis, or kidney transplantation (KT). Hemodialysis involves using a dialysis machine outside the body to simulate the kidneys' function of filtering blood. Peritoneal dialysis is a process in which the abdomen is filled with a fluid called dialysate, the abdominal lining (the peritoneum) acts as a filter and filters waste into the dialysate, and the dialysate is drained away with the waste at the end of the process. In transplantation a new kidney replaces the failed kidneys.³

Each option has advantages and disadvantages. Hemodialysis facilities are widely available in the US; however, patients need to travel to the dialysis centers and receive dialysis on site. Hemodialysis also requires a strict diet and fluid limit. Compared with peritoneal dialysis patients, hemodialysis patients need to consume more medications and therefore possibly spend more money on medications. Hemodialysis also has a home hemodialysis option, which can be used at home to reduce difficulties of scheduling and traveling. Patients can have more frequent dialysis during the week and probably have a more normal diet in case of home hemodialysis. Peritoneal dialysis can be self-administered by patients; however, the

dialysis fluid should be changed every day. Peritoneal dialysis requires fewer diet and fluid restrictions than hemodialysis.⁴

In case of kidney transplantation, because a transplanted kidney works like a normal kidney, patients do not need to continue dialysis, and they can also have a more normal diet. Patients who receive a transplant have a higher chance of living longer compared with other treatment options. However, the process of KT is complex and requires a major surgery. There are long waiting lines for a deceased donor, or patients need to be fortuitous to find a live kidney donor. After the transplantation, there is a chance that the body would reject the new kidney, so patients must take immunosuppressants to increase the chances of the body accepting the new kidney. Immunosuppressants may cause additional complications.⁴

For most ESRD patients, KT remains the best renal replacement practice.⁵ Studies have shown that transplantation has better outcomes than dialysis, with better mortality rates and long-term health outcomes associated with transplantation. KT recipients have lower risk of cardiovascular events, and they have better quality of life.⁶ Long-term mortality rates are about 68% lower for transplant recipients compared to non-recipients on prolonged dialysis. Survival rate after KT is significantly and negatively related to time on dialysis.⁷ However, considering the benefits of KT, only 14% of ESRD patients chose a transplantation option by either enrolling in the wait list (WL) or receiving a live donor kidney transplant (LDKT), within one year of ESRD onset.⁸

Dialysis is a costly and time-consuming treatment process. Most ESRD patients are eligible to enroll through Medicare. Considering the growing number of patients requiring ESRD and high cost of dialysis, Medicare's expenditure to cover ESRD patients continues to grow.⁸

While Medicare's ESRD population accounts for less than 1% of its total population, it has accounted for about 7% of overall Medicare spending in recent years.⁸ Medicare continues to apply new policies to reduce its expenditure by lowering its cost per person per year and increasing number of transplantations.

KT improves patient survival and quality of life, and it saves a significant amount of money for Medicare. The first section of this research focuses on differences in effect of informing patients about transplantation options on their transplantation status between for-profit and non-profit dialysis centers. In 2005, the Centers for Medicare and Medicaid Services (CMS) released a new version of Medical Evidence Form-2728 to emphasize the importance of transplantation. This form requires dialysis centers to indicate whether each patient was informed about KT; if the patient was not informed, the dialysis center must indicate why. Even though this form promotes KT education to assist the patients to make informed decisions, there is no standardized education about KT for ESRD patients.

The rate of informing patients about KT options, enrolling on the WL, and receiving LDKT differs among dialysis centers. A lower rate of enrolling on WL and LDKT among for-profit dialysis centers compared with non-profit dialysis centers has been documented in the literature.^{6,9-11} The first part of this study explores whether the association between informing patients about KT options and patient transplantation status within one year after being informed depended upon receipt of services at a for-profit versus a non-profit dialysis center. Patients can have one of the following statuses during the first year after being informed:

- (a) Deciding to enroll in the WL (WL enrolled)
- (b) Receiving an LDKT (LDKT received)

(c) Remaining on dialysis (reference category)

The second part of this study focused on Medicare's policy change in reimbursing dialysis centers. Medicare coverage for ESRD patients began in 1973, when about 16,000 patients required regular dialysis. In 2017, ESRD prevalence in the US was 746,557, a 2.5% increase over 2016. Medicare expenditures increased by 1.3% in 2017 compared with 2016. In 2017 Medicare's fee-for-service ESRD program cost about \$36 billion, which accounts for 7.2% of the overall Medicare payment for claims.⁸ Medicare has implemented various policies to contain the growing cost. The most recent change in reimbursement policy was implemented in January 2011 as a result of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. MIPPA mandates reimbursement reform to reduce expenditures, which led CMS to release the final ruling for implementation of the ESRD Prospective Payment System (PPS) or bundled payment in July 2010, effective from January 2011.¹²⁻¹⁴ In this payment system, Medicare reimburses dialysis centers with a fixed amount of \$230 per dialysis treatment per patient. This includes cost of dialysis, all injectable and equivalent oral medications, and any dialysis-related tests. Bundled payment systems provide incentives to use less costly treatments.

To prevent any possible inadequate treatment, The Quality Incentive Program was started in 2012 to ensure that dialysis centers meet certain criteria in controlling patients' average hemoglobin and urea reduction levels.¹⁵ If a dialysis centers fails to meet these criteria, Medicare will deduct penalties from the reimbursement.

Early research on the effect of the new reimbursement policy shows that utilization of less expensive drugs has increased after the policy implementation. However, the policy has

influenced other service types as well, in addition to adverse effects and cost shifting. For example, increased inpatient and emergency department blood transfusions imply cost shifting from dialysis centers to hospitals and emergency centers. This study aimed at exploring changes in Medicare's payments for dialysis and non-dialysis services. Cost categories of interest were total cost of care, total outpatient cost, outpatient dialysis cost, outpatient non-dialysis cost, and inpatient cost among new ESRD population after the policy implementation.

Part 1: Aim 1

KT Education and Transplantation Status

For most ESRD patients, transplantation is the best renal replacement practice.⁵ Patients might receive KT if they enroll on the WL or they receive an LDKT. The number of patients enrolled on the WL has increased over time. In 2017, there were more than 75,000 in the WL.⁸

Despite the high demand for a healthy kidney, the gap between the supply and demand has increased every year. The median time wait time for a deceased KT was more than 5 years in 2017.⁸ The total number of transplantations performed by year has increased over time; the increase is mostly due to increases in deceased KT, as LDKT has been fairly steady during the last 5 years. In 2017, 20,945 transplant surgeries were performed.⁸

The new version of the CMS Medical Evidence Form-2728, released in 2005, includes a query about whether a patient has been informed about KT. If the patient was not informed, the dialysis center must choose a reason from the following options "Medically unfit,"

“Unsuitable due to age,” “Psychologically unfit,” “Patient declines information,” “Patient has not been assessed,” and “Other.”¹⁶

L. M. Kucirkaa et al. used Form-2728 data from 2005 to 2007 and showed that among 236,079 patients who developed ESRD during study period, 30.1% were not informed about KT options. Among these, 42% were not assessed, 30.4% were medically unfit, and 16.9% were reported to be unsuitable due to age. They also showed that patients who are not informed about KT options have a 53% lower rate of enrollment on WL or receiving an LDKT¹⁷

Unequal Provision of KT Education

The rate of enrolling on the WL and receipt of LDKT differs among dialysis centers; the rate is significantly lower for for-profit dialysis centers than for non-profit dialysis centers.^{6,9–11} Literature shows that lower likelihood of being placed on a WL for patients treated in for-profit dialysis centers remains significant after controlling for possible confounders such as socioeconomic, demographic, and geographic factors.^{6,10,18}

Past studies show that more intensive education such as one-on-one discussions, spending sufficient time on patient education, and involving patient’s family members and social network in the process of transplant education have the potential to influence a patient’s decision on transplant and increased LDKT inquiries, completed transplant evaluation, and even receiving an LDKT.^{19–25} For example, Rodrigue et al showed that an intervention to involve family members and friends in the transplant education process was successful in increasing living donor inquiries, living donor evaluations, and even LDKT among the participants. The effect was greater in African Americans than whites for living donor

evaluations and LDKT, but not for living donor inquiries.^{19,20} The results show that high quality education has potential to not only increase transplantation but also to reduce the racial disparities.

Waterman et al. in a study on Heartland Kidney Network (Iowa, Kansas, Missouri, and Nebraska) from 2009 to 2011, showed a high variation in number of KT education practices dialysis centers use. Educational practices such as verbal recommendations to be evaluated for KT, referral of patients to an educational program, the opportunity to talk to a kidney recipient, detailed discussions about the risks and advantages of KT, and eight other practices were studied among dialysis centers. The result of their study indicates that dialysis centers that have higher rate of patients enrolled on WL use multiple transplant education practices.²⁶ This research included a survey on the knowledge of transplantation among educators, predominantly dialysis nurses and social workers. On average educators were able to answer only 50% of the questions correctly. Educators who reported low level of transplant knowledge were more likely to offer lower quality education such as verbal recommendation and referral to external transplant education programs. Only 18% of educators have reported detailed discussion about KT options with ESRD patients.²⁶

Balhara et al. surveyed 906 nephrologists practicing in the United States and concluded that most nephrologists believe that ideal time for educating patients is more than 20 minutes; however, most nephrologists spend less time, especially in for-profit dialysis centers. They argue that unequal provision of education might partially explain documented lower rate of enrollment on WL and LDKT in for-profit dialysis centers.²⁷

Public Health Significance

KT is the best renal replacement practice for most of the ESRD patients.⁵ It reduces mortality risk and improves quality of life.^{6,7} Because KT patients do not need dialysis anymore (unless the KT fails), this treatment option saves a significant amount of money from the Medicare's perspective. In 2017, the per-person-per-year (PPPY) cost for KT patients was \$35,817. However, the PPPY for dialysis patients was significantly higher (\$91,795 for hemodialysis and \$78,159 for peritoneal dialysis).⁸ The benefits of increasing the transplant rate for ESRD patients include lower mortality rate, better quality of life, and financial savings.

Educating ESRD patients about KT increases the likelihood of enrollment in the WL and receiving an LDKT.¹⁷ Previous studies show the positive association between educating patients about KT options and patient's KT status. The use of more knowledgeable educators and multiple educational practices were associated with a higher rate of waitlisted patients in dialysis centers at Heartland Kidney Network.²⁶ Research also shows there is a significant variation in how dialysis centers provide transplant education, which leads to variations in the rate of enrollment in the WL and rate of receiving an LDKT.²⁶

Considering these results - along with the lower rate of receiving an LDKT and enrolling in a WL in for-profit dialysis centers compared to non-profit dialysis centers, - it is important to understand whether the education provided in non-profit dialysis centers results in better WL enrollment and LDKT receipt than in for-profit dialysis centers.

Study Objective 1

The overall objective of this study was to understand if there is a difference between for-profit dialysis centers and non-profit dialysis centers in the quality of information provided to the patients about transplantation options. Patients can have one of the following statuses during the one year after being informed:

- (a) Decide to enroll in the WL (WL enrolled)
- (b) Receive an LDKT (LDKT received)
- (c) Remain on dialysis (reference category)

One could argue that if the association of education and odds of favorable outcomes occurring (after controlling for clustering effect, all available patient levels, and center level variables) differs between for-profit and non-profit dialysis centers, and if the type of patients being informed are similar across dialysis centers, it potentially indicates a difference in the quality of education provided between these two types of centers. If the result of our research confirms the hypothesis, one could conclude that for-profit dialysis centers provide lower quality educational practices.

Objective 1: To determine whether being informed about transplantation options affects patient's transplantation status; and to determine whether the effect differs by ownership status of the dialysis center.

Hypothesis 1: Being informed is associated with higher odds of choosing a transplantation option

Hypothesis 2: Being informed by non-profit dialysis centers increases the odds of choosing a transplant option more than being informed by for-profit dialysis centers

Part 2: Aim2a- Aim2e

History of Medicare's ESRD program

Medicare's ESRD program, which was initiated in 1973, provided health insurance for ESRD patients regardless of their age. Medicare costs for covering ESRD during first years of new policy were expected to be low, as only 16,000 patients required dialysis at the time.²⁸ On average, Medicare reimbursed independent facilities by \$138 per dialysis and hospital-based facilities by \$156.²⁹ Medicare's ESRD program cost \$229 million in 1973 and increased to \$1.8 billion in 1982. Prevalent cases of ESRD also increased to 64,000.³⁰ By 1982 Medicare's ESRD program accounted for 4% of its overall expenditures.³¹ The increasing share of the ESRD program from total expenditures motivated Medicare to introduce fixed payment for treatments that included all costs such as labor, dialysis, dialysis machine, and tools. Starting in 1983, Medicare reduced reimbursements to a per-treatment fixed rate for hospital dialysis centers (\$131) and freestanding centers (\$127). When considering inflation rate, dialysis centers received 35% less in 1989 than they did in 1983.¹² In 1989, the Amgen pharmaceutical company developed the erythropoietin stimulating agent (ESA) to be used for ESRD patients who have severe anemia. CMS used the capitation method to pay for ESA, and that led to lower utilization than the FDA had recommended.¹² To provide an incentive to use more ESAs, in 1991 Medicare implemented fee-for-service reimbursement for ESA.¹² This program (which was in effect for 20 years) provided an incentive to use more ESAs. In 2005, separately billable reimbursement components, largely derived by ESAs, accounted for 37% (\$2.9 billion) of the dialysis care cost.³² Along with concerns about high cost of ESA, new studies showed that over-using ESA for patients who do not suffer from severe anemia

could result in harm. This evidence led the Food and Drug Administration to issue a statement on over-using the drug for patients with mild anemia.¹²

Prospective Payment System

The July 2008 congressional passage of MIPPA, which mandates reimbursement reform to reduce expenditures, led CMS to release their final ruling for implementing the ESRD PPS program in July 2010, effective from January 2011.^{12,13}

Under the new reimbursement system, CMS reimburses \$230 per dialysis session. Payments for peritoneal dialysis is equal to hemodialysis to encourage more peritoneal dialysis. This includes dialysis cost, all injectable medications or their equivalent oral forms (ESA, iron, and vitamin D), and dialysis related tests.¹² By 2014, oral-only drugs were also included in the bundled payment.³³ Any administered drugs that are not specifically related to the disease are reimbursed separately. The new payment system eliminates the incentive to over-using ESA to maximize reimbursements.¹²

Pay for Performance Measures

Even though the new policy eliminates incentives to over-use ESAs, it increases the likelihood of inadequate treatment. CMS's pay-for-performance rule, which included three measures, was designed to address this concern. The first two measures were related to anemia management. According to FDA recommendation, ideal hemoglobin level in dialysis patients is 10-12 grams per deciliter. The first measure was the percentage of Medicare patients in each dialysis center who had less than 10 grams per deciliter average hemoglobin level; the second measure was the percentage of Medicare patients in each dialysis center who had more than 12 grams per deciliter average hemoglobin level; the third measure was

the average urea reduction ratios of more than 65%. The first measure was the most important measure with 50% weight; the second and third measures both had 25% weight. The national standard is 2% or less, 26% or less, 96% or more for first, second and third measures, respectively. If dialysis centers fail to meet these standards, Medicare will deduct penalties from their payment.²⁸

Research on Early Effects of New Policy

Studies assessing early treatment trends after the new payment policy showed that the new policy successfully provided incentives for dialysis centers to use lower cost therapies to manage anemia among their patients. Studies comparing utilization of ESA in 2010 and 2011 showed a significant decline in ESA utilization after PPS.³⁴ Even though the decline in ESA was substantially due to FDA's recommendation about more conservative usage of ESA, research shows that the bundled payment implementation had an impact as well.^{34,35}

The percentage of patients who received iron for anemia management increased by 5.5 percentage points from 2010 to 2011.³⁴ The percentage of patients who received intravenous iron increased by 10%-17% from October 2010 to October 2011.³⁵ Utilization of other less-expensive practices, such as using serum ferritin and blood cell transfusion, also increased after PPS.³⁵⁻³⁸ Increased inpatient and emergency department transfusions also increased after PPS, which shows a cost shift from dialysis centers to hospitals and emergency centers.³⁹ Overall, average hemoglobin level had been reported to be declining before 2011 and declined more after PPS.^{34,40}

Overall utilization of vitamin D has also declined, and there was a significant shift from intravenous vitamin D use to oral vitamin use, also from more expensive paricalcitol towards

a less expensive type, doxercalciferol.^{34,40} Use of antibiotics, levocarnitine, and alteplase has declined¹⁰ and use of cinacalcet and phosphate binders has increased.⁴⁰

Even though most patients could benefit from home dialysis or peritoneal dialysis, most patients receive in-center hemodialysis. Research shows that home dialysis and hemodialysis lead to the same clinical outcomes as in-center hemodialysis.⁴¹ Under PPS, for peritoneal dialysis Medicare reimburses dialysis centers the same amount as in-center hemodialysis. This payment includes payment for home dialysis training, equipment and supplies, and support services. Medicare also reimburses \$33.44 for any training add-ons, and geography adjusted payments range from \$20.03 to \$45.84.¹⁴

During the first year of PPS' implementation, rate of home hemodialysis increased by the same rate it as it had increasing since 2007 (0.2 percentage points per year). The use of peritoneal dialysis increased by about 1.2 percentage points in 2011 compared to 2010; this increase was not statistically significant.^{34,40} However, a two-year pre- and post-policy comparison shows a statistically significant increase in peritoneal dialysis use. Small dialysis organizations and non-profit dialysis centers increased peritoneal use faster than large organizations and for-profit dialysis centers.⁴²

One of the main concerns about bundling payments for dialysis - and the associated changed patterns in anemia management and use of other medications - was its adverse indirect effect on patients' health. Wang et al, in a two-year pre-and-post policy comparison study shows that among elderly patients, the risk of major adverse cardiovascular events, death, hospitalized congestive heart failure, and venous thromboembolism were similar before and after policy; the risk of stroke was lower for the study period of after policy. Risk of major

adverse cardiovascular events and all-cause mortality decreased significantly for African American patients after the PPS.⁴³

Public Health Significance

Medicare expanded its coverage to ESRD patients in 1973. As the number of ESRD patients has increased significantly since then, so did the Medicare's expenditure for ESRD patients. Despite the increasing total number of ESRD patients covered by Medicare, it accounts for less than 1% of Medicare's total population. However, this small portion of Medicare population accounts for a significant percentage of Medicare's total expenditure. To address the issue of growing costs of the program, Medicare has changed its reimbursement policy multiple times since 1973, most recently in January 2011.

The effects of this policy change on anemia management, use of vitamin D and other medications, and incidence and prevalence of dialysis modalities have been well studied. Studies have shown a shift in anemia management towards less expensive treatment and drugs. ESA use and doses have decreased, and the use of intravenous iron and blood transfusions have increased. Incidence and prevalence of home dialysis increased slightly after PPS.

However, the direct and indirect effects of PPS on Medicare's expenditure have not been studied well. Medicare changed its reimbursement policy for dialysis services in 2011 with the hope to control increasing Medicare's ESRD program expenditure. An in-depth study on Medicare's payments to dialysis centers and other providers could provide more insights on effect of the PPS in Medicare's expenditure structure.

Study Objectives 2a-2e

This aim explored the effect of PPS on Medicare expenditure for one-year care for patients who recently developed the ESRD. Total cost was further categorized to total outpatient cost, outpatient dialysis cost, outpatient non-dialysis cost, and inpatient cost. The effect of PPS on odds of having non-zero inpatient cost was further explored.

Objective 2a: To determine effect of PPS on one-year total cost

Objective 2b: To determine effect of PPS on one-year total outpatient cost

Objective 2c: To determine effect of PPS on one-year outpatient dialysis cost

Objective 2d: To determine effect of PPS on one-year outpatient non-dialysis cost

Objective 2e: To determine effect of PPS on one-year inpatient cost

Hypothesis 1: PPS significantly reduced the cost of care from Medicare's perspective for all cost categories.

METHODS

Data Source

This study used the United States Renal Data System (USRDS), a national data system that collects data on chronic kidney disease (CKD) and end-stage renal disease patients. The USRDS analyzes these data and releases an annual report on the prevalence and incidence of CKD and ESRD, patient demographics, treatment modalities, and Medicare's expenditure on ESRD program. USRDS is directly funded by The National Institute of Diabetes and Digestive and Kidney Diseases. USRDS also collaborates with CMS, the United Network for Organ Sharing (UNOS), and the ESRD networks. They provide a comprehensive source of data about ESRD patients. The following data sets from the USRDS have been used for this study.

- **CORE-PATIENTS: Patient Profile**

Patient profile has one record per patient in the USRDS database. This data set provides information on demographic such as date of birth, sex, race, ethnicity, zip code, age at first enrollment on WL, and ESRD-related data such as primary cause of ESRD, dialysis modality, date of first ESRD service, enrollment on WL, first transplant, date of death, and cause of death. This datafile was used to extract socio-demographic information about the patient.

- **CORE-MEDEVID: Medical Evidence Form**

Medical evidence form (CMS-2728) has information on employment status, insurance status, nephrology care before renal disease, primary cause of renal disease, start date of chronic renal dialysis, and patients' comorbidities. This form is also the source for whether the patient was informed about transplantation option and reasons why the patient was not informed.

Beginning in January 2005, this form asks whether the patient has been informed about KT options. If the patient has not been informed, this form provides a selection of reasons to choose from. This datafile was used to extract medical information such as comorbidities about the patient and whether the patient had been informed about the KT options.

- CORE-WAITLIST_KI: Transplant Wait List (Kidney)

This dataset has one record per patient per kidney WL event in the USRDS database. Demographic information, blood type, height and weight, previous transplants, additional organ enrollments, listing date and center, WL status, reason for inactive status, removal date from WL and reason for removal, date of death and USRDS assigned facility ID are available in this dataset. This datafile, along with Patient Profile, was used to exclude patients who enrolled on WL before filling the form CMS-2728.

- CORE-FACILITY: Annual facility survey

The CMS ESRD Annual Facility Survey and the CDC Dialysis Surveillance Survey is the sources of information on facilities. This dataset includes information on ownership status of the center, certification code (transplant center, dialysis center, etc.) and number of patients and staff personnel. The survey period is January 1 through December 31. This datafile was used to extract facility information.

- CORE-PAYHIST: Payer History

This data set contains a new record for each patient at each change in payer. It includes the start and end date for each period with specific payer category. If a patient's payer category changes, a new record would be available for the patient. Payers are categorized into the

following groups: 1. HMO. Group Health Organization, 2. MPAB. Medicare Primary, both Part A and Part B, 3. MPO: Medicare Primary, Other, 4. MSP-EGHP: Medicare as Secondary Payer with EGHP, 5. MSP-nonEGHP: Medicare as Secondary Payer, no EGHP, 6. OTH: Other/Unknown, and 7. WAIT: 90 Day Waiting Period. This datafile was used to extract insurance coverage information about the patients.

- Transplant dataset

This dataset includes minimum details about all transplants from all sources. Recipient and donor information such as, race, ethnicity, age, gender, and blood type are available in this dataset. The dataset also includes the relationship of living donor and recipient, transplant year, total number of transplants for patient, transplant failure time, whether patient accepts expanded criteria donor kidneys, and USRDS-assigned facility ID. This datafile was used to exclude patients who received KT before filling the form CMS-2728.

- Medicare Institutional Claims (2006-2016)/ Medicare Physician/Supplier Claims (2011-2016)

There are separate claims file for each year. These files record dialysis and non-dialysis claims for all ESRD patients. The source of the bill, primary diagnosis code, service date, number of dialysis sessions (if any), and Medicare's payment for each event is recorded. These datafiles were used to extract cost of services provided to ESRD patients by Medicare. Required variables to select target population are available in PATIENTS, MEDEVID, WAITLIST_KI, TX, and PAYER HISTORY sub-datasets. After identifying target population, these datasets were linked together using the USRDS patient ID that is available

in all datasets. Dialysis center-level information was merged to the data using the USRDS provider ID number which is available in MEDEVID and Institutional Claims files.

Study Design

Both Aim 1 and Aim 2 used population-based retrospective design.

The study population for Aim 1 was defined based on the following criteria:

- (a) Patients had to be 18 to 64 years old (patients who are 65 years old and older are deemed medically unsuitable for transplantation).
- (b) Patients had to have the study initiation date between January 1, 2005 and December 31, 2016.
- (c) Patients had to have a completed CMS-2728 Form within 45 days of study initiation.
(Medical evidence form CMS-2728 must be filled within 45 days of ESRD initiation.)

Patients were excluded if:

- (a) They enrolled in the transplant WL or received a KT prior to the study initiation date and prior to completing CMS-2728 Form.
- (b) They had missing CMS-2728 form completion date.
- (c) They had a dialysis start date before study initiation date.
- (d) They were missing the provider number for their dialysis center, that links the dialysis center variables with each patient, or missing the ownership status or patient informed status.
- (e) Their date of death was erroneously recorded as being before study initiation date, WL enrollment date, or transplantation date.

After applying inclusion and exclusion criteria, a total of 590,601 ESRD patients were included in this aim.

The study population for Aim 2 was defined based on the following criteria:

- a) Patients had to be 18 years old or older.
- b) Patients had to have their first ESRD service between January 1, 2006 and December 31, 2015.
- c) Patients had to have Medicare Part A and B coverage before the first ESRD service or during 92 days after that.
- d) Patients had to have completed a CMS-2728 Form within 45 days of study initiation.

In this study, Medicare part A and B coverage initiation date was defined as study initiation date. Each patient was followed for a year after study initiation (until December 31, 2016).

Patients were excluded if:

- a) They received a KT the day of or prior to the study end.
- b) They died the day of or prior to study end date.
- c) They had a discontinued Medicare part A and B coverage during study period.
- d) They had discontinued dialysis during the first three months after first ESRD service.
- e) They had no Medicare claims or had no dialysis sessions reported in Medicare claims.
- f) They had \$0 total cost.

After applying inclusion and exclusion criteria, a total of 415,025 ESRD patients were included in this aim.

Study Variables

Following tables show dependent and independent variables that were used to address study aims. They include the variable name, description, measures, and source of the variable. All the variables except education and income were available in the dataset (such as age, race, and ethnicity) or were derived using available variables (such as Patient's transplantation status)/ Education and income are not available in the dataset. Zip code-level education and income from American community survey data were used as proxy for individual education and income.

Table 1 Dependent Variables

Aim	Variable name	Variable Description	Variable type
Aim 1	Transplantation status	Patient's transplantation status	Categorical variable with three categories <ul style="list-style-type: none">• WL enrolled• LDKT received• Remaining on dialysis (reference category)
Aim 1	Patient Informed	Whether patient was informed about Kidney transplant or not	Categorical <ul style="list-style-type: none">• Informed• Uninformed (Reference Category)
Aim 2a	Total cost	The sum of all Medicare reimbursements for each patient over the study period	Continuous
Aim 2b	Total Outpatient Cost	The sum of Medicare reimbursements for outpatient and physician/ supplier services	Continuous

Aim	Variable name	Variable Description	Variable type
Aim 2c	Outpatient Dialysis Cost	The sum of Medicare reimbursements for all dialysis related services provided by dialysis centers	Continuous
Aim 2d	Outpatient non-dialysis Cost	The sum of Medicare reimbursements for all non-dialysis related services	Continuous
Aim 2e	Inpatient Cost	The sum of Medicare reimbursements for inpatient stays and skilled nursing facilities	Continuous
Aim 2e	Non-zero Inpatient cost	Whether the patient had non-zero inpatient cost (inpatient cost and skilled nursing facilities)	Categorical variable with two categories: <ul style="list-style-type: none"> • No (Reference category) • Yes

Table 2 Independent Variables

Aim	Variable name	Variable Description	Variable type
Aim 1	Patient Informed Status	Whether patient was informed about kidney transplant	Categorical variable with two categories <ul style="list-style-type: none"> • Uninformed (reference category) • Informed
Aim 1 Aim 2a-2e	Ownership Status	Ownership status of a dialysis center	Categorical variable with two categories <ul style="list-style-type: none"> • Non-profit (reference category) • For-profit
Aim 2a-2e	Time	The time elapsed since the start of the study in six-month period points	Continuous variable
Aim 2a-2e	PPS	Indicating whether the patient's study initiation date is before or after Medicare's PPS policy	Categorical variable with two categories <ul style="list-style-type: none"> • Pre-PPS (reference category) • Post-PPS

Aim	Variable name	Variable Description	Variable type
Aim 1 Aim 2a-2e	Age	Age at ESRD onset	Continuous variable
Aim 1 Aim 2a-2e	Race-Ethnicity	Race/ethnicity of the patient	Categorical variable with four categories <ul style="list-style-type: none"> • Non-Hispanic white (reference category) • Non-Hispanic black • Hispanic • Other
Aim 1 Aim 2a-2e	Education	Percentage of adults in the patient's zip code area with high school education or more	Continuous variable
Aim 1 Aim 2a-2e	Income	Median household income for the patient's zip code area in dollars	Continuous variable
Aim 1	Sex	Sex of the patient	Categorical variable with two categories

Aim	Variable name	Variable Description	Variable type
Aim 2a-2e			<ul style="list-style-type: none"> • Male (reference category) • Female
Aim 1	Insurance type	Patient's insurance type at time of ESRD onset	Categorical variable with five categories <ul style="list-style-type: none"> • Medicare (reference category) • Medicaid • Private insurance • Other insurance • Uninsured
Aim 1 Aim 2a-2e	Employment Status	Employment status of the patient	Categorical variable with five categories <ul style="list-style-type: none"> • Unemployed (reference category) • Employed • Retired due to age • Retired due to disability

Aim	Variable name	Variable Description	Variable type
			<ul style="list-style-type: none"> • Other
Aim 1 Aim 2a-2e	Nephrology care prior to ESRD onset	Whether patient had nephrology care prior to ESRD onset	Categorical variable with three categories <ul style="list-style-type: none"> • No (reference category) • Yes • Missing
Aim 1 Aim 2a-2e	Primary cause of disease ESRD	Primary cause of disease ESRD	Categorical variable with five categories <ul style="list-style-type: none"> • Diabetes (reference category) • Hypertension • Glomerulonephritis • Polycystic kidney disease • Other
Aim 1 Aim 2a-2e	Presence of hypertension	Whether the patient had hypertension at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category)

Aim	Variable name	Variable Description	Variable type
			<ul style="list-style-type: none"> • Yes
Aim 1 Aim 2a-2e	Presence of diabetes	Whether the patient had diabetes at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category) • Yes
Aim 1 Aim 2a-2e	Presence of cardiovascular disease (CVD)	Whether the patient had CVD at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category) • Yes
Aim 1 Aim 2a-2e	Presence of cancer	Whether the patient had cancer at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category) • Yes
Aim 1 Aim 2a-2e	Presence of chronic obstructive	Whether the patient had COPD at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category) • Yes

Aim	Variable name	Variable Description	Variable type
	pulmonary disease (COPD)		
Aim 1 Aim 2a-2e	Presence of disability	Whether the patient had disability at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category) • Yes
Aim 1 Aim 2a-2e	BMI	Body Mass Index at time of ESRD onset	Continuous variable
Aim 1 Aim 2a-2e	GFR EPI	Glomerular Filtration Rate Epidemiology Collaboration time of ESRD onset	Continuous variable
Aim 1 Aim 2a-2e	GFR MDRD	Glomerular Filtration Rate Modification of Diet in Renal Disease time of ESRD onset	Continuous variable
Aim 1 Aim 2a-2e	Current Smoker	Whether the patient was a current smoker at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category)

Aim	Variable name	Variable Description	Variable type
			<ul style="list-style-type: none"> • Yes
Aim 1 Aim 2a-2e	Alcohol dependence	Whether the patient was dependent on alcohol at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category) • Yes
Aim 1 Aim 2a-2e	Drug dependence	Whether the patient was dependent on drug at the time of ESRD onset	Categorical variable with two categories <ul style="list-style-type: none"> • No (reference category) • Yes
Aim 1 Aim 2a-2e	Number of dialysis stations	Number of dialysis stations at the dialysis facility that the patient is receiving dialysis	Continuous variable
Aim 1 Aim 2a-2e	ESRD Network	ESRD network	Categorical variable with 18 categories <ul style="list-style-type: none"> • Network 1 (CT, ME, MA, NH, RI, VT) • Network 2 (NY)

Aim	Variable name	Variable Description	Variable type
			<ul style="list-style-type: none"> • Network 3 (NJ, PR, VI) • Network 4 (DE, PA) • Network 5 (DC, MD, VA, WV) • Network 6 (GA, NC, SC) (Reference Category for Aim 2a-2e) • Network 7 (FL) • Network 8 (AL, MS, TN) • Network 9 (IN, KY, OH) • Network 10 (IL) • Network 11 (MI, MN, ND, SD, WI) • Network 12 (IA, KS, MO, NE) • Network 13 (AR, LA, OK)

Aim	Variable name	Variable Description	Variable type
			<ul style="list-style-type: none"> • Network 14 (TX) (reference category for Aim 1) • Network 15 (AZ, CO, NV, NM, UT, WY) • Network 16 (AK, ID, MT, OR, WA) • Network 17 (AS, Guam, HI, Mariana Islands, Northern CA) • Network 18 (Southern CA)
Aim 1	Year	Year of ESRD onset	Categorical variable with 12 categories <ul style="list-style-type: none"> • 2005 (reference category) • 2006 • 2007 • 2008

Aim	Variable name	Variable Description	Variable type
			<ul style="list-style-type: none"> • 2009 • 2010 • 2011 • 2012 • 2013 • 2014 • 2015 • 2016

Data Analysis

Aim 1

The analysis for Aim 1 was conducted in two main steps. In step 1, a multi-level analysis using mixed effect multinomial logistic regression model was used. The outcome was defined as a categorical variable with three categories: (a) Deciding to enroll in the WL (WL enrolled); (b) Receiving an LDKT (LDKT received); and (c) Remaining on dialysis (reference category).

To define the outcome, first the study initiation date using “Date of First ESRD Service” from **Patient Profile** dataset was defined. All patients were followed for one year after the study initiation date (365 days) and defined the study end date as:

Study End Date= Study Initiation Date +365

The following variables were used to define the outcome: “Date of first transplant,” “First transplant donor type,” and “First date patient is ever waitlisted” for a kidney transplant. Both date variables and type of donor are available in **Patient Profile**. Date of first transplant, date of other kidney transplants, and donor types are available in **Transplant** dataset. First date patient is ever waitlisted, and other possible enrollment on WL are available in **Transplant Wait List (Kidney)** as well. If a patient’s “Date of first transplant” was recorded as a date within the study period (including study initiation and study end date) and “First transplant donor type” was a live donor, the patient was categorized as “Receiving an LDKT (LDKT received)”. If a patient’s “First date patient is ever waitlisted” was recorded as a date within the study period (including study initiation and study end date) the patient was categorized as “Deciding to enroll in the WL (WL enrolled)”; otherwise, the patient was recorded as “Remaining on dialysis (reference category).”

The main two independent variables of interest were Patient Informed and Ownership Status; these variables and the interaction of the two variables were used to first determine whether informing

a patient about transplant options increased the odds of deciding to enroll in the WL or receiving an LDKT, and the second if the odds differed between for-profit and non-profit dialysis centers.

The formula for this analysis may be explained as:

$$\ln \left(\frac{P(R_{ij}=K)}{1-P(R_{ij}=K)} \right) = \gamma_{00} + \mu_{0j} + \gamma_{10} * Patient\ informed + \gamma_{11} Ownership\ status * Patient_informed$$

P= Probability that patient has the status K

γ_{00} : Grand mean of outcome across patients and centers

μ_{0j} : Random intercept $\sim N(\mu, \sigma^2_{\mu})$ (to allow variability in centers)

γ_{10} : Fixed effect, representing the estimate of association between patient level variables and outcome

γ_{11} : Fixed effect, representing the estimate of the association between interaction of patient level variable and center level variable with outcome

A secondary analysis was conducted for this aim to better understand the observed results from the above-mentioned analysis. An analysis on odds of being informed using a multi-level analysis using a mixed effect logistic regression model was performed. The dependent variable for this model was defined as Patient Informed and the main independent variable was Ownership Status of the dialysis center. Subgroup analysis for for-profit and non-profit dialysis centers were further conducted to understand the differences between the type of patients that were being informed between the two types of dialysis centers. SAS v. 9.4 (SAS Institute, Cary, NC) was used for all analysis in this aim.

Patients' demographic information was extracted from **Patient Profile** dataset. Age was calculated using ("Date of birth" – Study Initiation Date)/365. The number then was rounded down and used as Age. Gender was defined as Male (reference category) and Female using "Sex" variable in **Patient Profile**. About 0.01% of all patients in **Patient Profile** were missing the "Sex" variable, when the value was missing, gender was recorded as Male. The Race-Ethnicity variable was

defined using “Race of patient” and “Hispanic ethnicity.” Race-Ethnicity was defined as (non-Hispanic [NH] white, NH black, Hispanic, and other).

The American Community Survey^{44,45} 2011 tables linked to the USRDS data was used to define the level of education and income at the zip-code level for each individual. Education was measured as a percentage of adults in the patient’s zip code area with high school education or more (continuous variable in percent); income measured as median household income for the patient’s zip code area (continuous variable in dollars); education measured as a percentage of adults in the patient’s zip code area with some college education or more (continuous variable in percent).

Other patient level variables were defined using **Medical Evidence Form** (CMS-2728). Employment status was defined using “Current employment status.” Patients were categorized as Unemployed (current employment status recorded as Unemployed or Homemaker), Employed (current employment status recorded as Employed full time or Employed part time), Retired due to age, Retired due to disability, and Other (current employment status recorded as any other category). Insurance was defined using binary variables that indicates whether the patient had specific insurance coverage. Each patient’s insurance was categorized as Medicare if at least one of the “Medicare coverage” or “Medicare Advantage” were recorded as 1, Medicaid if the “Medicaid coverage” was recorded as 1, Private Insurance if “Employer Group Health Insurance” was recorded as 1, Other if “Other medical insurance” or “DVA coverage” were recorded as 1, or uninsured if “MEDCOV_NONE: No medical insurance” recorded as 1. For patients who did not have any insurance but were listed as “Patient is applying for ESRD Medicare Coverage,” insurance was categorized as Medicare.

Nephrology care prior to study initiation was defined using “NEPHCARE: Was patient under care of a nephrologist?” This was a Yes/No variable with significant proportion of missing values, so a category of “Missing” was included for this variable as well in the analysis.

The primary cause of ESRD was defined using “DISGRPC: Primary Cause of Renal Failure detailed group.” Categories are defined as Diabetes, Hypertension, Glomerulonephritis, Polycystic kidney disease, and Other (for Other urologic, Other cause, Unknown cause, or Missing cause).

The presence of comorbidities and behavioral characteristics were defined using binary (Yes/No) variables in **Medical Evidence Form**. Body mass index (BMI), estimated Glomerular Filtration Rate Epidemiology Collaboration (GFR EPI), and GFR Modification of Diet in Renal Disease (GFR MDRD) are continuous variables available from the **Medical Evidence Form**.

The analysis was controlled for the USRDS Network patient is associated with. There are 18 USRDS networks in the US, and this variable was used as a proxy to control for geographic variation. The year of study initiation was also controlled for, to adjust for changes over time.

Dialysis facility information is extracted from **FACILITY: CMS/CDC ESRD Annual Facility** dataset. The information in this data set includes the “The CMS ESRD Annual Facility Survey and the CDC Dialysis Surveillance Survey,” which provides information such as ownership status of the facility center, certification code of the facility center (dialysis center, hospital dialysis center, transplant center, etc.), number of staff and patients, and number of dialysis stations. Because the number of staff, patients, and dialysis stations were highly correlated, the number of dialysis stations was used as a proxy for the size of dialysis center. For each patient the provider number available from **Medical Evidence Form** (“PROVUSRD: USRDS Assigned Facility ID”) was assigned and linked the ownership status and number of dialysis stations from the **FACILITY: CMS/CDC ESRD Annual Facility** dataset using provider number and year variable in this

dataset. Patient Informed Status is defined using a Yes/No variable “PATINFORMED: Patient has been informed of kidney transplant options” in the **Medical Evidence Form**.

The number of days alive was used as a proxy for the number of days patient had during the study period to decide on transplantation. For the patients who remained on dialysis, this variable was defined as the number of days from study initiation to either date of death or the study end. Date of death was available in Patient Profile dataset as “Died: Date of Death.” For the patients who decided to enroll in the WL or to receive an LDKT this variable was defined as number of days from study initiation to the date of the event.

Aim 2a- Aim 2e

Interrupted time series analysis (ITSA) with ordinary least square (OLS) regressions were used to estimate the association between Time, PPS, and the interaction of Time and PPS with cost of care after controlling for other variables. An ITSA with logistic regression was used to estimate the association between these variables and having a non-zero inpatient cost. ITSA is a longitudinal study method widely used in public health and public policy research.⁴⁶ The analysis for Aim 2a-2e were conducted in six steps. First the total cost of care was calculated using Medicare claims, and then the cost was further categorized in four categories: Total Outpatient Cost, Outpatient Non-Dialysis Cost, Outpatient Dialysis Cost, and Inpatient Cost. Because 25% of patients had zero Inpatient Cost, the analysis of Inpatient Cost only included the patients who had non-zero Inpatient Cost. In another step, we explored changes in odds of having non-zero Inpatient Cost over time.

- (a) Total Cost: Calculated using Medicare reimbursement for all claims for each patient during the study period. Claim categories were inpatient, skilled nursing facilities, home health, hospice, outpatient, dialysis, and physician/supplier.

- (b) Total Outpatient Cost: Calculated using Medicare reimbursement for all institutional outpatient claims and all physician/supplier claims. Claim categories were home health, outpatient, dialysis, and physician/supplier.
- (c) Outpatient Dialysis Cost: Calculated using Medicare reimbursement for all outpatient dialysis services and all physician/supplier claims that had ESRD treatment facility as place of service.
- (d) Outpatient Non-Dialysis Cost: Calculated using Medicare reimbursements for all outpatient non-dialysis services and all physician/supplier claims that did not have ESRD treatment facility as place of service.
- (e) Inpatient Cost: Inpatient cost was calculated using Medicare reimbursement for all inpatient stays and skilled nursing facilities.

To calculate outcome variables, “Date of First ESRD Service” was collected from **Patient Profile** and it was linked to **Payer History** data set using the USRDS assigned patient identification number. **Payer History** had a record for each change in payer. It also included information on dual eligibility of Medicare and Medicaid. This data was used to determine whether the patient had Medicare part A and B coverage at the time of first ESRD service or during 92 days after that; only these patients were included in the study. The reason for using 92 days is that if the patient does not have health insurance or has insurance other than Medicare, Medicare coverage under ESRD program will not initiate until the fourth month after the dialysis treatment initiation.⁴⁷ The study initiation date was defined as the first date the Medicare part A and B initiated. Therefore, study initiation date could be any date from the first ESRD service and 92 days after. Each patient was followed up for one year after the study initiation date.

Study End Date= Study Initiation Date +365

After study initiation and end date definition, all Medicare claims were extracted for these patients during the study period. If a claim was recorded from a date before study initiation to a date after or recorded from a date before study end date to a date after end date, the following rules were used:

- 1) If the claim was inpatient or skilled nursing facility claim, the whole cost for cost calculation was used.
- 2) If the claim was not inpatient or skilled nursing facility claim, the cost was adjusted to the period that fell within the study period.

Claims that had negative value or were missing the Medicare reimbursement were not used for cost calculations. Medicare reimbursements were adjusted for Consumer Price Indexes (CPIs) based on the year of claim through date and used in 2016 USD.⁴⁸ All reimbursements were also adjusted for Geographic Adjustment Factor (Part A, inpatient, home health, skilled nursing facilities, and hospice claims) and CMS Geographic Practice Cost Index (Part B outpatient and physician/supplier claim) based on the year of claim through date and patient's zip code and state available in **Patient Profile**.⁴⁹⁻⁵¹

For ITSA, time was defined as a continuous variable with six-month period points from January 2006 to December 2015. For example, for patient who had their study initiation date at any point from January 2006 to June 2006, the time variable was defined as 0; July 2006 to December 2006 as 1. The last time point defined was 19 for patients who had their study initiation date from July 2015 to December 2015. The PPS variable was defined as 0 for all patients who has study initiation date before January 2011 (time 0-9) and defined as 1 after that (time 10-19). The interaction of the time and the PPS was used to estimate the effect of policy change on time trend. The formula for the analysis may be written as:

$$\text{Log}(Y_t) = \beta_0 + \beta_1 \text{Time}_t + \beta_2 \text{PPS} + \beta_3 \text{Time}_t * \text{PPS} + \alpha_1 X_1 + \dots + \alpha_n X_n$$

Y_t : The outcome variable at time t (for example total cost)

Time: The time elapsed since the start of the study in 6-month period points

PPS: A dummy variable indicating the pre-PPS period (coded 0) or the post-PPS period (coded 1)

$\text{Time}_t * \text{PPS}$: Interaction term between time and PPS

$X_1 - X_n$: Other independent variables

β_0 : The baseline level for Y_t at $\text{Time}=0$

β_1 : The change in outcome associated with one unit increase in time (representing the underlying pre-PPS time trend)

β_2 : The immediate change following the PPS

β_3 : Change in the time trend after PPS

$\alpha_1 - \alpha_n$: Association between other independent variables and the outcome

Age, gender, race-ethnicity, education, income, employment status, nephrology care prior to ESRD, primary cause of ESRD, presence of comorbidities and behavioral characteristics, BMI, GFR EPI, GFR MDRD, and network were defined by the exact same way as the Aim 1. The proportion of days the patient was eligible for both Medicare and Medicaid during the study period was calculated using **Payer History**, and then was categorized as Never (the patient was not dually eligible during the study period), Partially dual eligible (if the patient was dual eligible for at least one day but not for all study period), and Always dual eligible (if patient was dual eligible for the entire study period). Initial Medicare eligibility was defined as a categorical variable with four categories of ESRD, Age, Disability, and Other using “First Medicare enrollment reason code” variable from **Patient Profile**. Hemoglobin was extracted from **Medical Evidence Form**.

Provider was derived from claims and was defined as the facility/provider that the patient received the most of their dialysis sessions. The provider to facility survey was then linked using the same method described for Aim 1 to extract Ownership Status and the number of dialysis stations.

Human Subject Considerations

The study used USRDS data which is a de-identified data and does not have patient information.

The study was reviewed with Health Science Center Institute review board prior to access the data.

USRDS had also reviewed the study before approving the access to data.

JOURNAL ARTICLE I

BENEFICIAL EFFECT OF PROVIDING KIDNEY TRANSPLANTATION

INFORMATION ON TRANSPLANTATION STATUS DIFFERS BETWEEN FOR-

PROFIT AND NON-PROFIT DIALYSIS CENTERS

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Abbreviations:

BMI: Body Mass Index; CVD: Cardiovascular Disease; CMS: Centers for Medicare & Medicaid Services; ESRD: End-Stage Renal Disease; EPI: Epidemiology Collaboration; GFR: Glomerular Filtration Rate; ICC: Intra-Class Correlation Coefficient; LDKT: Live Donor Kidney Transplant; MDRD: Modification of Diet in Renal Disease; NH: Non-Hispanic; COPD: Chronic Obstructive Pulmonary Disease; OR: Odds Ratio; US: United States; USD: United States Dollar; USRDS: United States Renal Data System; WL: Waiting list; ZIP: Zone Improvement Plan.

Key words: Kidney transplantation, transplantation information, transplantation education, for-profit, non-profit, dialysis centers

Abstract

Informing End-Stage Renal Disease patients about kidney transplantation options increases the likelihood of kidney transplant waiting list (WL) enrollment and live donor kidney transplant (LDKT) receipt. Patients in for-profit dialysis centers have a lower rate of WL enrollment and LDKT receipt. This study examined if the ownership status of dialysis centers modified the association between informing patients about transplantation options and patients' transplantation status. Multi-level analysis using mixed-effect multinomial logistic regression was performed using the United States Renal Data System (USRDS) data (January 2005-December 2017). The study showed that informing patients improved the odds of WL enrollment and LDKT receipt. However, the effect of informing patients on transplantation status was less pronounced at for-profit as compared with non-profit centers (Non-profit: WL-enrollment OR: 2.23 [95%CI: 2.07-2.40], LDKT-receipt OR: 3.35 [95%CI: 2.65-4.25]; For-profit: WL-enrollment OR: 1.73 [95%CI: 1.66-1.79], LDKT-receipt OR: 2.35 [95%CI: 2.08-2.66]), although, the odds of informing patients was higher for for-profit centers, and type of patients informed were similar across both types of centers. Information provided by for-profit centers was less effective and potentially lower quality than those provided by non-profit centers. Standardized guidelines for transplantation information provision are needed, in order to ensure similar informational quality across centers.

Introduction

More than 120,000 patients develop End-Stage Renal Disease (ESRD) in the United States (US) each year¹, and require renal replacement therapies, which include dialysis and/or kidney transplantation (hereafter referred to as transplantation). The two transplantation options available to ESRD patients are: 1) enrolling in the deceased donor waiting list (WL); or 2) receiving a Living Donor Kidney Transplant (LDKT). For many ESRD patients, transplantation, as opposed to dialysis, remains the medically optimal renal replacement therapy because transplantation improves survival and is cost-effective.¹⁻³ In 2017, the adjusted all-cause mortality rate was 165/1,000 for dialysis patients and 29/1,000 for transplantation patients. In the same year, total Medicare ESRD expenditures/person/year were about \$90,600 for dialysis patients and \$35,800 for transplantation patients.¹ However, in 2016 only 14% of ESRD patients enrolled in the WL or received a deceased or live donor kidney transplant within one year of ESRD onset.¹

Prior studies showed that informing ESRD patients about transplantation options increased the likelihood of choosing transplantation options.⁴⁻⁶ Nevertheless, there is no standardized transplantation information provision guideline for dialysis centers to follow. This has resulted in a wide variation in transplantation information provided, in terms of both the quality (defined as details and intensity), and quantity (defined as number and duration) of the information sessions. In a study involving 170 dialysis centers, there was high level of variation between centers in both the quality and quantity of transplantation information sessions provided to ESRD patients.⁷ The quality ranged from oral recommendations for transplantation evaluation, referral to external transplantation information programs, to detailed intensive discussions about transplantation.⁷ The study also showed that dialysis centers, which used more intensive informational sessions for

patients, had higher proportions of patients enrolling in WL.⁷ A national survey-based study concluded that most nephrologists (81%) believed that the ideal duration for educating patients about transplantation is ≥ 20 minutes; however, 57% nephrologists spent < 20 minutes.⁸ This study also showed that duration of information sessions provided to patients was positively correlated with the quality of the sessions.⁸

Furthermore, studies show that there were differences in transplantation information provided between for-profit and non-profit dialysis centers. For-profit dialysis centers were less likely than non-profit dialysis centers to use longer duration and more intensive transplantation information sessions.⁷⁻⁹ Differences in informational quality may influence transplantation decisions made by patients being served by for-profit versus non-profit dialysis centers. Studies showed a lower rate of choosing transplantation options among patients in for-profit dialysis centers than among those in non-profit dialysis centers.^{5,10-12} Although there are differences in transplantation information provided between for-profit and non-profit dialysis centers, it remains unknown if provision of differential quality of information between these dialysis centers explains the lower rate of choosing transplantation options among ESRD patients in for-profit dialysis centers, or if these differences are due to number and type of ESRD patients being informed.

In this study, we examined if the ownership status (for-profit vs. non-profit) modified the association between informing patient about transplantation options and patient's transplantation status by using the interaction term between ownership status of a dialysis center and whether the patient was informed about transplantation options (informed vs. not informed). If the association between informing a patient about transplantation options and the patient's transplantation status

differs between for-profit and non-profit dialysis centers, it might indicate a difference in quality of information provided between these dialysis centers, and consequently might explain the observed variation in patient's transplantation status. In addition, this study also examined the likelihood of patients being informed about transplantation options in for-profit and non-profit dialysis centers, to examine if there is a difference in quantity of information sessions provided by these centers, and also examined the type of patients being informed by these centers.

Methods

Study design and Data Source

This study used the United States Renal Data System (USRDS) data from January 2005-December 2017¹. USRDS is a national database that includes information on all patients with ESRD, and all dialysis facilities in the United States. We used the following datasets: Patient Profile, Medical Evidence Form (CMS-2728), Transplant WL (Kidney), Transplant, and ESRD Annual Facility Survey. The CMS-2728 Form is typically completed by the dialysis facility for each patient within 45 days of ESRD service initiation. We also used the U.S. 2010 Census data linked to the USRDS to obtain the level of education and income at the zip-code-level for each patient.^{13,14} The study begins on January 2005 because prior to this month the CMS-2728 Form did not have data on whether the patient was informed about transplantation options.

Since ESRD diagnosis date is not present in the USRDS data, the USRDS researcher's guide utilizes the date of first ESRD service provision as the date of ESRD incidence.¹⁵ In this study, the date of first ESRD service provision was considered the study initiation date for each patient and the patient was followed for a year after study initiation (until December 31st 2017). Dialysis center

information for each patient was extracted from the ESRD Annual Facility Survey conducted during the year of study initiation. To be eligible for this study, patients (a) had to be 18-64 years old at study initiation (patients ≥ 65 years are deemed medically unsuitable for transplantation); (b) had to have the study initiation date between 1st January 2005 and 31st December 2016; and (c) had to have a completed CMS-2728 Form within 45 days of study initiation. Patients were excluded if they (a) enrolled in the transplant WL or received a kidney transplant prior to the study initiation date or prior to completing CMS-2728 Form; (b) had missing medical evidence form (CMS-2728) date; (c) had a dialysis start date before study initiation date; (d) had missing provider number for their dialysis center (required for data linkage), or missing ownership status or patient informed status; or (e) date of death was erroneously recorded as being before study initiation, waiting list enrollment, or transplantation dates. A total of 588,550 ESRD patients were included in this study.

Dependent variable

The dependent variable, “Transplantation Status”, was defined as the first transplantation-related decision that a patient made during the study period. However, if the patient enrolled in WL and received LDKT after that within a year, the patient was classified as having received LDKT. This variable was categorized into three categories: (a) WL enrolled; (b) LDKT received; and (c) Continuing on dialysis (reference category).

Independent variables

The two independent variables of interest were “Ownership Status” and “Patient Informed Status”. Ownership Status was a binary variable measuring for-profit ownership status of a patient’s dialysis center (for-profit coded as 1, and non-profit coded as 0). Patient Informed Status was a binary variable measuring whether a patient was informed about transplantation options within 45 days of study initiation (informed patients coded as 1, not informed coded as 0). The data on whether or not patient was informed was obtained from the CMS-2728 form, and this study only included patients who had completed CMS-2728 form within 45 days of study initiation. The interaction between Ownership Status and Patient Informed Status was used to determine whether the ownership status of a dialysis center modified the association between informing patients and transplantation status.

Other covariates controlled for were, patient sociodemographic, clinical, and behavioral characteristics at study initiation date, and dialysis center characteristics. Patient socio-demographic characteristics included age at study initiation (continuous variable in years); gender (male, female); race-ethnicity (non-Hispanic [NH] white, NH black, Hispanic, other); education measured as a percent of adults in the patient’s ZIP code area with some college education or more (continuous variable in percent); income measured as median household income for the patient’s ZIP code area (continuous variable in USD); employment status at study initiation (unemployed, employed, retired due to age, retired due to disability, other); and insurance status at study initiation (Medicare, Medicaid, private insurance, other insurance, uninsured). Past studies show that education and income at the U.S. zip-code-level are valid measures for patient’s socio-economic status.^{16,17} Patient clinical characteristics included receipt of nephrology care prior to study

initiation (yes, no, missing); primary cause of ESRD (diabetes, hypertension, glomerulonephritis, polycystic kidney disease, and other); binary variables indicating the presence of comorbidities such as hypertension, diabetes, cardiovascular disease [CVD], cancer and chronic obstructive pulmonary disease [COPD] at study initiation; presence of disability at study initiation (yes, no); Body Mass Index (BMI) at study initiation (continuous variable); Glomerular Filtration Rate Epidemiology Collaboration [GFR-EPI] at study initiation (continuous variable); and GFR Modification of Diet in Renal Disease [GFR-MDRD] at study initiation (continuous variable). Patient behavioral characteristics included being a smoker at study initiation (yes, no); alcohol dependence at study initiation (yes, no); and drug dependence at study initiation (yes, no).

Dialysis center characteristics included: the number of dialysis stations in a dialysis center (proxy for size of the dialysis center – continuous variable); and the regional ESRD network the dialysis center belonged to (18 network categories). In addition to patient and dialysis center characteristics, year of study initiation (2005-2016) and number of days alive after study initiation (continuous variable in days) were also controlled for. If a patient died during the study period, it was calculated as the number of days from the beginning of the study period to death; if not, it was recorded as 365 days.

Analysis

All analyses were performed using SAS v.9.4 (SAS Institute, Cary, NC). Table 1 illustrates descriptive statistics for all independent variables by transplantation status categories. Table 2 descriptively illustrates characteristics associated with patients who were informed versus not informed about transplantation options, and further explores if these associations were different between non-profit and for-profit dialysis centers.

Characteristics associated with transplantation status

Multi-level analysis using mixed-effect multinomial logistic regression estimation was performed to evaluate the modifying effect of ownership status on the association between patient informed status and transplantation status, after controlling for other covariates (Table 3). Since the study data are organized at two levels (center and patient level), we accounted for correlations between individual patients who are nested within a dialysis center by using random intercepts for centers in the mixed-effect regression estimation. Income was logarithmically transformed to improve model-fit and statistical significance in the regressions.

Characteristics associated with whether or not patients were informed about transplantation options

In order to estimate if a dialysis center's ownership status affected the likelihood of patients being informed, as well as to understand if the modifying effect of the ownership status was due to differences in types of patients being informed in the dialysis centers with different ownership status, we performed three multi-level analysis using mixed-effect logistic regressions (Table 4). First the effect of ownership status on the likelihood of a patient being informed was estimated after controlling for other covariates, and then sub-group analyses were performed to see if characteristics of patients being informed differed by the two type of ownership status (not-profit and for-profit). Income was logarithmically transformed to improve model-fit and statistical significance in the regressions.

Sensitivity analysis

About 88,000 patients died during the study period, or were reported to be medically unfit for transplantation. These patients had a shorter time or lower chance of choosing a transplantation option during the study period compared with the rest of the patients. In addition, about 10,000

patients were informed by transplant centers. These patients have a higher chance of being informed and receiving transplantation due to the service mission and goal of these centers (and not necessarily because of the effect of patient information). Sensitivity analysis was performed by excluding both the patients who died/were declared medically unfit during the study period, and those informed by transplant centers. A total of 491,590 ESRD patients were included in the sensitivity analysis.

Study Results

Characteristics associated with transplantation status

Of 588,550 patients, 12.26% (72,127) enrolled in WL, 1.40% (8,223) received an LDKT, and 86.35% (508,200) remained on dialysis, (Table 1). Patients who chose either of the transplantation options were less likely to be treated in for-profit dialysis centers (78 to 81%), as compared with patients continuing on dialysis (84%). In addition, patients who chose either of the transplantation options were more likely to be informed about the transplantation options (93 to 95%), as compared with patients continuing on dialysis (84%).

Patients who were younger, were male, were NH-White, belonged to more educated and higher income ZIP code areas, were employed, and had private insurance were more likely to choose either of the transplantation options. Clinically, patients who had nephrology care prior to study initiation, did not have certain chronic ailments such as diabetes, CVD, cancer and COPD, were not disabled, had lower average BMI, and had slightly worse glomerular filtration rates at study initiation were more likely to choose either of the transplantation options. Patients who were smokers, and alcohol or drug dependent were less likely to choose either of the transplantation options. Regionally, patients belonging to the northeastern centers were more likely to choose either of the transplantation options, and patients belonging to the southern centers were less likely

to choose either of the transplantation options. Patients alive for more days after study initiation were more likely to choose either of the transplantation options.

Characteristics associated with whether or not patients were informed about transplantation options

Of 588,550 patients, 84.78% (498,967) were informed and 15.22% (89,583) were not informed about transplantation options (Table 2). Majority of the patients initiated dialysis at a for-profit dialysis center (83.69%) and these patients were more likely to be informed about transplant options compared with patients who initiated dialysis at a non-profit dialysis center (85.63% vs 80.41%). Informed patients were more likely to enroll in transplant WL (13.38% vs. 6.01%) and to receive an LDKT (1.57% vs. 0.42%) compared with patients who were not informed. Although for-profit dialysis centers had a higher proportion of informed patients than non-profit dialysis centers, a lower proportion of informed patients at for-profit dialysis centers versus non-profit chose either of the transplantation options (14.22% vs. 18.92%).

Overall, patients who were younger, were male, and were not non-Hispanic white, belonged to higher income ZIP code areas, and were employed and privately insured were more likely to be informed. Education, although significant, did not have a meaningful group difference. Clinically, patients who had nephrology care prior to study initiation, had no comorbidities such as CVD, cancer and COPD, but had hypertension, were not disabled, and had worse GRF values were more likely to be informed. The difference in BMI, between patients who were informed and not informed, was statistically significant but not clinically meaningful. Behaviorally, smokers, and drug or alcohol dependent patients were less likely to be informed. The likelihood of being informed increased over time during these 12 years (2005-2016).

Characteristics associated with being informed (versus not) were examined separately for patients at for-profit and non-profit dialysis centers (Table 2). The socio-demographic, clinical and behavioral patient characteristics associated with being informed were similar irrespective of the ownership status, and were in the same direction as described above for the overall sample.

Multiple regression examining characteristics associated with transplantation status

Given individual patients were nested within dialysis centers, intra-class correlation coefficients (ICCs) were calculated for each outcome category, i.e., WL-enrolled and LDKT-received. We found that 11% (ICC=0.11, WL-enrolled) and 21% (ICC=0.21, LDKT-received) of variations were explained by clustering. In addition to random intercept, regressions with random coefficients were also performed, especially to assess the interaction effects across the different levels. However, we were not able to get complete parameter estimates due to the lack of convergence. Based on these findings a random intercept model was used for the final regression (Table 3).

The regression analysis (Table 3) established that ownership status modified the effect of patient informed status on transplantation status. Overall informing patients statistically increased the odds of patients enrolling in WL and receiving LDKT, as compared with not informing patients. Nevertheless, the adjusted odds were significantly lower for patients at for-profit dialysis centers versus patients at non-profit dialysis centers (Non-profit dialysis centers: (1) WL-enrolled OR: 2.23 [95%CI: 2.07-2.40]; (2) LDKT-received OR: 3.35 [95%CI: 2.65-4.25]. For-profit dialysis centers: (1) WL-enrolled OR: 1.73 [95%CI: 1.66-1.79]; (2) LDKT-received OR: 2.35 [95%CI: 2.08-2.66]). The patient socio-demographic, clinical, behavioral, dialysis center, and other characteristics were similarly associated with choosing either of the two transplantation options in the adjusted regression (Table 3), as they were in the descriptive unadjusted analyses above (Table 1).

Sensitivity analysis performed after excluding patients who died/were deemed medically unfit for transplantation during the first year after study initiation (study period), or patients who were informed by transplant centers provided the same results. (Appendix: Table 1)

Multiple regression examining characteristics associated with whether or not patients were informed about transplantation options

Three sets of multi-level analyses using mixed-effect logistic regression estimations were performed to examine characteristics associated with whether or not patients were informed about transplantation options. In the first logistic regression analysis all patients were included. This analysis showed that patients at for-profit dialysis centers were more likely to be informed about transplantation options than patients at non-profit dialysis centers (Table 4) (OR: 1.32 [95%CI: 1.21-1.44]). The second and third logistic regressions were performed to examine characteristics associated with being informed among patients treated at for-profit and non-profit dialysis centers, respectively. These regressions showed that the characteristics of patients associated with being informed were the same between for-profit and non-profit dialysis centers, and the direction of the association were same as those estimated in the first logistic regression containing the entire patient sample (Table 4), and also similar to the unadjusted descriptive analyses performed above (Table 2). However, as compared with the descriptive statistics (Table 2) the association of race-ethnicity with being informed reversed in the three adjusted regressions, such that non-Hispanic whites were more likely to be informed in the adjusted regressions.

Discussion

This is the first study to use the nationally representative USRDS data to examine the modifying effect of a dialysis center's ownership status on the association between informing a patient about transplantation options and their transplantation status. This study found that informed patients at

for-profit dialysis centers were less likely to choose either of the transplantation options as compared with informed patients at non-profit dialysis centers. Furthermore, the odds of patients being informed at the for-profit dialysis centers were higher than non-profit dialysis centers. In addition, the type of patients being informed (in terms of the socio-demographic, clinical and behavioral characteristics), in centers with either types of ownership status were similar, and not statistically different.

Past studies were consistent with our results and showed that for-profit dialysis centers, compared with non-profit dialysis centers, had lower overall adjusted likelihood of patients enrolling in WL or receiving an LDKT.^{5,10-12} Moreover, patients who were informed about transplantation options were more likely to choose a transplantation option.⁴⁻⁶ However this is the first study, to our knowledge, that has looked at whether patients from for-profit dialysis centers had a lower likelihood of choosing either of the transplantation options in spite of being informed as compared with patients from non-profit dialysis centers, thereby possibly indicating a quality difference in information provided based on ownership status.

This study established that for-profit dialysis centers informed more patients and informed similar type of patients as compared with non-profit dialysis centers, yet the information provided by for-profit dialysis centers was less effective in improving the likelihood of choosing transplantation options. These findings suggest that although for-profit dialysis centers are investing effort in informing more patients about transplantation options, the quality and intensity of information provided is probably lacking. Previous studies support the possibility of differential quality of transplantation information by ownership status, by showing that providers at for-profit dialysis centers were less likely to engage in high quality more intense informational strategies that improved WL enrollment or LDKT receipt.⁷⁻⁹

The study findings highlight the challenges associated with lack of guidelines for a standardized transplantation information program. More than 80% of ESRD patients receive care in for-profit dialysis centers. The disparity in the effectiveness of transplantation information, overall low rates of patients seeking transplantation options, and the excessive cost burden of ESRD and dialysis on federal funds and the society, raises significant concerns about the absence of standardized transplantation information programs. Past studies have evaluated well-designed and intensive informational strategies such as clinical and home-based education, culturally sensitive education, information provided to both patients and family members, one-on-one discussions, and sufficiently long and detailed information programs. The studies show that these strategies have the potential to increase the willingness to receive transplantation, WL enrollment, and LDKT receipt.^{4-6,18-22} In 2014, a report on best practices for transplant education for live kidney donations was published, based on a consensus conference attended by transplant professionals, patients, and other stakeholders.²³ The importance of providing transplant-related information to reduce transplant barriers was discussed and summarized in this conference report.²³ Nevertheless, more work needs to be done to develop comprehensive guidelines for information for both types of kidney transplantation given the clinical and economic burden at stake.

Our study also had other interesting findings about characteristics associated with patients who chose either of the transplantation options. These findings were similar to previous findings. Sociodemographically, past studies also found that patients who were younger,^{5,6,11,24-26} were male,^{5,6,11,24} were NH-White,^{24,25,27} had higher education level,²⁵ belonged to a higher socioeconomic status,^{5,27} and were employed^{6,25} were more likely to choose either of the transplantation options. Clinically, past studies found that patients who had nephrology care before ESRD onset,^{5,6,11} did not have chronic comorbid conditions,^{5,11} were not disabled,⁵ and had lower

BMI^{5,11} were more likely to choose either of the transplantation option. Behaviorally, past studies found that smokers and alcohol or drug dependent patients were less likely to choose a transplantation option.^{5,11} Regional trends with higher likelihood of choosing a transplantation option among the northeastern centers and lower among southern centers were also similar in the literature.^{10,28}

Few studies investigated factors associated with informing a patient about transplantation options.^{4,6,29–31} However, the findings of these studies were similar to our study. These studies also found that patients who were younger,⁴ male,^{4,29,30} and employed⁶ were more likely to be informed. Patients who had nephrology care before ESRD onset,^{4,6} did not have comorbid conditions such as CVD, cancer, COPD,⁴ had better functional status,³¹ and were not drug or alcohol dependent,^{4,6} were more likely to be informed. There was no consensus on the association between race-ethnicity^{4,6,29,30} and being informed in the literature.

Insurance has been shown to be an important factor associated with access to transplantation. Past studies showed that patients who have private insurance are more likely to be informed about transplantation options,^{4,6} to be evaluated for a transplant,³² and to choose a transplantation option by enrolling in WL or receiving an LDKT.^{5,6,11,25} Transplant patients need to receive immunosuppressive medications to prevent transplant rejections. These medications are highly costly and transplant patients rely on their health insurance coverage for these medications. Private insurance provides better and longer coverage of immunosuppressive medications. Currently Medicare provides coverage for kidney transplantation and covers 80% of immunosuppressive medications for 36 months after the transplantation.³³ Discontinued coverage might result in nonadherence to immunosuppressants and eventually transplant failure, and past studies showed Medicare patients have difficulty paying for these medications.³⁴ Patient's ability to continuously

receive these medications might be a barrier to both patient's decision to pursue a transplant option and nephrologist's decision to inform the patient about these options. Our findings suggest that higher rates of choosing transplantation options and being informed about transplantation, among privately insured patients, is potentially correlated with their coverage of immunosuppressive medications. Therefore, extension of Medicare coverage for these medications beyond 36 months has the potential to overcome this barrier and improve receipt of kidney transplants.

Our study has some limitations. First, there is no information in the data about the duration and type of transplantation information sessions provided to the ESRD patients. Hence, this study only controlled for a binary variable indicating whether or not a patient was informed about transplantation options. Second, the data did not have information on patient-level education and income, which might be associated with using dialysis centers of different ownership status, likelihood of patients being informed about transplantation options, and having access to transplantation. These associations can confound the adjusted effects estimated in this study. However, this study used the U.S. 2010 Census data to control for zip-code-level income and education variables, which have been shown to be consistent measures for personal socioeconomic status.^{16,17} Irrespective of the limitations, it is important to understand that the USRDS is a population-based nationally representative data with high quality clinical, socio-demographic, and dialysis center level information. Consequently, the findings of this study are critical for understanding the relationship between patient informed status and transplantation status, and the modifying effect of a dialysis center's ownership status.

In conclusion, this study found a differential effect of informing patients on transplantation status based on the ownership status of the dialysis centers. Information provided by for-profit dialysis centers were less effective than those provided by non-profit dialysis centers, in spite of for-profit

dialysis centers informing more patients and informing similar type of patient as compared with non-profit dialysis centers. This study's findings highlight the importance of informing patients about various transplantation options, and the need for developing guidelines to standardize transplantation information provided, to ensure similar informational quality across centers.

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Table 1 Descriptive Statistics Illustrating the Patient, Dialysis Center, and Other Characteristics Associated with Transplantation Status

	All ESRD patients N= 588,550			
	WL enrolled N= 72,127 (12.26%)	LDKT received N= 8,223 (1.40%)	Continuing on dialysis N= 508,200 (86.35%)	p-value
Ownership Status (%)				
For-profit	80.64	78.03	84.21	<0.0001
Non-profit	19.36	21.97	15.79	
Patient Informed Status (%)				
Informed	92.54	95.44	83.51	<0.0001
Not informed	7.46	4.56	16.49	
Patient Socio-Demographic Characteristics				
Age at study initiation (years)	47.30 (11.71) [†]	42.76 (13.01) [†]	51.99 (9.97) [†]	<0.0001
Gender (%)				
Male	63.33	64.84	57.70	<0.0001
Female	36.67	35.16	42.30	
Race-ethnicity (%)				
Non-Hispanic White	42.06	66.60	41.28	<0.0001
Non-Hispanic Black	28.97	11.99	35.70	
Hispanic	20.64	16.39	17.59	
Other	8.33	5.02	5.43	
Education (percent some college education & above in ZIP code area)	48.61 (14.56) [†]	51.26 (14.87) [†]	46.02 (14.71) [†]	<0.0001
Income (median household income in ZIP code area – USD)	52,841 (20,843) [†]	59,298 (22,718) [†]	46,893 (18,255) [†]	<0.0001
Employment status at study initiation (%)				
Unemployed	30.91	20.58	39.75	<0.0001
Employed	33.36	50.80	13.93	
Retired due to age	5.45	4.12	7.15	
Retired due to disability	20.40	10.37	33.83	
Other	9.88	14.13	5.34	
Insurance status at study initiation (%)				
Medicare	28.73	16.55	44.24	<0.0001
Medicaid	17.16	8.79	23.89	
Private insurance	43.68	62.59	21.81	
Other insurance	10.00	11.71	9.29	
Uninsured	0.43	0.36	0.77	
Patient Clinical Characteristics				
Nephrology care prior to study initiation (%)				
Yes	66.66	68.71	52.65	<0.0001
No	24.35	24.43	33.71	
Missing	8.99	6.86	13.64	
Primary cause of ESRD (%)				
Diabetes	43.03	25.16	51.33	<0.0001
Hypertension	22.82	17.62	24.51	
Glomerulonephritis	18.54	34.88	8.37	
Polycystic kidney disease	4.85	7.31	1.67	
Other	10.76	15.03	14.12	
Presence of hypertension at study initiation (%)				
Yes	87.34	83.23	85.68	<0.0001

	All ESRD patients N= 588,550			
	WL enrolled N= 72,127 (12.26%)	LDKT received N= 8,223 (1.40%)	Continuing on dialysis N= 508,200 (86.35%)	p-value
No	12.66	16.77	14.32	
Presence of diabetes at study initiation (%)				
Yes	48.40	28.75	59.76	<0.0001
No	51.60	71.25	40.24	
Presence of CVD* at study initiation (%)				
Yes	25.89	17.21	45.25	<0.0001
No	74.11	82.79	54.75	
Presence of cancer at study initiation (%)				
Yes	1.68	1.97	4.61	<0.0001
No	98.32	98.03	95.39	
Presence of COPD at study initiation (%)				
Yes	1.86	1.03	7.26	<0.0001
No	98.14	98.97	92.74	
Presence of Disability at study initiation (%)				
Yes	4.52	2.02	16.71	<0.0001
No	95.48	97.98	83.29	
BMI at study initiation (continuous)	29.16 (6.71) [†]	27.78 (6.20) [†]	30.96 (8.96) [†]	<0.0001
GFR EPI at study initiation (continuous)	8.39 (4.99) [†]	8.18 (4.92) [†]	9.62 (6.27) [†]	<0.0001
GFR MDRD at study initiation (continuous)	8.66 (4.06) [†]	8.13 (3.86) [†]	9.8 (4.71) [†]	<0.0001
Patient Behavioral Characteristics				
Smoker at study initiation (%)				
Yes	4.57	3.78	9.91	<0.0001
No	95.43	96.22	90.09	
Alcohol dependence at study initiation (%)				
Yes	1.21	0.29	2.76	<0.0001
No	98.79	99.71	97.24	
Drug dependence at study initiation (%)				
Yes	0.52	0.28	2.85	<0.0001
No	99.48	99.72	97.15	
Dialysis Center Characteristics				
Number of dialysis stations (count)	21.12 (9.79) [†]	20.33 (9.76) [†]	21.64 (9.76) [†]	<0.0001
Regional ESRD Network (%)				
Network 1 (CT, ME, MA, NH, RI, VT)	4.09	5.85	2.53	<0.0001
Network 2 (NY)	7.23	8.73	5.23	
Network 3 (NJ, PR, VI)	4.11	4.80	4.16	
Network 4 (DE, PA)	5.22	4.48	3.76	
Network 5 (DC, MD, VA, WV)	6.05	6.58	5.79	
Network 6 (GA, NC, SC)	7.15	4.33	10.44	
Network 7 (FL)	3.85	4.12	6.40	
Network 8 (AL, MS, TN)	5.54	3.94	6.42	
Network 9 (IN, KY, OH)	5.53	8.40	7.62	
Network 10 (IL)	4.54	6.54	3.99	
Network 11 (MI, MN, ND, SD, WI)	6.61	9.30	5.52	
Network 12 (IA, KS, MO, NE)	3.35	4.40	3.59	
Network 13 (AR, LA, OK)	3.10	2.40	4.98	

	All ESRD patients N= 588,550			
	WL enrolled N= 72,127 (12.26%)	LDKT received N= 8,223 (1.40%)	Continuing on dialysis N= 508,200 (86.35%)	p-value
Network 14 (TX)	10.34	8.61	10.09	
Network 15 (AZ, CO, NV, NM, UT, WY)	4.91	6.57	4.75	
Network 16 (AK, ID, MT, OR, WA)	2.42	3.56	2.84	
Network 17 (AS, Guam, HI, Mariana Islands, Northern CA)	8.88	3.41	4.03	
Network 18 (Southern CA)	7.08	3.98	7.86	
Other Variables				
Year of study initiation (%)				
2005	5.16	8.40	4.95	<0.0001
2006	9.17	12.16	8.11	
2007	8.80	10.31	8.18	
2008	8.75	9.80	8.35	
2009	9.17	9.84	8.61	
2010	8.83	8.18	8.59	
2011	8.98	7.62	8.49	
2012	9.15	7.33	8.49	
2013	8.88	6.91	8.64	
2014	8.23	6.51	8.95	
2015	7.61	6.58	9.34	
2016	7.27	6.36	9.30	
Number of days alive after study initiation (days)	362.35 (23.57) [†]	364.47 (10.00) [†]	336.02 (81.03) [†]	<0.0001

Note: *CVD: atherosclerotic heart disease, congestive heart failure, peripheral vascular disease, cerebrovascular disease, and other cardiac problem

[†] Mean with standard deviation in parenthesis presented for continuous variables

Abbreviations: ESRD - End-Stage Renal Disease; WL - Wait List; LDKT - Live Donor Kidney Transplant; CVD - Cardiovascular Disease; COPD - Chronic Obstructive Pulmonary Disease; BMI - Body Mass Index; GFR EPI - Glomerular Filtration Rate Epidemiology Collaboration; GFR MDRD - Glomerular Filtration Rate Modification of Diet in Renal Disease.

Table 2 Descriptive Statistics Illustrating the Patient, Dialysis Center, and Other Characteristics Associated with Patients Being Informed About Transplantation Options

	All ESRD patients N=588,550			ESRD patients at For-profit dialysis centers N=492,555 83.69%			ESRD patients at Non-profit dialysis centers N= 95,995 16.31%		
	Informed N=498,967 (84.78%)	Not informed N= 89,583 (15.22%)	p-value	Informed N= 421,775 (85.63%)	Not informed N= 70,780 (14.37%)	p-value	Informed N= 77,192 (80.41%)	Not informed N= 18,803 (19.59 %)	p-value
Transplantation Status (%)									
WL enrolled	13.38	6.01	<.0001	12.77	6.07	<.0001	16.68	5.79	<.0001
LDKT received	1.57	0.42		1.45	0.42		2.24	0.41	
Continuing on dialysis	85.05	93.57		85.78	93.51		81.08	93.80	
Ownership Status (%)									
For-profit	84.53	79.01	<.0001	100	100	<.0001	0.00	0.00	<.0001
Non-profit	15.47	20.99		0.00	0.00		100	100	
Patient Socio-Demographic Characteristics									
Age at study initiation (years)	51.05 (10.5) ⁺	52.59 (9.79) ⁺	<.0001	51.14 (10.43) ⁺	52.62 (9.77) ⁺	<.0001	50.57 (10.89) ⁺	52.49 (9.89) ⁺	<.0001
Gender (%)									
Male	58.69	57.42	<.0001	58.55	57.16	<.0001	59.42	58.40	0.01
Female	41.31	42.58		41.45	42.84		40.58	41.60	
Race-ethnicity (%)									
Non-Hispanic White	41.14	44.98	<.0001	40.71	44.33	<.0001	43.50	47.42	<.0001
Non-Hispanic Black	34.72	33.60		34.89	33.82		33.76	32.76	
Hispanic	18.31	15.91		18.96	17.01		14.79	11.77	
Non-Hispanic other	5.83	5.51		5.44	4.84		7.96	8.04	
Education (percent some college education & above in ZIP code area)	46.44 (14.68) ⁺	46.22 (14.97) ⁺	<.0001	46.12 (14.57) ⁺	45.60 (14.81) ⁺	<.0001	48.18 (15.14) ⁺	48.59 (15.36) ⁺	0.01
Income (median household income in ZIP code area – USD)	47,951 (18,937) ⁺	46,925 (18,073) ⁺	<.0001	47,696 (18,723) ⁺	46,389 (17,612) ⁺	<.0001	49,348 (20,007) ⁺	48,943 (19,582) ⁺	0.15
Employment status at study initiation (%)									
Unemployed	37.99	40.65	<.0001	38.15	40.67	<.0001	37.16	40.54	<.0001
Employed	17.93	10.70		17.72	10.77		19.04	10.40	
Retired due to age	6.81	7.41		6.91	7.41		6.27	7.42	
Retired due to disability	31.04	36.37		31.08	36.33		30.84	36.49	
Other	6.23	4.87		6.14	4.80		6.69	5.15	
Insurance status at study initiation (%)									
Medicare	41.30	45.55	<.0001	41.57	45.73	<.0001	39.87	44.88	<.0001
Medicaid	22.47	25.01		22.40	24.90		22.80	25.42	
Private insurance	26.09	19.31		26.33	19.97		24.81	16.83	
Other	9.44	9.26		9.04	8.65		11.62	11.55	
Uninsured	0.70	0.87		0.66	0.75		0.90	1.32	
Patient Clinical Characteristics									
Nephrology care prior to study initiation (%) [*]									
Yes	56.39	44.58	<.0001	55.52	43.73	<.0001	61.11	47.80	<.0001
No	31.16	39.54		31.17	38.26		31.12	44.34	
Missing	12.45	15.88		13.31	18.01		7.77	7.86	
Primary cause of ESRD (%)									
Diabetes	50.21	48.43	<.0001	50.52	49.51	<.0001	48.52	44.34	<.0001

	All ESRD patients N=588,550			ESRD patients at For-profit dialysis centers N=492,555 83.69%			ESRD patients at Non-profit dialysis centers N= 95,995 16.31%		
	Informed N=498,967 (84.78%)	Not informed N= 89,583 (15.22%)	p-value	Informed N= 421,775 (85.63%)	Not informed N= 70,780 (14.37%)	p-value	Informed N= 77,192 (80.41%)	Not informed N= 18,803 (19.59 %)	p-value
Hypertension	24.59	22.07		25.40	23.32		20.20	17.37	
Glomerulonephritis	10.36	7.91		9.86	7.49		13.05	9.50	
Polycystic kidney disease	2.32	1.15		2.25	1.15		2.70	1.15	
Other	12.52	20.45		11.97	18.53		15.54	27.64	
Presence of hypertension at study initiation (%)									
Yes	86.45	82.50	<.0001	86.40	82.81	<.0001	86.73	81.34	<.0001
No	13.55	17.50		13.60	17.19		13.27	18.66	
Presence of diabetes at study initiation (%)									
Yes	57.89	58.16	0.13	58.28	59.01	0.0003	55.78	54.98	0.04
No	42.11	41.84		41.72	40.99		44.22	45.02	
Presence of CVD* at study initiation (%)									
Yes	41.39	48.63	<.0001	41.00	47.94	<.0001	43.50	51.25	<.0001
No	58.61	51.37		59.00	52.06		56.50	48.75	
Presence of cancer at study initiation (%)									
Yes	3.76	6.71	<.0001	3.66	6.16	<.0001	4.31	8.81	<.0001
No	96.24	93.29		96.34	93.84		95.69	91.19	
Presence of COPD at study initiation (%)									
Yes	6.09	8.82	<.0001	5.97	8.42	<.0001	6.77	10.30	<.0001
No	93.91	91.18		94.03	91.58		93.23	89.70	
Presence of Disability at study initiation (%)									
Yes	13.49	23.47	<.0001	13.51	22.93	<.0001	13.37	25.47	<.0001
No	86.51	76.53		86.49	77.07		86.63	74.53	
BMI at study initiation (continuous)	30.69 (8.61) [†]	30.73 (9.26) [†]	<.0001	30.76 (8.63) [†]	30.83 (9.25) [†]	<.0001	30.30 (8.49) [†]	30.36 (9.27) [†]	0.0004
GFR EPI at study initiation (continuous)	9.33 (5.97) [†]	10.10 (6.91) [†]	<.0001	9.37 (5.99) [†]	10.16 (6.94) [†]	<.0001	9.15 (5.84) [†]	9.89 (6.79) [†]	<.0001
GFR MDRD at study initiation (continuous)	9.55 (4.58) [†]	10.10 (4.94) [†]	<.0001	9.59 (4.59) [†]	10.14 (4.95) [†]	<.0001	9.37 (4.49) [†]	9.93 (4.89) [†]	<.0001
Patient Behavioral Characteristics									
Smoker at study initiation (%)									
Yes	8.94	10.47	<.0001	8.67	9.74	<.0001	10.37	13.25	<.0001
No	91.06	89.53		91.33	90.26		89.63	86.75	
Alcohol dependence at study initiation (%)									
Yes	2.29	3.90	<.0001	2.21	3.71	<.0001	2.73	4.59	<.0001
No	97.71	96.10		97.79	96.29		97.27	95.41	
Drug dependence at study initiation (%)									
Yes	2.30	3.75	<.0001	2.18	3.14	<.0001	2.98	6.07	<.0001
No	97.70	96.25		97.82	96.86		97.02	93.93	
Dialysis Center Characteristics									
Number of dialysis stations (count)	21.58 (9.74) [†]	21.4 (9.96) [†]	<.0001	21.51 (9.25) [†]	21.46 (9.32) [†]	<.0001	21.99 (12.04) [†]	21.18 (12.07) [†]	<.0001
Regional ESRD Network (%)									
Network 1 (CT, ME, MA, NH, RI, VT)	2.62	3.60	<.0001	2.46	3.22	<.0001	3.50	5.02	<.0001
Network 2 (NY)	5.60	5.13		3.88	3.12		14.97	12.69	
Network 3 (NJ, PR, VI)	4.35	3.13		4.00	2.07		6.26	7.13	

	All ESRD patients N=588,550			ESRD patients at For-profit dialysis centers N=492,555 83.69%			ESRD patients at Non-profit dialysis centers N= 95,995 16.31%		
	Informed N=498,967 (84.78%)	Not informed N= 89,583 (15.22%)	p-value	Informed N= 421,775 (85.63%)	Not informed N= 70,780 (14.37%)	p-value	Informed N= 77,192 (80.41%)	Not informed N= 18,803 (19.59 %)	p-value
Network 4 (DE, PA)	3.89	4.32		3.86	4.13		4.06	5.03	
Network 5 (DC, MD, VA, WV)	5.75	6.28		5.77	6.60		5.64	5.11	
Network 6 (GA, NC, SC)	9.70	11.33		9.87	11.99		8.73	8.88	
Network 7 (FL)	6.17	5.42		6.75	6.17		3.00	2.57	
Network 8 (AL, MS, TN)	6.23	6.50		6.46	7.19		5.00	3.91	
Network 9 (IN, KY, OH)	7.30	7.83		7.64	8.24		5.44	6.31	
Network 10 (IL)	4.16	3.72		4.46	4.36		2.51	1.29	
Network 11 (MI, MN, ND, SD, WI)	5.73	5.57		4.79	4.59		10.85	9.25	
Network 12 (IA, KS, MO, NE)	3.53	3.79		3.26	3.38		5.02	5.36	
Network 13 (AR, LA, OK)	4.77	4.37		5.28	4.81		1.97	2.75	
Network 14 (TX)	10.57	7.53		12.04	8.95		2.51	2.11	
Network 15 (AZ, CO, NV, NM, UT, WY)	4.74	5.05		4.70	5.64		4.97	2.85	
Network 16 (AK, ID, MT, OR, WA)	2.52	4.33		2.15	2.71		4.56	10.42	
Network 17 (AS, Guam, HI, Mariana Islands, Northern CA)	4.66	4.40		4.22	3.57		7.08	7.51	
Network 18 (Southern CA)	7.71	7.70		8.40	9.27		3.93	1.81	
Other Variables									
Year of study initiation (%)									
2005	4.69	6.91	<.0001	4.39	6.73	<.0001	6.31	7.58	<.0001
2006	7.65	11.88		7.18	11.69		10.19	12.63	
2007	7.66	11.77		7.30	11.78		9.59	11.79	
2008	7.89	11.38		7.64	11.45		9.24	11.14	
2009	8.41	10.23		8.25	10.22		9.31	10.29	
2010	8.42	9.66		8.35	9.91		8.81	8.70	
2011	8.48	8.86		8.51	9.07		8.29	8.07	
2012	8.86	6.85		8.99	6.73		8.12	7.28	
2013	9.12	5.99		9.41	5.79		7.55	6.71	
2014	9.35	5.90		9.72	6.07		7.36	5.27	
2015	9.76	5.41		10.15	5.35		7.63	5.62	
2016	9.71	5.16		10.10	5.22		7.61	4.91	

Note: *CVD: atherosclerotic heart disease, congestive heart failure, peripheral vascular disease, cerebrovascular disease, and other cardiac problem

[†] Mean with standard deviation in parenthesis presented for continuous variables

Abbreviations: ESRD - End-Stage Renal Disease; WL - Wait List; LDKT - Live Donor Kidney Transplant; CVD - Cardiovascular Disease; COPD - Chronic Obstructive Pulmonary Disease; BMI - Body Mass Index; GFR EPI - Glomerular Filtration Rate Epidemiology Collaboration; GFR MDRD - Glomerular Filtration Rate Modification of Diet in Renal Disease.

Table 3 Adjusted Odds Ratios Demonstrating the Effect of Patient, Dialysis Center, and Other Characteristics on Transplantation Status

	WL enrolled OR Estimate (95% CI) (Reference: Continuing on dialysis)	LDKT received OR Estimate (95% CI) (Reference: Continuing on dialysis)
Informed versus Not informed Comparison:		
For For-profit	1.73 (1.66, 1.79)**	2.35 (2.08, 2.66)**
For Non-Profit	2.23 (2.07, 2.40)**	3.35 (2.65, 4.25)**
Patient Socio-Demographic Characteristics		
Age at study initiation	0.97 (0.97, 0.97)**	0.94 (0.94, 0.94)**
Gender (Reference: Male)		
Female	0.82 (0.81, 0.84)**	0.78 (0.74, 0.82)**
Race-ethnicity (Reference: Non-Hispanic White)		
Non-Hispanic Black	0.77 (0.75, 0.79)**	0.22 (0.20, 0.24)**
Hispanic	1.05 (1.02, 1.08)**	0.67 (0.62, 0.72)**
Non-Hispanic Other	1.09 (1.05, 1.13)**	0.39 (0.35, 0.44)**
Education	1.01 (1.01, 1.01)*	1.01 (1.01, 1.01)**
Logarithm of Income	1.50 (1.46, 1.55)**	2.10 (1.94, 2.27)**
Employment status at study initiation (Reference: Unemployed)		
Employed	1.64 (1.60, 1.68)**	2.47 (2.31, 2.65)**
Retired due to age	1.28 (1.23, 1.34)**	1.69 (1.49, 1.93)**
Retired due to disability	1.07 (1.04, 1.09)**	1.06 (0.97, 1.16)
Other	1.34 (1.30, 1.39)**	1.80 (1.65, 1.96)**
Insurance status at study initiation (Reference: Medicare)		
Medicaid	0.89 (0.87, 0.91)**	0.74 (0.67, 0.82)**
Private insurance	1.78 (1.74, 1.82)**	2.90 (2.70, 3.12)**
Other	1.27 (1.23, 1.31)**	2.06 (1.88, 2.25)**
Uninsured	0.45 (0.39, 0.50)**	0.41 (0.28, 0.60)**
Patient Clinical Characteristics		
Nephrology care prior to study initiation (Reference: No)		
Yes	1.76 (1.73, 1.80)**	2.02 (1.91, 2.14)**
Missing	1.11 (1.07, 1.15)**	1.13 (1.02, 1.25)*
Primary cause of ESRD (Reference: Diabetes)		
Hypertension	1.00 (0.97, 1.03)	1.14 (1.03, 1.25)**
Glomerulonephritis	1.34 (1.30, 1.38)**	2.19 (2.00, 2.40)**
Polycystic kidney disease	1.77 (1.68, 1.86)**	2.13 (1.89, 2.41)**
Other	0.80 (0.77, 0.83)**	1.04 (0.94, 1.15)
Presence of hypertension at study initiation (Reference: No)		
Yes	1.16 (1.12, 1.19)**	1.12 (1.05, 1.20)**
Presence of diabetes at study initiation (Reference: No)		
Yes	0.96 (0.93, 0.98)**	0.74 (0.68, 0.80)**
Presence of CVD at study initiation (Reference: No)		
Yes	0.66 (0.65, 0.68)**	0.60 (0.56, 0.64)**
Presence of Cancer at study initiation (Reference: No)		
Yes	0.43 (0.41, 0.46)**	0.42 (0.35, 0.49)**
Presence of COPD at study initiation (Reference: No)		
Yes	0.54 (0.51, 0.58)**	0.46 (0.38, 0.57)**
Presence of Disability at study initiation (Reference: No)		
Yes	0.47 (0.45, 0.49)**	0.38 (0.32, 0.44)**
BMI at study initiation	0.97 (0.97, 0.97)**	0.95 (0.95, 0.95)**

	WL enrolled OR Estimate (95% CI) (Reference: Continuing on dialysis)	LDKT received OR Estimate (95% CI) (Reference: Continuing on dialysis)
GFR EPI at study initiation	0.98 (0.98, 0.99)**	0.98 (0.98, 0.99)**
GFR MDRD at study initiation	0.99 (0.99, 0.99)**	0.98 (0.97, 0.99)**
Patient Behavioral Characteristics		
Smoker at study initiation (Reference: No)		
Yes	0.51 (0.49, 0.53)**	0.42 (0.37, 0.47)**
Alcohol dependence at study initiation (Reference: No)		
Yes	0.94 (0.87, 1.01)	0.29 (0.20, 0.42)**
Drug dependence at study initiation (Reference: No)		
Yes	0.26 (0.24, 0.29)**	0.25 (0.17, 0.37)**
Dialysis Center Characteristics		
Number of dialysis stations	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**
Regional ESRD Network (Reference: Network 14 - TX)		
Network 1 (CT, ME, MA, NH, RI, VT)	1.39 (1.27, 1.53)**	1.65 (1.39, 1.96)**
Network 2 (NY)	1.27 (1.17, 1.38)**	1.65 (1.41, 1.92)**
Network 3 (NJ, PR, VI)	1.06 (0.97, 1.16)	1.26 (1.06, 1.49)**
Network 4 (DE, PA)	1.51 (1.39, 1.64)**	1.39 (1.17, 1.64)**
Network 5 (DC, MD, VA, WV)	0.96 (0.88, 1.03)	1.15 (0.98, 1.34)
Network 6 (GA, NC, SC)	0.73 (0.68, 0.78)**	0.57 (0.48, 0.66)**
Network 7 (FL)	0.59 (0.54, 0.63)**	0.63 (0.54, 0.75)**
Network 8 (AL, MS, TN)	1.02 (0.95, 1.10)	1.04 (0.88, 1.23)
Network 9 (IN, KY, OH)	0.83 (0.77, 0.89)**	1.21 (1.05, 1.39)**
Network 10 (IL)	1.16 (1.06, 1.26)**	1.77 (1.51, 2.07)**
Network 11 (MI, MN, ND, SD, WI)	1.34 (1.24, 1.45)**	1.85 (1.60, 2.14)**
Network 12 (IA, KS, MO, NE)	0.92 (0.84, 1.01)	1.03 (0.87, 1.23)
Network 13 (AR, LA, OK)	0.72 (0.66, 0.79)**	0.68 (0.56, 0.83)**
Network 15 (AZ, CO, NV, NM, UT, WY)	0.88 (0.82, 0.96)**	1.03 (0.88, 1.20)
Network 16 (AK, ID, MT, OR, WA)	0.68 (0.61, 0.75)**	0.75 (0.62, 0.91)**
Network 17 (AS, Guam, HI, Mariana I, N. CA)	1.75 (1.62, 1.90)**	0.84 (0.70, 1.01)
Network 18 (Southern CA)	0.79 (0.74, 0.86)**	0.42 (0.36, 0.50)**
Other Variables		
Year of study initiation (Reference: 2005)		
2006	1.13 (1.07, 1.18)**	0.95 (0.85, 1.05)
2007	1.10 (1.05, 1.16)**	0.83 (0.74, 0.92)**
2008	1.09 (1.04, 1.14)**	0.81 (0.72, 0.90)**
2009	1.12 (1.07, 1.18)**	0.82 (0.73, 0.91)**
2010	1.11 (1.06, 1.17)**	0.71 (0.63, 0.80)**
2011	1.13 (1.08, 1.19)**	0.66 (0.59, 0.74)**
2012	1.14 (1.08, 1.19)**	0.65 (0.57, 0.73)**
2013	1.06 (1.01, 1.11)*	0.58 (0.52, 0.66)**
2014	0.89 (0.85, 0.94)**	0.49 (0.44, 0.56)**
2015	0.77 (0.73, 0.80)**	0.46 (0.41, 0.52)**
2016	0.71 (0.68, 0.75)**	0.42 (0.37, 0.48)**
Number of days alive after study initiation	1.01 (1.01, 1.01)**	1.01 (1.01, 1.02)**

Note: * : Significant at P<0.05, ** : Significant at P<0.01

Abbreviations: ESRD - End-Stage Renal Disease; WL - Wait List; LDKT - Live Donor Kidney Transplant; CVD - Cardiovascular Disease; COPD - Chronic Obstructive Pulmonary Disease; BMI - Body Mass Index; GFR EPI - Glomerular Filtration Rate Epidemiology Collaboration; GFR MDRD - Glomerular Filtration Rate Modification of Diet in Renal Disease.

Table 4. Adjusted Odds Ratios Demonstrating the Effect of Patient, Dialysis Center, and Other Characteristics on Patients Being Informed About Transplantation Options

	All dialysis centers	For-profit dialysis centers	Non-profit dialysis centers
	OR Estimate (95% CI)	OR Estimate (95% CI)	OR Estimate (95% CI)
Ownership status (Reference: Non-profit)			
For-profit	1.32 (1.21, 1.44)**		
Patient Socio-Demographic Characteristics			
Age at study initiation	0.98 (0.98, 0.98)**	0.98 (0.98, 0.98)**	0.98 (0.98, 0.98)**
Gender (Reference: Male)			
Female	0.97 (0.95, 0.99)**	0.97 (0.95, 0.99)**	0.96 (0.92, 0.99)*
Race-ethnicity (Reference: Non-Hispanic-White)			
Non-Hispanic-Black	0.95 (0.93, 0.98)**	0.96 (0.93, 0.99)**	0.93 (0.88, 0.98)**
Hispanic	0.97 (0.94, 0.99)*	0.97 (0.94, 1.01)	0.96 (0.89, 1.03)
Non-Hispanic-other	0.94 (0.90, 0.98)*	0.94 (0.90, 0.99)*	0.96 (0.88, 1.05)
Education	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**
Logarithm of Income	1.18 (1.14, 1.22)**	1.20 (1.15, 1.24)**	1.15 (1.07, 1.23)**
Employment status at study initiation (Reference: Unemployed)			
Employed	1.47 (1.42, 1.51)**	1.43 (1.38, 1.48)**	1.65 (1.53, 1.77)**
Retired due to age	1.11 (1.07, 1.15)**	1.12 (1.07, 1.16)**	1.06 (0.98, 1.15)
Retired due to disability	1.04 (1.02, 1.06)**	1.04 (1.01, 1.06)**	1.10 (1.05, 1.16)**
Other	1.23 (1.18, 1.28)**	1.23 (1.18, 1.28)**	1.23 (1.12, 1.35)**
Insurance status at study initiation (Reference: Medicare)			
Medicaid	0.96 (0.94, 0.99)**	0.97 (0.94, 0.99)*	0.94 (0.89, 0.99)*
Private insurance	1.24 (1.20, 1.27)**	1.24 (1.21, 1.27)**	1.28 (1.20, 1.36)**
Other	1.10 (1.06, 1.14)**	1.08 (1.04, 1.12)**	1.15 (1.08, 1.23)**
Uninsured	0.61 (0.55, 0.67)**	0.63 (0.56, 0.70)**	0.53 (0.44, 0.64)**
Patient Clinical Characteristics			
Nephrology care prior to study initiation (Reference: No)			
Yes	1.69 (1.66, 1.72)**	1.64 (1.60, 1.67)**	1.92 (1.84, 2.01)**
Missing	0.93 (0.91, 0.96)**	0.90 (0.87, 0.93)**	1.09 (1.01, 1.19)*
Primary cause of ESRD (Reference: Diabetes)			
Hypertension	0.93 (0.91, 0.96)**	0.94 (0.91, 0.97)**	0.91 (0.85, 0.97)**
Glomerulonephritis	0.99 (0.96, 1.03)	1.00 (0.96, 1.05)	0.94 (0.87, 1.02)
Polycystic kidney disease	1.51 (1.40, 1.63)**	1.49 (1.37, 1.62)**	1.56 (1.32, 1.83)**
Other	0.62 (0.60, 0.64)**	0.65 (0.63, 0.67)**	0.55 (0.51, 0.58)**
Presence of hypertension at study initiation (Reference: No)			
Yes	1.12 (1.10, 1.15)**	1.11 (1.08, 1.14)**	1.17 (1.11, 1.24)**
Presence of diabetes at study initiation (Reference: No)			
Yes	1.00 (0.97, 1.02)	1.00 (0.97, 1.03)	0.98 (0.93, 1.04)
Presence of CVD at study initiation (Reference: No)			
Yes	0.86 (0.85, 0.88)**	0.87 (0.85, 0.89)**	0.83 (0.80, 0.87)**
Presence of Cancer at study initiation (Reference: No)			
Yes	0.57 (0.55, 0.59)**	0.60 (0.57, 0.63)**	0.49 (0.45, 0.53)**
Presence of COPD at study initiation (Reference: No)			
Yes	0.86 (0.84, 0.89)**	0.87 (0.84, 0.91)**	0.82 (0.77, 0.88)**
Presence of Disability at study initiation (Reference: No)			
Yes	0.52 (0.51, 0.53)**	0.53 (0.51, 0.54)**	0.48 (0.46, 0.50)**

BMI at study initiation	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**
GFR EPI at study initiation	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**
GFR MDRD at study initiation	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**	0.99 (0.98, 0.99)**
Patient Behavioral Characteristics			
Smoker at study initiation (Reference: No)			
Yes	0.97 (0.95, 1.00)	0.99 (0.96, 1.03)	0.93 (0.87, 0.99)*
Alcohol dependence at study initiation (Reference: No)			
Yes	0.77 (0.73, 0.80)**	0.74 (0.70, 0.78)**	0.82 (0.74, 0.91)**
Drug dependence at study initiation (Reference: No)			
Yes	0.76 (0.72, 0.79)**	0.81 (0.77, 0.78)**	0.65 (0.59, 0.72)**
Dialysis Center Characteristics			
Number of dialysis stations	1.01 (1.01, 1.01)**	1.01 (1.01, 1.01)**	0.99 (0.99, 0.99)**
Regional ESRD Network (Reference: Network 14 - TX)			
Network 1 (CT, ME, MA, NH, RI, VT)	0.57 (0.47, 0.70)**	0.56 (0.45, 0.71)**	0.70 (0.42, 1.16)
Network 2 (NY)	0.76 (0.64, 0.90)**	0.76 (0.62, 0.93)**	0.99 (0.64, 1.53)
Network 3 (NJ, PR, VI)	1.03 (0.85, 1.26)	1.21 (0.96, 1.51)	0.99 (0.62, 1.59)
Network 4 (DE, PA)	0.75 (0.63, 0.89)**	0.79 (0.65, 0.95)*	0.94 (0.59, 1.51)
Network 5 (DC, MD, VA, WV)	0.79 (0.67, 0.92)**	0.78 (0.66, 0.93)**	1.12 (0.70, 1.78)
Network 6 (GA, NC, SC)	0.76 (0.66, 0.88)**	0.73 (0.63, 0.85)**	1.24 (0.80, 1.94)
Network 7 (FL)	0.85 (0.72, 0.99)*	0.84 (0.71, 0.98)*	1.19 (0.72, 1.95)
Network 8 (AL, MS, TN)	0.82 (0.70, 0.96)*	0.77 (0.65, 0.90)**	1.47 (0.92, 2.37)
Network 9 (IN, KY, OH)	0.85 (0.74, 0.99)*	0.88 (0.75, 1.03)	1.01 (0.64, 1.58)
Network 10 (IL)	0.85 (0.71, 1.01)	0.84 (0.70, 1.01)	1.63 (0.94, 2.81)
Network 11 (MI, MN, ND, SD, WI)	0.77 (0.65, 0.90)**	0.78 (0.65, 0.93)**	1.02 (0.66, 1.56)
Network 12 (IA, KS, MO, NE)	0.73 (0.62, 0.87)**	0.74 (0.61, 0.90)**	0.99 (0.62, 1.56)
Network 13 (AR, LA, OK)	0.86 (0.74, 1.01)	0.88 (0.74, 1.04)	0.79 (0.46, 1.33)
Network 15 (AZ, CO, NV, NM, UT, WY)	0.69 (0.60, 0.80)**	0.68 (0.58, 0.80)**	1.11 (0.72, 1.71)
Network 16 (AK, ID, MT, OR, WA)	0.60 (0.50, 0.73)**	0.71 (0.57, 0.88)**	0.64 (0.41, 0.98)*
Network 17 (AS, Guam, HI, Mariana I, N. CA)	0.74 (0.63, 0.89)**	0.79 (0.65, 0.96)*	0.98 (0.64, 1.52)
Network 18 (Southern CA)	0.67 (0.57, 0.79)**	0.67 (0.57, 0.79)**	1.25 (0.76, 2.07)
Other Variables			
Year of study initiation (Reference: 2005)			
2006	0.95 (0.91, 0.99)*	0.95 (0.90, 0.99)*	0.94 (0.86, 1.03)
2007	0.98 (0.94, 1.02)	0.98 (0.93, 1.03)	0.98 (0.89, 1.07)
2008	1.07 (1.03, 1.12)**	1.09 (1.04, 1.14)**	1.04 (0.95, 1.15)
2009	1.34 (1.28, 1.40)**	1.38 (1.31, 1.44)**	1.22 (1.11, 1.34)**
2010	1.48 (1.42, 1.55)**	1.51 (1.44, 1.59)**	1.40 (1.27, 1.54)**
2011	1.62 (1.55, 1.69)**	1.67 (1.59, 1.75)**	1.48 (1.34, 1.64)**
2012	2.40 (2.29, 2.52)**	2.68 (2.54, 2.82)**	1.62 (1.46, 1.79)**
2013	2.85 (2.71, 2.99)**	3.30 (3.12, 3.48)**	1.64 (1.48, 1.82)**
2014	2.96 (2.82, 3.10)**	3.27 (3.10, 3.45)**	1.97 (1.77, 2.20)**
2015	3.52 (3.35, 3.69)**	3.96 (3.75, 4.19)**	2.11 (1.89, 2.36)**
2016	3.69 (3.51, 3.88)**	4.00 (3.78, 4.23)**	2.59 (2.31, 2.91)**

Note: * : Significant at P<0.05, ** : Significant at P<0.01

Abbreviations: ESRD - End-Stage Renal Disease; WL - Wait List; LDKT - Live Donor Kidney Transplant; CVD - Cardiovascular Disease; COPD - Chronic Obstructive Pulmonary Disease; BMI - Body Mass Index; GFR EPI - Glomerular Filtration Rate Epidemiology Collaboration; GFR MDRD - Glomerular Filtration Rate Modification of Diet in Renal Disease.

JOURNAL ARTICLE II

Changes in Medicare's ESRD program expenditure after implementing Bundled payment in 2011

American Journal of Kidney Disease

Abstract

Background: In July 2008, congress passed Medicare Improvements for Patients and Providers Act (MIPPA) that mandated reimbursement reform to reduce Medicare end stage renal disease (ESRD) program expenditure, which led CMS to release final ruling for implementation of the ESRD Prospective Payment System (PPS) or bundled payment on July 2010, effective from January 2011. In this study we examined the effect of PPS on Medicare's cost of one year care for newly developed ESRD patients. Total cost was further categorized into total outpatient cost, outpatient dialysis cost, outpatient non-dialysis cost, and inpatient cost. we also examined the changes in odds of having a non-zero inpatient cost.

Methods: We used the United States Renal Data System (USRDS) data collected from January 2006 to December 2016. Interrupted time series analysis (ITSA) with ordinary least square (OLS) regressions were used to estimate the association between Time, PPS, and the interaction of Time and PPS with cost of care after controlling for patient and dialysis center characteristics. An ITSA with logistic regression was also used to estimate the association between these variables and odds of having a non-zero inpatient cost.

Results: Before PPS, Medicare's total expenditure was steady over time, however right after PPS, the expenditure decreased by time: -0.84% [95% CI: (-0.97, -0.72)]. Total outpatient cost and Outpatient dialysis cost both had a downward trend before PPS: -0.55% [95% CI: (-0.61, -0.48)] and -0.95% [95% CI: (-1.05, -0.85)], respectively; even though cost for both categories

immediately increased after PPS, the decreasing trend continued over time. Outpatient non-dialysis cost was growing by time before PPS, 1.31% [95% CI: (1.12, 1.50)], and the growth continued with an immediate decrease after PPS. Inpatient cost was increasing with time before PPS, 1.84% [95% CI: (1.67, 2.00)]; inpatient cost significantly dropped after PPS and continued to decline over time. Odds of having a non-zero inpatient cost was declining before PPS and with immediate drop in the probability after PPS, the probability continued to decline over time.

Discussion: PPS policies have potential to reduce the cost of care and policy change in one setting such as payment to dialysis services could also influence the cost of care in other settings such as inpatient care.

Introduction

Since 1973 Medicare has provided health insurance for end stage renal disease (ESRD) patients regardless of their age. Medicare cost for covering ESRD during first years of new policy was expected to be low, as only 16,000 patients required dialysis in 1973.¹ Over years, number of ESRD patients and cost of healthcare provided for these patients have grown. By 1982 total number of ESRD patients increased to 64,000 and total expenditure for these patients increased to \$1.8 billion.² By 1982 Medicare's ESRD program accounted for 4% of its overall expenditure.³ Increasing share of ESRD program from total expenditures, motivated Medicare to introduce fixed payment for treatments that included all costs such as labor, dialysis, dialysis machine, and tools in 1983.^{1,4} Considering inflation rate, in 1989 dialysis centers received 35% less than what they used to receive in 1983.¹ In 1989 the erythropoietin stimulating agent (ESA), developed by pharmaceutical company Amgen, was approved for use in dialysis patients suffering from severe anemia. CMS used capitated method to pay for ESA,⁵ which resulted in lower use of ESA than what was recommended by FDA.¹ To provide an incentive to use more ESAs, in 1991 Medicare implemented fee-for-service reimbursement for ESA.¹ This program (which was in effect for 20 years) provided incentive to use more ESAs over years. In 2005, separately billable reimbursement components, largely derived by ESAs, accounted for 37% (2.9 billion) of the dialysis care cost.⁶ Cost of Medicare's ESRD program continued to grow over years, to the point that while Medicare's ESRD population accounted for 1% of its total population, in 2016 it has accounted for about 7.2% (\$35.4 billion) of Medicare fee-for-service spending.⁷ The most recent change in reimbursement policy was implemented in Jan-2011. In July 2008, congress passed the "Medicare Improvements for Patients and Providers Act (MIPPA)". MIPPA mandates reimbursement reform to reduce expenditures, which led CMS to release final ruling for implementation of the ESRD

Prospective Payment System (PPS) or bundled payment in July 2010, effective from January 2011.^{1,8}

Under the new reimbursement system, CMS initially reimbursed \$230 per dialysis session (the reimbursement is subject to change by year). The reimbursement covered dialysis cost, all injectable medications or their equivalent oral forms (ESA, iron, and vitamin D), and dialysis related tests.^{1,8} Any administered drugs that are not specifically related to the disease would be reimbursed separately. The new payment system, eliminated the incentive to over-using ESA to maximize reimbursements.¹

One of the main concerns about any bundle payment system is the incentive to underuse medications or to replace them with less expensive medications in order to reduce the cost of care and maximize the profitability. For example, it was a concern that changes in anemia management practice in dialysis centers would adversely affect patient's health. Preliminary analysis showed that ESA dosing has reduced after 2011. Even though the decline in ESA has been substantially related to FDA's recommendation about more conservative usage of ESA specially for patients with mild anemia,^{9,10} which was published in June 2011, research showed that bundle payment implementation had an impact as well.¹¹ Utilization of less expensive anemia management practices such as intravenous iron, serum ferritin and blood cell transfusion utilization both in inpatient and outpatient setting increased as well.^{10,12-15} Compared with 2009, increased utilization of less expensive vitamin D also was observed after 2011.^{9,16} Under the bundled payment, Medicare incentivizes peritoneal dialysis (PD) by offering the equal payment as hemodialysis despite lower medication costs, on average, in PD; according to early research after 2011 use of PD increased about 1.2 percentage points in 2011 compared to 2010, however this increase was not statistically significant.^{9,16} 2-year pre, and post policy comparison on the other side, showed a

statistically significant increase in PD use; small dialysis organizations and non-profit dialysis centers increased PD use faster than large organizations and for-profit dialysis centers.¹⁷ Wang et al, in a 2-year pre-and-post policy comparison study showed that among elderly patients, risk of major adverse cardiovascular events, death, hospitalized congestive heart failure, and venous thromboembolism were similar before and after policy; the risk of stroke was lower for study period of after policy. Risk of major adverse cardiovascular events and all-cause mortality decreased significantly for African American patients after the policy change.¹⁸ Despite well studied effects of PPS on utilization and health outcome, direct and indirect effects of PPD on cost of care has not been well studied. Our goal was to explore the effect of PPS on Medicare expenditure for one-year of care for patients who recently developed the ESRD. Cost categories of interest were total cost, total outpatient cost, outpatient dialysis cost, outpatient non-dialysis cost, and inpatient cost.

Methods

Study design and Data Source

This study used USRDS data from January 2006 to December 2016. USRDS is a national data system that includes information on all patients with ESRD, Medicare claims for ESRD patients covered by Medicare, and information about dialysis facilities in the United States. We extracted data from the following USRDS datasets: Patient Profile, Medical Evidence Form (CMS-2728), Institutional claims, Physician/Supplier claims, and CMS/CDC ESRD Annual Facility Survey. We also used the American Community Survey (ACS) 2011, 5 year estimate public use data linked to the USRDS to define the level of education and income at the zip-code level for each individual.^{19,20}

To be eligible for this study, patients (a) had to be 18 years old and above; (b) had to have their first ESRD service between 1st January 2006 and 31st December 2015; (c) had to have Medicare Part A and B coverage before the first ESRD service or during 92 days after that; (d) had to have a completed CMS-2728 Form within 45 days of study initiation.

In this study, the first day patient had Medicare part A and B coverage during the 92 days of first ESRD services was defined as study initiation date. Each patient was followed for a year after study initiation (until December 31st, 2016). Patients were excluded if they (a) received a kidney transplant the day of or prior to the study end; (b) died the day of or prior to study end date; (c) had discontinued Medicare part A and B coverage during study period; (d) had discontinued dialysis during the first 3 months after first ESRD service; (e) had no Medicare claims or had no dialysis sessions reported in Medicare claims; (f) had 0\$ total cost. A total of 415,025 ESRD patients were included in this study.

Dependent variables

The dependent variables were defined as 5 categories of direct medical cost reimbursed by Medicare during the study period, and a binary variable indicating whether Medicare reimbursement for inpatient services for a patient during the study period was 0 or non-zero. We defined the cost categories as:

- (a) Total cost: The sum of all Medicare reimbursements for each patient over the study period
- (b) Total outpatient cost: The sum of Medicare reimbursements for outpatient and physician/supplier services
- (c) Outpatient dialysis cost: The sum of Medicare reimbursements for all dialysis related services provided by dialysis centers. This category included all institutional claims

involving dialysis services and all physician/supplier claims that had ESRD treatment facility as place of service.

- (d) Outpatient non-dialysis cost: The sum of Medicare reimbursements for all outpatient non-dialysis services. This cost equals total outpatient cost minus outpatient dialysis cost.
- (e) Inpatient cost: The sum of Medicare reimbursements for inpatient stays and skilled nursing facilities.
- (f) Non-zero inpatient cost: A binary variable indicating whether Medicare's reimbursement for inpatient care for the patient was 0 or non-zero.

All costs were reported in 2016 USD using the Consumer Price Index's (CPI's)²¹ medical care component. Costs were adjusted for geographic variation using CMS Geographic Adjustment Factor for Part A and CMS Geographic Practice Cost Index for Part B claims.²²⁻²⁴

Independent variables

The two independent variables of interest were Time and PPS. Time was defined as a continuous variable measuring time from January 2006 to ESRD onset date for each patient. Time is measured in 6-month period points. Time was defined as 0 for all patients with study initiation date from January 2006 to June 2006, and 19 for all patients with study initiation from July 2015 to December 2015. PPS was a binary variable measuring whether the patient developed ESRD on or after January 2011, time 10 to 19, (coded as 1) with patient developing ESRD before January 2011 as the reference category, time 0 to 9, (coded as 0). The interaction of Time and PPS was used to determine whether PPS modified the association between Time and cost of care.

Other independent variables were patient characteristics at the time of ESRD onset and dialysis center characteristics. The three types of patient characteristics controlled for were: socio-

demographic, clinical, and behavioral. Socio-demographic characteristics included age at ESRD onset (continuous variable in years); gender (male, female); race-ethnicity (non-Hispanic [NH] white, NH black, Hispanic, and other); education measured as a percentage of adults in the patient's ZIP code area with some college education or more (continuous variable in percent); income measured as median household income for the patient's ZIP code area (continuous variable in dollars); employment status (unemployed, employed, retired due to age, retired due to disability, and other); Medicare and Medicaid Dual Eligibility during the study period (never dual eligible, partially dual eligible, and always dual eligible); initial Medicare eligibility reason (ESRD, age, disability, other). Past studies show that education and median household income at the U.S. zip code level are valid proxies for patient's individual education and income.^{25,26} Patient clinical characteristics included receipt of nephrology care prior to ESRD onset (yes, no, missing); primary cause of ESRD (diabetes, hypertension, glomerulonephritis, polycystic kidney disease, and other); binary variables indicating the presence or absence of comorbidities such as hypertension, diabetes, cardiovascular disease [CVD], cancer and chronic obstructive pulmonary disease [COPD]; presence of disability (yes, no); BMI (continuous variable); Hemoglobin (continuous variable); Glomerular Filtration Rate Epidemiology Collaboration [GFR EPI] (continuous variable); and GFR Modification of Diet in Renal Disease [GFR MDRD] (continuous variable). Patient behavioral characteristics included being a current smoker (yes, no); alcohol dependence (yes, no); and drug dependence (yes, no).

Dialysis center characteristics included in the analyses were, Ownership status of dialysis center (for-profit, non-profit, missing); the number of dialysis stations in a dialysis center (proxy for the size of the dialysis center – continuous variable); and the regional ESRD network (18 categories).

Dialysis center assigned to a patient was extracted from Medicare claims as the center that patient received the most dialysis sessions at.

Analysis

Table 1 illustrates the descriptive statistics for all independent variables for all patients, and separately for patients who developed ESRD before and after PPS, to understand if the type of patients before and after the PPS were characteristically different. Table 2 descriptively illustrates cost of care for all patients and separately for patients who developed ESRD before and after PPS to understand if the unadjusted cost of care has changed after PPS compared with before PPS.

Characteristics Associated with Cost of Care

Interrupted time series analysis (ITSA) with ordinary least square (OLS) regressions were used to estimate the association between Time, PPS, and the interaction of Time and PPS with cost of care after controlling for patient and dialysis center characteristics. An ITSA with logistic regression was also used to estimate the association between these variables and having a non-zero inpatient cost. ITSA is a longitudinal study method widely used in public health and public policy research.²⁷ We used this method to estimate the change over time (time trend), immediate change after policy change, and the effect of policy change on time trend. All cost variables were right-skewed. We used logarithmically transformed cost as dependent variable in the ordinary least square (OLS) regression. Less than 1% of observations had \$0 as outpatient, outpatient dialysis, or outpatient non-dialysis cost. We added \$1 to these dependent variables for each observation. About 25% of observations had \$0 as inpatient cost; we used two-part model to first estimate the probability of having non-zero inpatient cost; then OLS regression of logarithmically transformed inpatient cost to estimate effect of independent variables on inpatient cost only among those patient who had

non-zero inpatient cost. We used bivariate analyses to select the variables that were significant at the level of $P \leq 0.1$ for the final inclusion in the multi-variable models. The Halvorsen Palmquist method was used to correct the marginal effects from the log-OLS regressions before presentation in Table 3 and Table 4.²⁸

Sensitivity analysis

In April 2013 government's mandatory payment reductions in the Medicare fee-for-service (FFS) program known as "sequestration" went into effect.²⁹ Based on this law, Medicare FFS claims with dates-of-service or dates-of-discharge on or after April 1, 2013, would incur a 2 percent reduction in Medicare payment. We performed sensitivity analysis by excluding patients with study initiation date in July 2012 and after to examine whether the results were sensitive to excluding these patients. A total of 273,397 patients were included in sensitivity analysis. All analyses were performed using SAS v. 9.4 (SAS Institute, Cary, NC). Figures are created using R version 3.3.2.

Study Results

Characteristics of patient population for pre- and post-Policy Change

Of 415,025 patients, 50.29% (208,735) developed ESRD from 2006 to 2010 (pre-PPS) and 49.71% (206,290) from 2011 to 2015 (post-PPS) (Table 1). Patients in post-PPS group were slightly younger, more likely to be male, more likely to be non-Hispanic White, belonged to slightly more educated and higher income ZIP-code areas but were more likely to be unemployed, more likely to be dual eligible for Medicare and Medicaid, and more likely to have disability as their initial reason for Medicare coverage compared with pre-PPS patients. Clinically, these patients were

more likely to have nephrology care before ESRD onset, more likely to have hypertension and diabetes as primary cause of ESRD, more likely to have chronic conditions such as hypertension, diabetes, COPD, and disability, but less likely to have CVD compared with pre-PPS patients. These patients had higher average BMI, and slightly worse hemoglobin and glomerular filtration rate compared with pre-PPS patients. Behaviorally, these patients were less likely to be a current smoker and alcohol or drug dependent compared with pre-PPS group. Compared with pre-PPS, more patients in post-policy change group initiated dialysis at a for-profit dialysis center (Table 1).

Cost of care for ESRD patients from Medicare's Perspective

Table 2 represents the average total cost, total outpatient cost, outpatient dialysis cost, outpatient non-dialysis, inpatient cost (with and without zero values), and proportion of patients with non-zero inpatient cost for all patients, pre-PPS, and post-PPS patient groups. For all cost categories, the average cost was lower for post-PPS group compared with pre-policy change group. The highest difference belonged to total cost category (\$109,167 vs. \$100,742) and the lowest difference to outpatient dialysis cost (\$27,430 vs. \$26,063). After PPS, patients were less likely to have non-zero inpatient cost.

Multiple regression examining characteristics associated with cost of care

Four OLS regressions were performed with logarithmically transformed total cost, total outpatient cost, outpatient dialysis cost, and outpatient non-dialysis cost (Table 3). For inpatient care, we performed a logistic regression to examine characteristics associated with whether or not the patient had non-zero inpatient cost and an OLS with logarithmically transformed inpatient care cost for only those patients who had non-zero inpatient cost (Table 4). All estimates presented for

OLS analysis in Table 3 and Table 4 are transformed to percentage change estimates using $100*(e^{(\beta_{x_i} * x_i)} - 1)$ formula.

Changes in cost at time (t) compared with cost in Time=0 was calculated using these results and is visualized in figures 1a-1e. X-axis represents time and Y-axis represents percentage change compared with Time 0 for each cost category calculated by the following formula:

Overall estimate at time=t compared with time=0: $100 \times (e^{(\beta_{time} * t + \beta_{PPS} * PPS + \beta_{time*PPS} * t)} - 1)$

Immediate change in cost after PPS is calculated by difference between overall association of time at t=10 and t=9.

Before PPS, time was not significantly associated with total cost: 0.04% [95% CI: (-0.05, 0.13)], however, after PPS time was associated with lower total cost: -0.88% [95% CI: (-0.96, -0.79)]. There was also an immediate change -1.20% in total cost after PPS. (Figure 1a). Before PPS, time was associated with lower total outpatient and outpatient dialysis cost: -0.52% [95% CI: (-0.58, -0.45)] and -0.92% [95% CI: (-1.03, -0.82)], respectively. Even though after PPS, the direction of the association remained the same for both cost categories, PPS was associated with immediate jump in cost, 4.21% for outpatient and 13.00% for outpatient dialysis cost. (Figure 1b, Figure 1c). before PPS, time was not significantly associated with outpatient non-dialysis cost before PPS. However, with a significant immediate drop in after PPS (11.33%), time was associated with higher outpatient non-dialysis cost after PPS: 1.38% [95% CI: (1.25, 1.51)]. (Figure 1d)

Before PPS, time was associated with higher inpatient cost before PPS: 1.88% [95% CI: (1.7, 2.004)]. PPS resulted in a significant immediate drop in inpatient cost (8.38%); after PPS, time was associated with lower inpatient cost: -2.50% [95% CI: (-2.73, -2.27)]. (Figure 1e) Before PPS, odds of having a non-zero inpatient cost reduced by time: 0.99 [95% CI: (0.99, 0.99)]; after PPS,

time was associated with lower odds of having non-zero inpatient cost as well. Figure 1f shows the predicted probability of having a non-zero cost from the logistic regression over time.

Overall, age was associated with higher cost of care (all cost categories) and higher likelihood of having non-zero inpatient cost. Females compared with males, and non-Hispanic Blacks compared with non-Hispanic whites had higher cost of care (except for outpatient dialysis cost) and higher likelihood of having non-zero inpatient cost. Hispanic or patients from other racial-ethnic groups however, had lower cost of care lower odds of having a non-zero inpatient cost. Patients who were dually eligible for Medicare and Medicaid had higher cost compared to non-dually eligible patients. Overall, patients who were initially eligible for Medicare due to reasons other than ESRD had higher cost of care and odds of having non-zero inpatient cost. Having nephrology care prior to ESRD onset was associated with lower cost of care (except for outpatient dialysis cost) and lower odds of having inpatient cost; for outpatient dialysis cost, it was associated with higher cost. Having chronic conditions such as diabetes, CVD, cancer, COPD, and disability, but not hypertension was overall associated with higher cost of care and higher odds of having inpatient cost. BMI was associated with increased cost of care. Being a current smoker or alcohol dependent was associated with lower cost of care; however, alcohol dependence was associated with higher inpatient cost and higher odds of having non-zero inpatient cost. Drug dependence was associated with higher total cost and inpatient cost and higher odds of having non-zero inpatient cost. patient who received most of their dialysis sessions at a for-profit dialysis center, had higher cost of care (in all categories) and higher odds of having non-zero inpatient cost.

Discussion

In this study, we explored the effect of Medicare reimbursement policy change for dialysis services, which was implemented in January 2011, on Medicare's expenditure of providing care during one-year for ESRD patients who recently developed ESRD. This study found that while before PPS time was not associated with total cost, after PPS it was associated with declining cost. association of time and PPS with other cost categories differed from total cost. Adjusted total outpatient cost and outpatient dialysis cost had a declining trend before PPS; for both of the categories cost of care had an immediate increase after PPS but the declining trend continued after PPS. Outpatient non-dialysis cost continued to increase after an immediate drop in cost after PPS. On the other hand, increasing inpatient care cost had an immediate decline after PPS and declined afterwards. Probability of having a nonzero inpatient cost continued to decline after an immediate decrease after PPS.

Results from the sensitivity analysis were similar for total cost, outpatient non-dialysis, inpatient cost and probability of having a non-zero inpatient cost. For outpatient and outpatient dialysis cost, the results showed an immediate increase in both cost categories (similar to original model), however after PPS cost increased by time. Figures 4a-4f visualize the change over time for cost category from sensitivity analysis.

Medicare's ESRD program started in 1973, ever since its ESRD program's cost continued to grow both due to increase number of ESRD incidents and increase cost of care per patient. In 2017, ESRD prevalence in the US was 746,557 which compared to 2016 increased by 2.5%. Medicare's expenditure also increased by 1.3% in 2017 compared with 2016. CMS has implemented multiple policies over years to contain the ESRD cost, In January 2011 CMS implemented PPS to contain dialysis cost by bundling services provided by dialysis centers under one single payment per

dialysis session. Previous studies have explored dialysis center's response to the bundled payment. After the policy change, dialysis centers have shifted towards replacing utilization of expensive drugs with less expensive ones. For example, research shows shift from utilizing ESA to IV iron or blood transfusion both in inpatient and outpatient setting;¹²⁻¹⁵ there was also a significant shift from intravenous vitamin D use to oral vitamin use and from more expensive paricalcitol towards a less expensive type, doxercalciferol.^{9,16} Use of antibiotics, levocarnitine, and alteplase has declined and utilization of cinacalcet and phosphate binders has increased.¹⁶ However, the effect of the PPS on Medicare's cost of care has not been well studied. Every year USRDS releases an "Annual Data Report" which provides information on Medicare's ESRD population and its expenditure.³⁰ Expenditures presented in these reports are not adjusted for patient characteristics, geographic factors, and inflation. However, it provides a perspective of Medicare's expenditure for the whole population over years, and categorized by age, gender, and race ethnicity. Figure 2 and Figure 3 show unadjusted versus adjusted for CPI total expenditure and unadjusted versus adjusted for CPI PPPY expenditure calculated from USRDS annual data report 2019, respectively. Even though all these costs are unadjusted for patient characteristics and they include all ESRD patients regardless of the inclusion and exclusion criteria listed in the paper, total and PPPY expenditure adjusted for CPI show a declining cost after 2011 which supports our findings. USRDS report shows that Medicare's PPPY expenditure increases by age; females have higher cost compared with males; non-Hispanic blacks have higher expenditure compared with non-Hispanic whites, but Hispanic patients have lower cost compared with non-Hispanics. Patients with hypertension, glomerulonephritis, polycystic kidney disease, or other reasons as primary reason of ESRD have lower cost of care compared with patients with diabetes as their primary reason.³⁰ These statistics were consistent with our findings.

Our study has some limitations. First, our findings are not generalizable to all ESRD population and facilities, we have excluded prevalent patients, and patients who died or received a transplant during the first year. Second, based on “sequestration” law that went into effect on April 2013²⁹ government mandated 2% reduction in payments for Medicare fee-for-service (FFS) services. Estimates in our model might have been influenced with this policy change and evolving CMS payment policies. To address this issue, we performed a sensitivity analysis and results remained very close to the original estimates for all cost categories other than dialysis and outpatient non-dialysis cost. Third, the data did not have information on patient-level education and income which might be associated with cost of care and chance of hospitalization. These associations can confound the adjusted effects estimated in this study. However, this study used the U.S. Census data to control for the zip code-level income and education levels, which have been shown to be consistent proxies of personal socio-economic status.^{19, 20} Irrespective of the limitations, it is important to understand that the USRDS is a highly reliable population-based nationally representative dataset with high quality Medicare claims data, clinical, socio-demographic, and dialysis center level information.^{31,32}

In conclusion, this study found that Medicare’s policy PPS reduced the cost of care from Medicare’s perspective. It also showed that policy changes in dialysis payment could also influence the cost of care in other settings such as inpatient. The findings of this study showed that bundle payment policies have a potential to reduce cost of care, however clinical outcome of such policies need to be studied as well.

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Table 1 Descriptive Statistics Illustrating the Patient, Dialysis Center, and Other Characteristics Before and After Policy Change

	2006-2015 N=415,025	Pre-PPS 2006-2010 N=208,735 (50.29)	Post-PPS 2011-2015 N=206,290 (49.71%)	P-value
Patient Socio-Demographic Characteristics				
Age at study initiation (years)	63.99 (14.74) [†]	64.08 (14.90)	63.90 (14.59) [†]	<0.0001
Gender (%)				
Male	55.32	54.92	55.72	<0.0001
Female	44.68	45.08	44.28	
Race-ethnicity (%)				
Non-Hispanic White	52.00	51.77	52.24	<0.0001
Non-Hispanic Black	28.68	29.50	27.83	
Hispanic	14.17	13.89	14.46	
Non-Hispanic other	5.15	4.84	5.47	
Education (percent some college & above in ZIP code area)	47.12 (15.23) [†]	47.07 (15.25) [†]	47.16 (15.20) [†]	0.01
Income (median household income in ZIP code area – USD)	49,416 (19,964) [†]	49,033 (19,831) [†]	49,805 (20,091) [†]	<0.0001
Employment status at study initiation (%)				
Unemployed	26.80	25.81	27.81	<0.0001
Employed	4.98	4.89	5.07	
Retired due to age	42.61	43.39	41.84	
Retired due to disability	23.91	24.06	23.76	
Other	1.68	1.85	1.52	
Medicare and Medicaid Dual Eligibility				
Never dual eligible	52.61	53.48	51.72	<0.0001
Partially dual eligible	12.23	11.90	12.57	
Always dual eligible	35.16	34.62	35.71	
Initial Medicare Eligibility Reason				
ESRD	31.47	31.30	31.63	<0.0001
Age	52.58	53.40	51.77	
Disability	9.25	7.78	10.73	
Other	6.70	7.52	5.87	
Number of days from first ESRD service to study initiation date	19.81	20.09	19.54	0.08
Patient Clinical Characteristics				
Nephrology care prior to ESRD onset (%)				
Yes	62.09	60.71	63.51	<0.0001
No	26.38	28.28	24.45	
Missing	11.53	11.01	12.04	
Primary cause of ESRD (%)				
Diabetes	48.66	48.34	49.00	<0.0001
Hypertension	31.10	30.51	31.70	
Glomerulonephritis	7.23	7.52	6.93	
Polycystic kidney disease	1.74	1.76	1.72	
Other	11.27	11.88	10.65	
Presence of hypertension at study initiation (%)				
Yes	88.37	87.43	89.32	<0.0001
No	11.63	12.57	10.68	
Presence of diabetes at study initiation (%)				
Yes	57.65	56.24	59.07	<0.0001
No	42.35	43.76	40.93	
Presence of CVD* at study initiation (%)				
Yes	53.87	55.63	52.09	<0.0001
No	46.13	44.37	47.91	
Presence of cancer at study initiation (%)				
Yes	6.53	6.60	6.46	0.056
No	93.47	93.40	93.54	
Presence of COPD at study initiation (%)				
Yes	9.14	9.02	9.26	0.009
No	90.86	90.98	90.74	
Presence of Disability at study initiation (%)				
Yes	17.13	16.58	17.68	<0.0001
No	82.87	83.42	82.32	
BMI at study initiation (continuous)	29.56 (7.95) [†]	29.30 (7.89) [†]	29.83 (8.00) [†]	<0.0001
GFR EPI at study initiation (continuous)	9.46 (5.24) [†]	9.50 (5.33) [†]	9.42 (5.15) [†]	0.005
GFR MDRD at study initiation (continuous)	10.11 (4.51) [†]	10.16 (4.54) [†]	10.07 (4.48) [†]	<0.0001
Hemoglobin at study initiation (continuous)	10.08 (19.56) [†]	10.45 (25.07) [†]	9.70 (11.54) [†]	<0.0001
Patient Behavioral Characteristics				

	2006-2015 N=415,025	Pre-PPS 2006-2010 N=208,735 (50.29)	Post-PPS 2011-2015 N=206,290 (49.71%)	P-value
Current smoker at study initiation (%)				
Yes	6.64	6.72	6.56	0.04
No	93.36	93.28	93.44	
Alcohol dependence at study initiation (%)				
Yes	1.28	1.35	1.22	0.0002
No	98.72	98.65	98.78	
Drug dependence at study initiation (%)				
Yes	1.14	1.26	1.02	<0.0001
No	98.86	98.74	98.98	
Dialysis Center Characteristics				
Ownership Status				
For-profit	82.70	80.25	85.18	<0.0001
Non-profit	13.61	15.99	11.20	
Missing	3.69	3.76	3.63	
Number of dialysis stations (count)	16.27 (2.99) [†]	16.24 (2.87) [†]	16.30 (3.11) [†]	<0.0001
ESRD Network (%)				
• Network 1 (CT, ME, MA, NH, RI, VT)	3.58	3.66	3.50	<0.0001
• Network 2 (NY)	5.34	5.49	5.18	
• Network 3 (NJ, PR, VI)	4.33	4.38	4.29	
• Network 4 (DE, PA)	3.80	3.84	3.76	
• Network 5 (DC, MD, VA, WV)	5.97	5.90	6.05	
• Network 6 (GA, NC, SC)	9.95	9.97	9.93	
• Network 7 (FL)	6.27	6.25	6.29	
• Network 8 (AL, MS, TN)	6.14	6.04	6.24	
• Network 9 (IN, KY, OH)	7.59	7.76	7.41	
• Network 10 (IL)	4.49	4.46	4.53	
• Network 11 (MI, MN, ND, SD, WI)	6.55	6.82	6.27	
• Network 12 (IA, KS, MO, NE)	4.20	4.25	4.15	
• Network 13 (AR, LA, OK)	4.77	4.77	4.78	
• Network 14 (TX)	9.69	9.69	9.67	
• Network 15 (AZ, CO, NV, NM, UT, WY)	4.24	4.09	4.40	
• Network 16 (AK, ID, MT, OR, WA)	2.92	2.86	2.98	
• Network 17 (AS, Guam, HI, Mariana Islands, Northern CA)	4.04	3.86	4.22	
• Network 18 (Southern CA)	6.13	5.92	6.35	

Note: *CVD: atherosclerotic heart disease, congestive heart failure, peripheral vascular disease, cerebrovascular disease, and other cardiac problem

[†] Mean with standard deviation in parenthesis presented for continuous variables

Abbreviations: ESRD - End-Stage Renal Disease; CVD - Cardiovascular Disease; COPD - Chronic Obstructive Pulmonary Disease; BMI - Body Mass Index; GFR EPI - Glomerular Filtration Rate Epidemiology Collaboration; GFR MDRD - Glomerular Filtration Rate Modification of Diet in Renal Disease.

Table 2 Descriptive Analysis Illustrating Cost of Care Before and After Policy Change

	2006-2015 N=415,025	Pre-PPS 2006-2010 N=208,735	Post-PPS 2011-2015 N=206,290	P-value
Total Cost of Care*	104,980 (70,658)	109,167 (73,568)	100,742 (67,321)	<0.0001
Outpatient Care Cost*	62,636 (26,051)	64,255 (27,701)	60,998 (24,157)	<0.0001
Outpatient Dialysis Care Cost*	35,886 (9,951)	36,825 (11,354)	34,935 (8,185)	<0.0001
Outpatient Non-Dialysis Care Cost*	26,750 (23,781)	27,430 (24,111)	26,063 (23,423)	<0.0001
Inpatient Care Cost (With Zero Values) *	42,192 (56,090)	44,745 (57,5561)	39,609 (54,444)	<0.0001
Inpatient Care Cost (Without Zero Values) *	56,435 (58,347)	57,558 (59,362)	55,203 (57,187)	<0.0001
Non-zero Inpatient Cost (%)	73.19	77.74	71.75	<0.0001

Note: *All numbers represent mean and standard deviation in parenthesis in \$.

Table 3 Effects of the Independent Variables on Medicare's 1-Year Cost of Care

Variable	Total Cost of Care	Outpatient Care Cost	Outpatient Dialysis Care Cost	Outpatient Non-Dialysis Care Cost
Time during Pre-PPS	0.04 (-0.05, 0.13)	-0.52 (-0.58, -0.45)**	-0.92 (-1.03, -0.82)**	0.13 (-0.01, 0.26)
PPS (Reference: Pre-PPS)				
Post-PPS	-1.20 (-1.91, -0.49)**	4.21 (3.65, 4.77)**	13.00 (12.06, 13.95)**	-11.33 (-12.27, -10.39)**
Time during Post-PPS	-0.88 (-0.96, -0.79)**	-0.80 (-0.87, -0.74)**	-1.41 (-1.51, -1.31)**	1.38 (1.25, 1.51)**
Patient Socio-Demographic Characteristics				
Age at study initiation	-0.84 (-0.92, -0.76)**	-0.73 (-0.79, -0.67)**	-1.58 (-1.67, -1.48)**	0.77 (0.65, 0.9)**
Age at study initiation- squared	0.01 (0.01, 0.01)**	0.01 (0.01, 0.01)**	0.01 (0.01, 0.01)**	0.01 (0.01, 0.01)**
Gender (Reference: Male)				
Female	5.47 (5.08, 5.87)**	1.63 (1.35, 1.92)**	-1.07 (-1.5, -0.64)**	11.44 (10.83, 12.05)**
Race-ethnicity (Reference: Non-Hispanic White)				
Non-Hispanic Black	2.07 (1.58, 2.56)**	0.93 (0.57, 1.29)**	-0.87 (-1.43, -0.32)**	1.53 (0.81, 2.25)**
Hispanic	-4.29 (-4.89, -3.68)**	-2.88 (-3.34, -2.42)**	-1.6 (-2.32, -0.87)**	-6.70 (-7.57, -5.83)**
Non-Hispanic Other	-9.70 (-10.49, -8.90)**	-7.27 (-7.88, -6.66)**	-2.55 (-3.54, -1.54)**	-16.29 (-17.37, -15.19)**
Education	0.04 (0.03, 0.06)**	0.02 (0.01, 0.03)**	0.00 (-0.01, 0.02)	0.02 (0.00, 0.04)
Logarithm of Income	-2.25 (-2.81, -1.70)**	-1.19 (-1.61, -0.77)**	-0.04 (-0.69, 0.63)	-0.32 (-1.15, 0.52)
Employment status at study initiation (Reference: Unemployed)				
Employed	-11.04 (-11.82, -10.25)**	-6.16 (-6.78, -5.54)**	-1.12 (-2.13, -0.1)**	-17.97 (-19.03, -16.9)**
Retired due to age	1.41 (0.83, 2.00)**	1.24 (0.80, 1.67)**	1.30 (0.62, 1.98)**	1.38 (0.52, 2.24)**
Retired due to disability	3.13 (2.58, 3.68)**	1.94 (1.54, 2.34)**	-1.72 (-2.32, -1.11)**	6.98 (6.15, 7.82)**
Other	-8.92 (-10.21, -7.61)**	-5.73 (-6.73, -4.72)**	-5.48 (-7.04, -3.9)**	-11.96 (-13.79, -10.10)**
Medicare and Medicaid Dual Eligibility (Reference: Never dual eligible)				
Always dual eligible	11.40 (10.71, 12.10)	5.20 (4.71, 5.69)**	3.14 (2.4, 3.89)**	13.97 (12.94, 15.02)**
Partially dual eligible	11.78 (11.27, 12.30)**	7.37 (7.00, 7.74)**	5.19 (4.63, 5.75)**	19.63 (18.82, 20.44)**
Initial Medicare Eligibility Reason (Reference: ESRD)				
Age	9.45 (8.70, 10.21)**	6.53 (5.99, 7.08)**	2.46 (1.64, 3.28)**	17.72 (16.53, 18.91)**
Disability	16.47 (15.57, 17.39)**	8.06 (7.43, 8.69)**	-0.95 (-1.84, -0.05)**	27.57 (26.11, 29.04)**
Other	3.16 (2.28, 4.04)**	2.47 (1.82, 3.12)**	-1.41 (-2.38, -0.43)**	9.17 (7.80, 10.54)**
Number of days from first ESRD service to study initiation date	-0.30 (-0.31, -0.29)**	-0.14 (-0.15, -0.14)**	-0.11 (-0.12, -0.10)**	-0.23 (-0.24, -0.22)**
Patient Clinical Characteristics				
Nephrology care prior to study initiation (Reference: No)				
Yes	-13.64 (-14.01, -13.26)**	-4.13 (-4.44, -3.82)**	5.60 (5.07, 6.13)**	-18.1 (-18.62, -17.58)**
Missing	1.30 (0.65, 1.95)**	0.29 (-0.18, 0.77)**	-1.39 (-2.12, -0.66)**	0.09 (-0.85, 1.03)
Primary cause of ESRD (Reference: Diabetes)				
Hypertension	-4.63 (-5.13, -4.13)**	-3.70 (-4.07, -3.32)**	-0.91 (-1.5, -0.30)**	-9.25 (-9.95, -8.55)**
Glomerulonephritis	-5.40 (-6.16, -4.63)**	-4.92 (-5.49, -4.34)**	-2.84 (-3.75, -1.92)**	-12.16 (-13.2, -11.11)**
Polycystic kidney disease	-14.91 (-16.12, -13.69)**	-8.46 (-9.43, -7.48)**	0.42 (-1.24, 2.11)	-26.31 (-27.85, -24.73)**
Other	3.46 (2.75, 4.17)**	-0.97 (-1.47, -0.46)**	-7.18 (-7.91, -6.44)**	4.27 (3.22, 5.32)**
Presence of hypertension at study initiation (Reference: No)				
Yes	-3.63 (-4.18, -3.09)**	-1.37 (-1.79, -0.95)**	1.82 (1.15, 2.49)**	-5.83 (-6.61, -5.05)**
Presence of diabetes at study initiation (Reference: No)				
Yes	6.28 (5.76, 6.81)**	3.85 (3.47, 4.24)**	-0.11 (-0.68, 0.46)	12.85 (12.03, 13.67)**
Presence of CVD at study initiation (Reference: No)				
Yes	10.96 (10.53, 11.39)**	4.57 (4.27, 4.87)**	0.34 (-0.11, 0.80)	14.11 (13.46, 14.76)**
Presence of Cancer at study initiation (Reference: No)				
Yes	5.56 (4.78, 6.34)**	6.19 (5.61, 6.78)**	1.75 (0.88, 2.62)**	13.67 (12.44, 14.91)**

Variable	Total Cost of Care	Outpatient Care Cost	Outpatient Dialysis Care Cost	Outpatient Non-Dialysis Care Cost
Presence of COPD at study initiation (Reference: No)				
Yes	8.06 (7.37, 8.75) **	3.10 (2.60, 3.59) **	-1.17 (-1.91, -0.43) **	9.82 (8.79, 10.86) **
Presence of Disability at study initiation (Reference: No)				
Yes	25.23 (24.62, 25.85) **	12.24 (11.83, 12.66) **	-3.43 (-3.98, -2.88) **	33.8 (32.84, 34.78) **
BMI at study initiation	-0.48 (-0.6, -0.36) **	0.41 (0.32, 0.50) **	1.11 (0.96, 1.25) **	-0.74 (-0.92, -0.56) **
BMI at study initiation Squared	0.01 (0.01, 0.01) **	0.01 (0.00, 0.02) *	-0.01 (-0.01, -0.01) **	0.02 (0.01, 0.02) **
GFR EPI at study initiation	0.53 (0.47, 0.59) **	0.07 (0.02, 0.11) **	-0.48 (-0.55, -0.42) **	0.70 (0.61, 0.79) **
GFR MDRD at study initiation	0.39 (0.32, 0.46) **	0.24 (0.19, 0.29) **	-0.05 (-0.13, 0.03)	0.83 (0.73, 0.93) **
Hemoglobin at study initiation	-0.02 (-0.02, -0.01) **	-0.01 (-0.02, -0.01) **	-0.01 (-0.01, 0.00)	-0.02 (-0.03, -0.01) **
Patient Behavioral Characteristics				
Current Smoker at study initiation (Reference: No)				
Yes	-3.85 (-4.57, -3.13) **	-4.11 (-4.65, -3.57) **	-3.37 (-4.21, -2.53) **	-4.76 (-5.81, -3.71) **
Alcohol dependent at study initiation (Reference: No)				
Yes	-1.39 (-3.00, 0.25)	-3.78 (-4.95, -2.59) **	-7.13 (-8.89, -5.34) **	-0.89 (-3.27, 1.54)
Drug dependent at study initiation (Reference: No)				
Yes	7.15 (5.29, 9.05) **	-4.60 (-5.84, -3.35) **	-10.41 (-12.22, -8.56) **	3.37 (0.75, 6.05) *
Dialysis Center Characteristics				
Ownership status (Reference: Non-profit)				
For-profit	5.75 (5.17, 6.33) **	5.04 (4.62, 5.47) **	4.58 (3.92, 5.25) **	6.57 (5.72, 7.42) **
Missing	-16.66 (-17.54, -15.79) **	-24.39 (-24.98, -23.8) **	-61.76 (-62.23, -61.29) **	-11.99 (-13.34, -10.62) **
Number of dialysis stations	0.09 (0.03, 0.15) **	0.05 (0.01, 0.09) *	0.09 (0.02, 0.16) **	0.02 (-0.06, 0.11)
Network (Reference: Network 6 - GA, NC, SC)				
Network 1 (CT, ME, MA, NH, RI, VT)	-0.06 (-1.19, 1.07)	-6.97 (-7.76, -6.19) **	-5.85 (-7.08, -4.60) **	-1.73 (-3.36, -0.09) *
Network 2 (NY)	1.87 (0.86, 2.88) **	-7.96 (-8.64, -7.28) **	-5.87 (-6.95, -4.78) **	-2.44 (-3.85, -1.00) **
Network 3 (NJ, PR, VI)	3.37 (2.27, 4.47) **	-0.75 (-1.53, 0.04)	-4.72 (-5.88, -3.53) **	7.91 (6.24, 9.60) **
Network 4 (DE, PA)	3.00 (1.89, 4.14) **	-2.83 (-3.62, -2.03) **	-3.57 (-4.79, -2.34) **	2.41 (0.78, 4.07) **
Network 5 (DC, MD, VA, WV)	-1.39 (-2.31, -0.46) **	-7.58 (-8.22, -6.93) **	-7.73 (-8.73, -6.71) **	-4.29 (-5.6, -2.95) **
Network 7 (FL)	3.09 (2.14, 4.04) **	-2.01 (-2.68, -1.33) **	-5.53 (-6.54, -4.51) **	7.28 (5.83, 8.75) **
Network 8 (AL, MS, TN)	-1.1 (-2.01, -0.19) *	0.08 (-0.61, 0.77)	2.27 (1.17, 3.37) **	-1.95 (-3.27, -0.61) **
Network 9 (IN, KY, OH)	1.13 (0.24, 2.02) *	-1.09 (-1.74, -0.44) **	0.93 (-0.10, 1.97)	-1.15 (-2.42, 0.13)
Network 10 (IL)	-1.90 (-2.91, -0.88) **	-3.61 (-4.35, -2.87) **	-1.64 (-2.81, -0.45) **	-3.21 (-4.67, -1.72) **
Network 11 (MI, MN, ND, SD, WI)	-0.38 (-1.29, 0.54)	-1.77 (-2.45, -1.10) **	4.81 (3.69, 5.94) **	-1.57 (-2.89, -0.22) *
Network 12 (IA, KS, MO, NE)	-2.94 (-3.96, -1.90) **	-2.76 (-3.53, -1.99) **	4.82 (3.54, 6.12) **	-5.52 (-6.98, -4.04) **
Network 13 (AR, LA, OK)	0.80 (-0.21, 1.81)	-1.47 (-2.20, -0.73) **	-0.59 (-1.74, 0.58)	1.21 (-0.27, 2.71)
Network 14 (TX)	6.83 (5.93, 7.75) **	3.28 (2.63, 3.94) **	-2.22 (-3.18, -1.24) **	15.28 (13.84, 16.74) **
Network 15 (AZ, CO, NV, NM, UT, WY)	-5.95 (-6.95, -4.93) **	-7.56 (-8.30, -6.82) **	-4.21 (-5.40, -3.01) **	-9.97 (-11.38, -8.54) **
Network 16 (AK, ID, MT, OR, WA)	-11.53 (-12.6, -10.44)	-8.34 (-9.17, -7.50) **	1.94 (0.50, 3.40) **	-18.27 (-19.73, -16.79) **
Network 17 (AS, Guam, HI, Mariana I, N. CA)	-10.42 (-11.41, -9.41) **	-10.05 (-10.79, -9.30) **	-1.76 (-3.03, -0.48) **	-23.52 (-24.76, -22.25) **
Network 18 (Southern CA)	-9.09 (-9.99, -8.18) **	-10.43 (-11.10, -9.77) **	-9.27 (-10.31, -8.22) **	-14.89 (-16.12, -13.64) **
N	415,025	415,025	415,025	415,025
R ²	0.16	0.11	0.09	0.16
RMSE	0.59	0.44	0.68	0.86

Note: * : Significant at P<0.05, ** : Significant at P<0.01

Abbreviations: ESRD - End-Stage Renal Disease; Cardiovascular Disease; COPD - Chronic Obstructive Pulmonary Disease; BMI - Body Mass Index; GFR EPI - Glomerular Filtration Rate Epidemiology Collaboration; GFR MDRD - Glomerular Filtration Rate Modification of Diet in Renal Disease; RMSE - Root Mean Square Error.

Table 4 Effects of the Independent Variables on Medicare's 1-Year Cost of inpatient care and chance of having non-zero inpatient cost

Variable	OR: Non-zero inpatient cost	Inpatient Cost
Time during Pre-PPS	0.98 (0.98, 0.99) **	1.88 (1.71, 2.04) **
PPS (Reference: Pre-PPS)		
Post-PPS	0.78 (0.76, 0.81) **	-8.38 (-9.61, -7.13) **
Time during Post-PPS	0.99 (0.99, 0.99) **	-0.73 (-0.89, -0.56) **
Patient Socio-Demographic Characteristics		
Age at study initiation	0.97 (0.96, 0.97) **	0.11 (-0.05, 0.28)
Age at study initiation- squared	1.01 (1.01, 1.01) **	-0.01 (-0.01, -0.01) **
Gender (Reference: Male)		
Female	1.25 (1.23, 1.27) **	8.99 (8.23, 9.76) **
Race-ethnicity (Reference: Non-Hispanic White)		
Non-Hispanic Black	1.05 (1.03, 1.08) **	1.87 (0.95, 2.79) **
Hispanic	0.93 (0.91, 0.96) **	-5.19 (-6.33, -4.03) **
Non-Hispanic Other	0.82 (0.80, 0.85) **	-8.19 (-9.78, -6.58) **
Education	1.00 (0.99, 1.01)	0.09 (0.07, 0.12) **
Logarithm of Income	1.02 (0.99, 1.04)	-4.83 (-5.85, -3.80) **
Employment status at study initiation (Reference: Unemployed)		
Employed	0.75 (0.73, 0.78) **	-11.39 (-13.07, -9.67) **
Retired due to age	1.05 (1.02, 1.08) **	-0.64 (-1.70, 0.42)
Retired due to disability	1.14 (1.11, 1.16) **	1.27 (0.25, 2.29) *
Other	0.81 (0.77, 0.85) **	-6.56 (-9.40, -3.62) **
Medicare and Medicaid Dual Eligibility (Reference: Never dual eligible)		
Always dual eligible	1.30 (1.26, 1.33) **	18.92 (17.51, 20.35) **
Partially dual eligible	1.39 (1.36, 1.42) **	11.64 (10.69, 12.60) **
Initial Medicare Eligibility Reason (Reference: ESRD)		
Age	1.27 (1.23, 1.30) **	4.57 (3.20, 5.96) **
Disability	1.64 (1.58, 1.69) **	14.91 (13.27, 16.58) **
Other	1.04 (1.01, 1.07) *	0.24 (-1.44, 1.95)
Number of days from first ESRD service to study initiation date	0.99 (0.99, 0.99) **	-0.18 (-0.20, -0.17) **
Patient Clinical Characteristics		
Nephrology care prior to study initiation (Reference: No)		
Yes	0.57 (0.56, 0.58) **	-18.78 (-19.43, -18.13) **
Missing	1.05 (1.02, 1.08) **	2.37 (1.18, 3.57) **
Primary cause of ESRD (Reference: Diabetes)		
Hypertension	0.86 (0.84, 0.88) **	-2.37 (-3.31, -1.42) **
Glomerulonephritis	0.86 (0.84, 0.89) **	-1.80 (-3.33, -0.25) *
Polycystic kidney disease	0.59 (0.56, 0.63) **	-16.80 (-19.32, -14.2) **
Other	1.07 (1.03, 1.10) **	10.56 (9.18, 11.96) **
Presence of hypertension at study initiation (Reference: No)		
Yes	0.90 (0.88, 0.92) **	-5.91 (-6.89, -4.92)
Presence of diabetes at study initiation (Reference: No)		
Yes	1.23 (1.20, 1.25) **	5.13 (4.17, 6.10) **
Presence of CVD at study initiation (Reference: No)		
Yes	1.50 (1.48, 1.53) **	13.15 (12.32, 13.98) **
Presence of Cancer at study initiation (Reference: No)		
Yes	1.11 (1.07, 1.14) **	0.87 (-0.47, 2.24)
Presence of COPD at study initiation (Reference: No)		
Yes	1.46 (1.41, 1.51) **	9.64 (8.40, 10.89) **
Presence of Disability at study initiation (Reference: No)		
Yes	1.79 (1.75, 1.83) **	36.02 (34.84, 37.20) **
BMI at study initiation	0.96 (0.96, 0.97) **	-1.35 (-1.58, -1.13) **
BMI at study initiation Squared	1.01 (1.01, 1.01) **	0.01 (0.01, 0.02) **
GFR EPI at study initiation	1.02 (1.01, 1.02) **	0.98 (0.88, 1.09) **
GFR MDRD at study initiation	1.00 (0.99, 1.01)	0.74 (0.62, 0.87) **
Hemoglobin at study initiation	0.99 (0.99, 0.99) *	0.00 (-0.02, 0.01)
Patient Behavioral Characteristics		

Variable	OR: Non-zero inpatient cost	Inpatient Cost
Current Smoker at study initiation (Reference: No)		
Yes	1.01 (0.98, 1.04)	-3.77 (-5.13, -2.38) **
Alcohol dependent at study initiation (Reference: No)		
Yes	1.12 (1.04, 1.20) **	0.40 (-2.66, 3.56)
Drug dependent at study initiation (Reference: No)		
Yes	1.47 (1.37, 1.58) *	19.58 (15.7, 23.58) **
Dialysis Center Characteristics		
Ownership status (Reference: Non-profit)		
For-profit	1.17 (1.14, 1.20) **	2.42 (1.36, 3.49) **
Missing	1.05 (1.01, 1.10) *	-6.36 (-8.21, -4.47) **
Number of dialysis stations	1.01 (1.01, 1.01) **	0.09 (-0.03, 0.21)
Network (Reference: Network 6 - GA, NC, SC)		
Network 1 (CT, ME, MA, NH, RI, VT)	1.18 (1.12, 1.23) **	13.45 (11.10, 15.86) **
Network 2 (NY)	1.21 (1.16, 1.26) **	20.08 (17.87, 22.33) **
Network 3 (NJ, PR, VI)	1.23 (1.18, 1.29) **	8.27 (6.15, 10.44) **
Network 4 (DE, PA)	1.20 (1.14, 1.26) **	12.14 (9.88, 14.45) **
Network 5 (DC, MD, VA, WV)	1.14 (1.09, 1.18) **	6.65 (4.79, 8.55) **
Network 7 (FL)	1.42 (1.36, 1.48) **	5.32 (3.52, 7.14) **
Network 8 (AL, MS, TN)	0.99 (0.95, 1.03)	-4.25 (-5.91, -2.55) **
Network 9 (IN, KY, OH)	1.14 (1.10, 1.18) **	3.33 (1.65, 5.04) **
Network 10 (IL)	1.02 (0.98, 1.07)	2.14 (0.18, 4.14) *
Network 11 (MI, MN, ND, SD, WI)	1.01 (0.98, 1.05)	4.28 (2.49, 6.10) **
Network 12 (IA, KS, MO, NE)	1.01 (0.97, 1.05)	-4.65 (-6.54, -2.72) **
Network 13 (AR, LA, OK)	1.07 (1.02, 1.11) **	2.59 (0.67, 4.55) **
Network 14 (TX)	1.18 (1.14, 1.23) **	9.78 (8.02, 11.56) **
Network 15 (AZ, CO, NV, NM, UT, WY)	0.94 (0.90, 0.98) **	-0.38 (-2.43, 1.71)
Network 16 (AK, ID, MT, OR, WA)	0.73 (0.69, 0.76) **	-12.01 (-14.11, -9.87) **
Network 17 (AS, Guam, HI, Mariana I, N. CA)	0.70 (0.67, 0.74) **	-1.60 (-3.71, 0.57)
Network 18 (Southern CA)	0.78 (0.75, 0.81) **	4.71 (2.73, 6.73) **
N	415,025	310,284
R ²	-	0.07
RMSE	-	0.95

Note: * : Significant at P<0.05, ** : Significant at P<0.01

Abbreviations: ESRD - End-Stage Renal Disease; Cardiovascular Disease; COPD - Chronic Obstructive Pulmonary Disease; BMI - Body Mass Index; GFR EPI - Glomerular Filtration Rate Epidemiology Collaboration; GFR MDRD - Glomerular Filtration Rate Modification of Diet in Renal Disease; RMSE - Root Mean Square Error.

Figure 1a: Total Cost

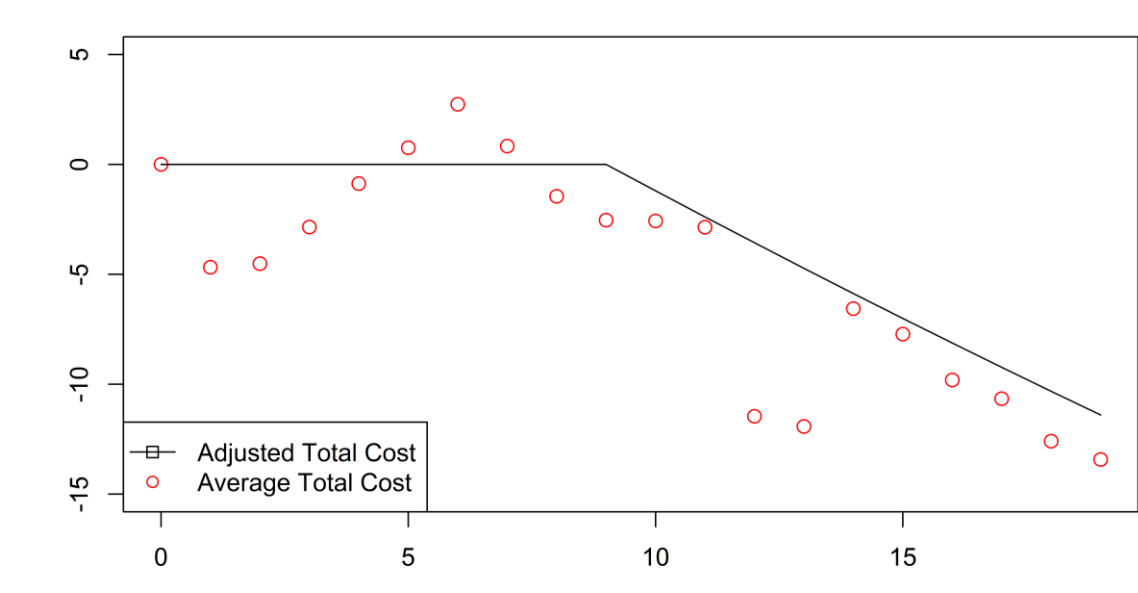


Figure 1b: Total Outpatient Cost

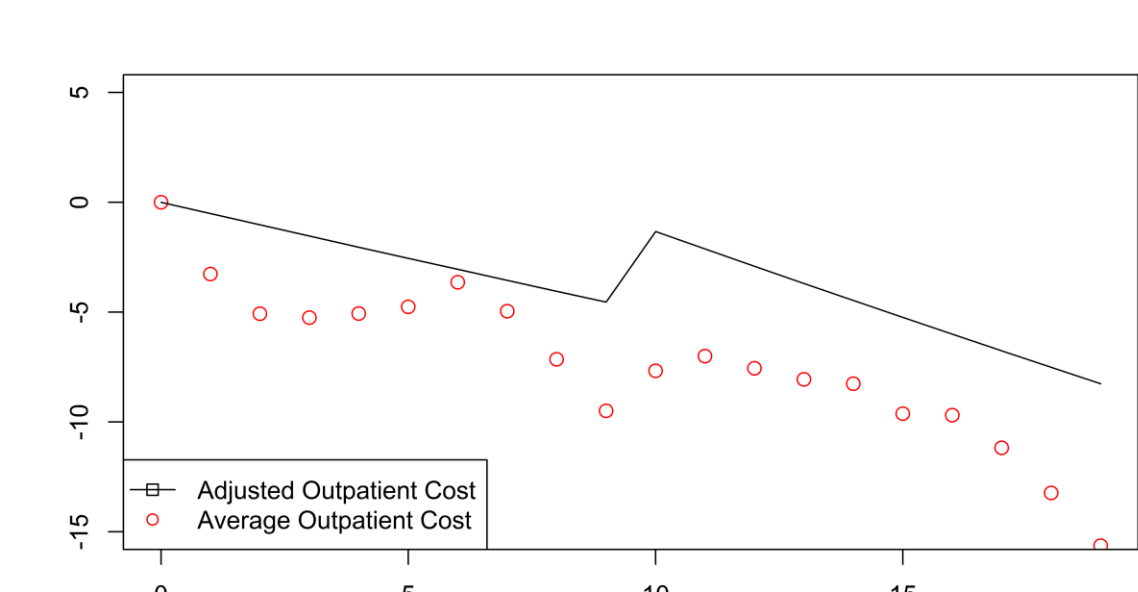


Figure 1c: Outpatient Dialysis Cost

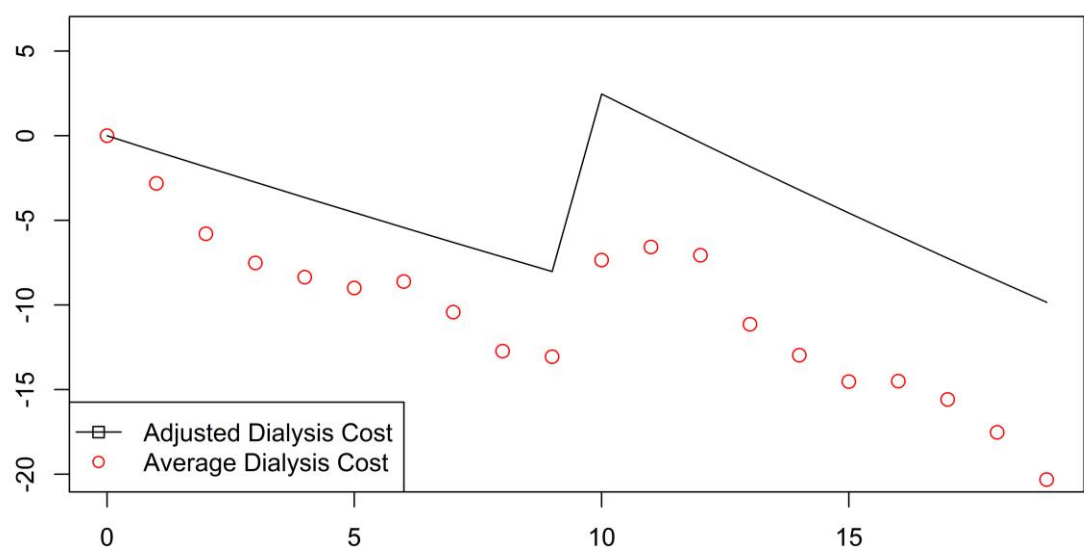


Figure 1d: Outpatient non-dialysis Cost

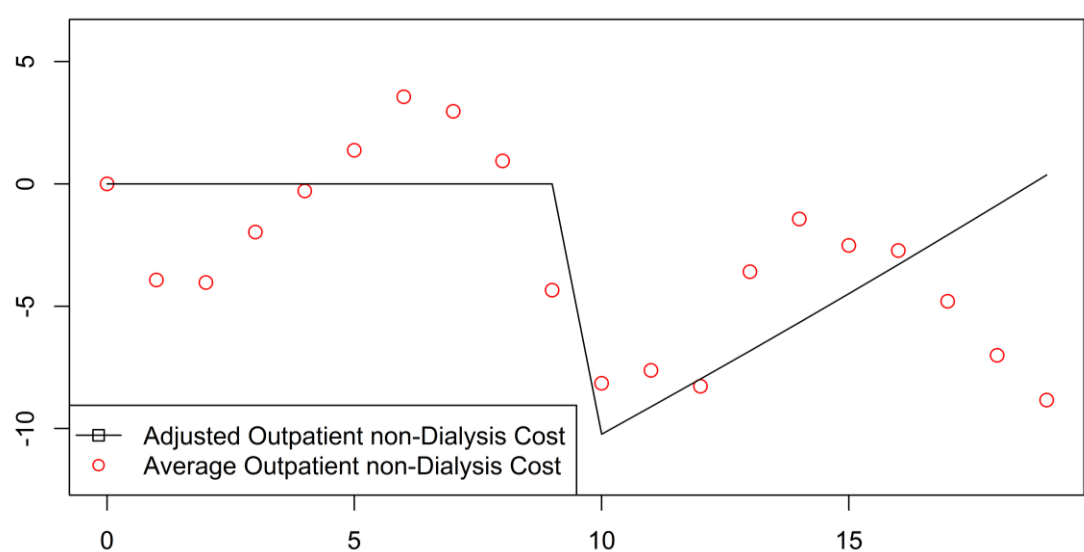


Figure 1e: Inpatient Cost

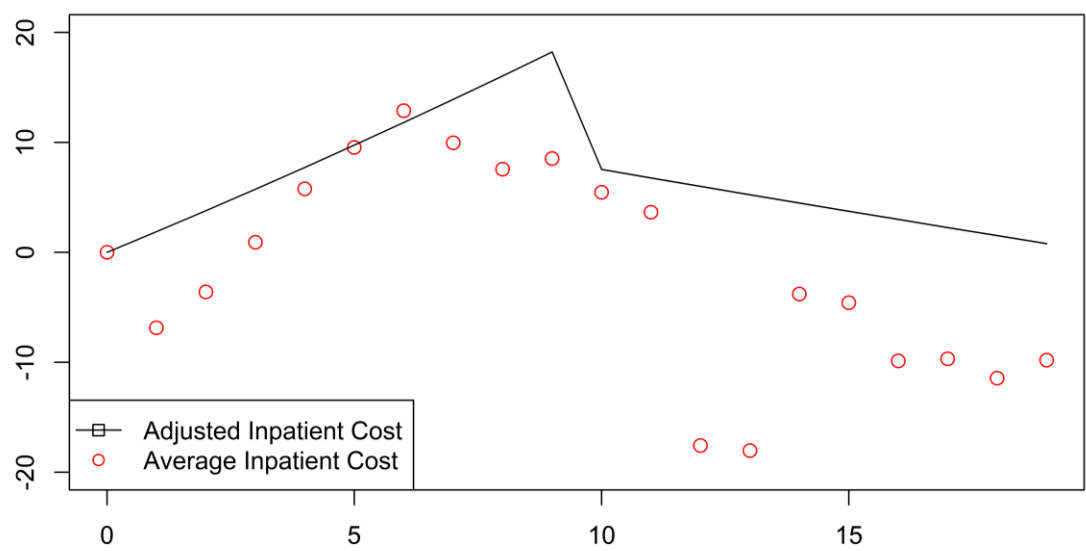


Figure 1f: Probability of having non-zero Inpatient Cost

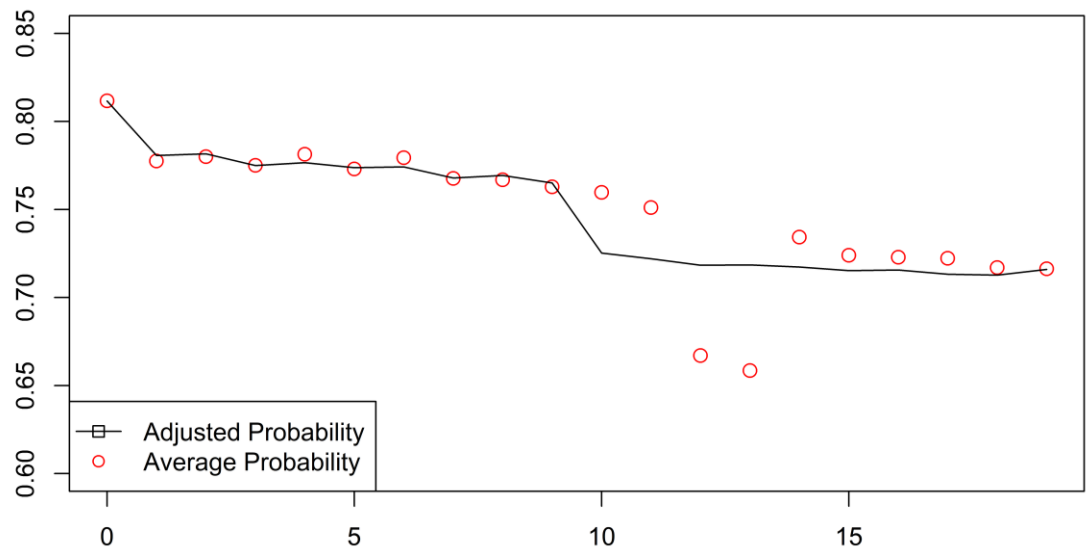


Figure 2: Medicare Total ESRD Expenditure Adjusted/Unadjusted to CPI by Year

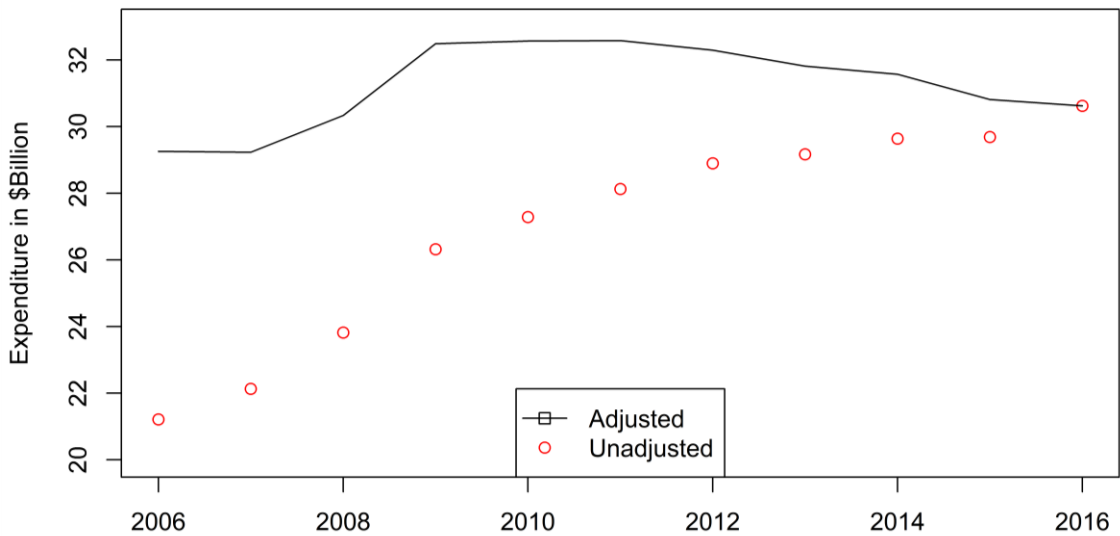


Figure 3: Medicare Expenditure PPPY adjusted/Unadjusted to CPI by year

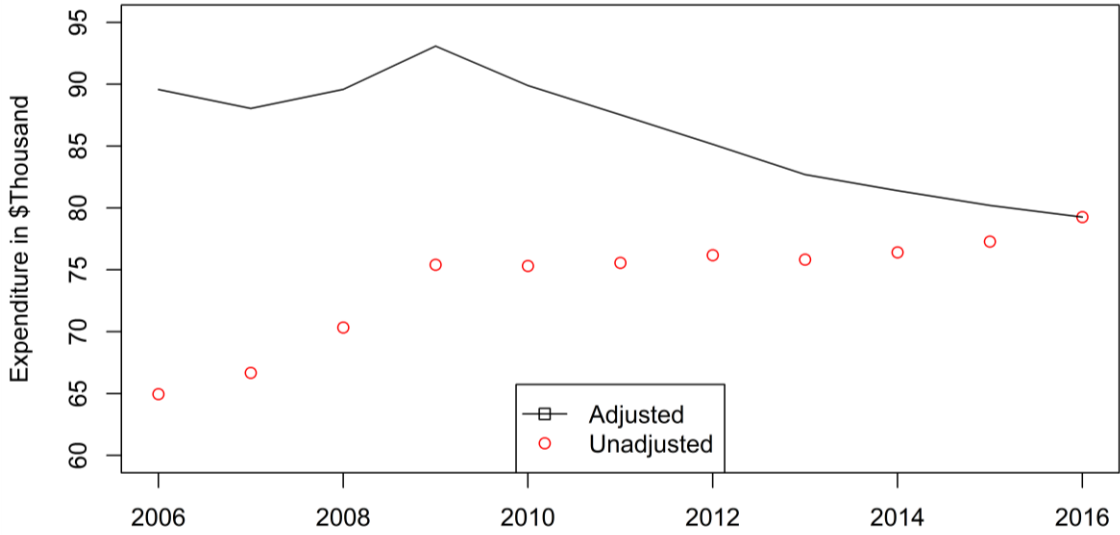


Figure 4a: Sensitivity Analysis – Total Cost

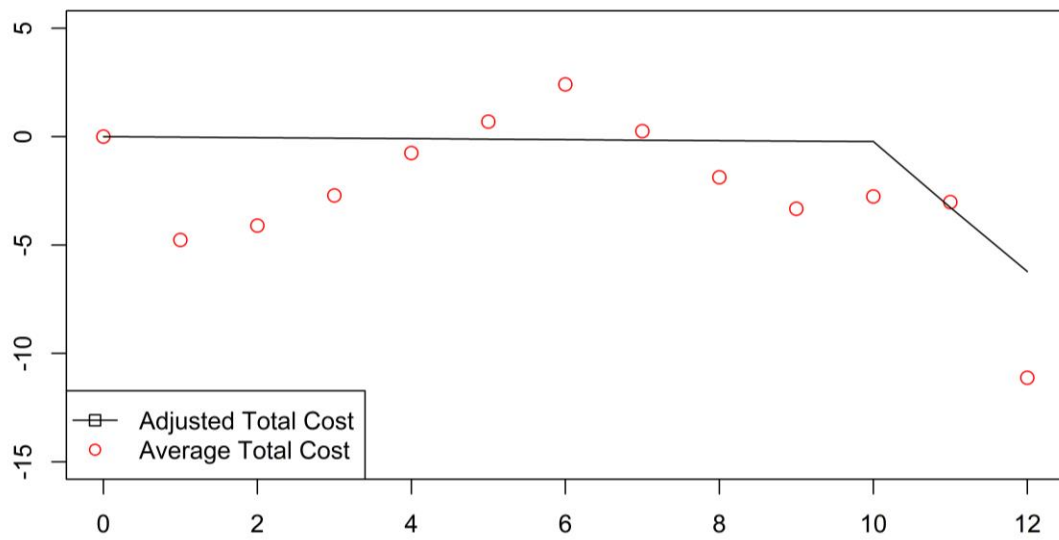


Figure 4b: Sensitivity Analysis – Total Outpatient Cost

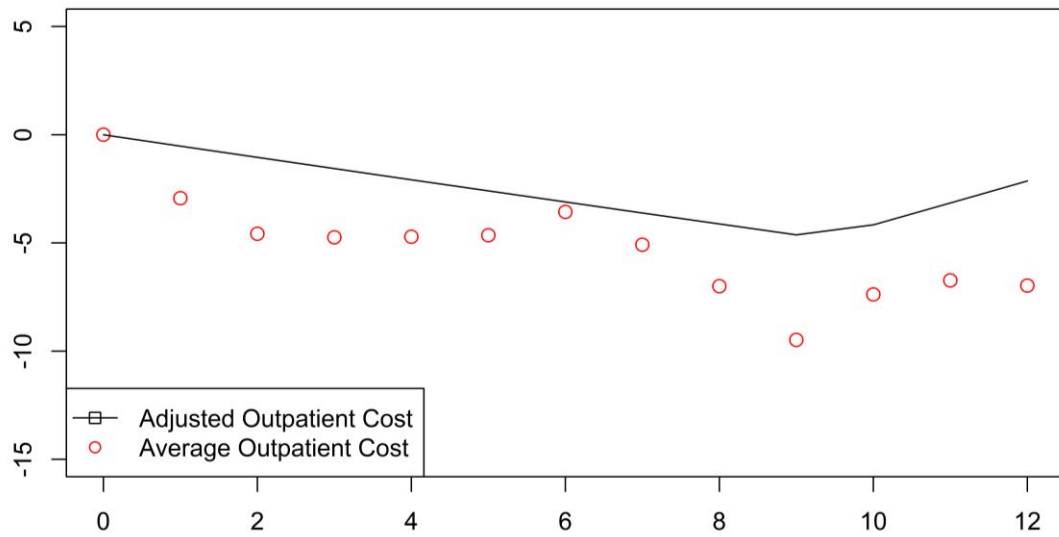


Figure 4c: Sensitivity Analysis – Outpatient Dialysis Cost

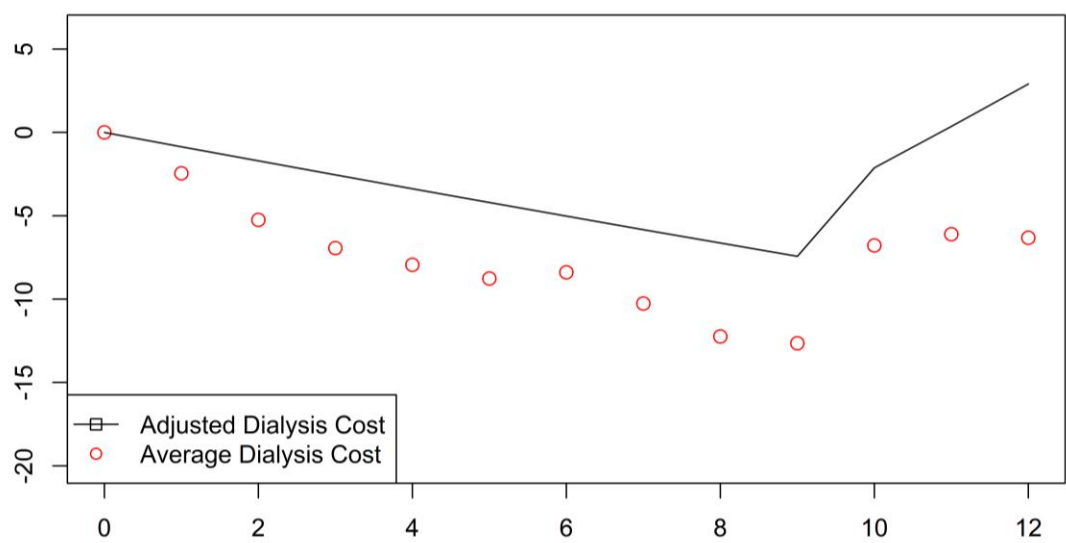


Figure 4d: Sensitivity Analysis – Outpatient non-Dialysis Cost

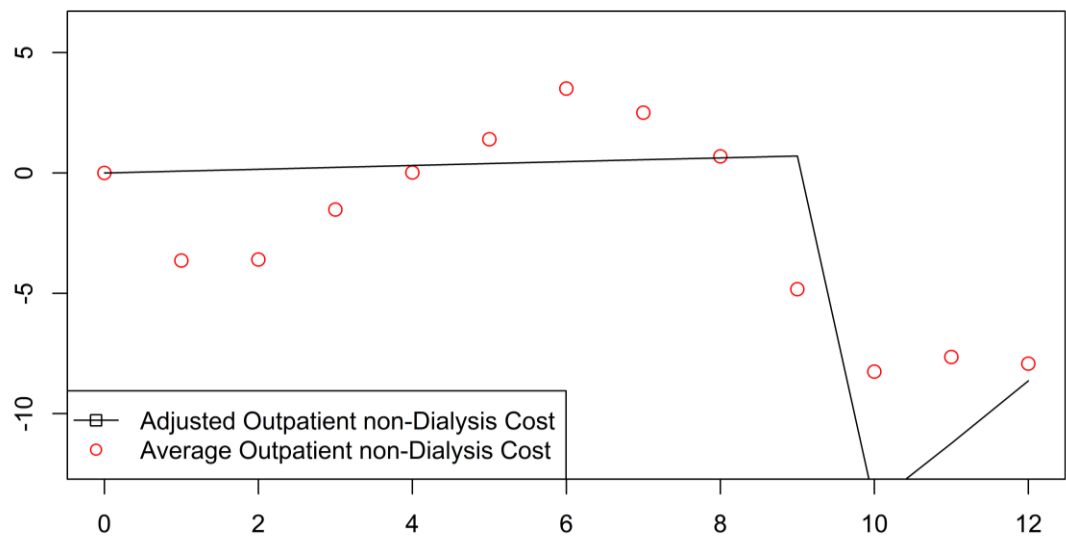


Figure 4e: Sensitivity Analysis – Inpatient Cost

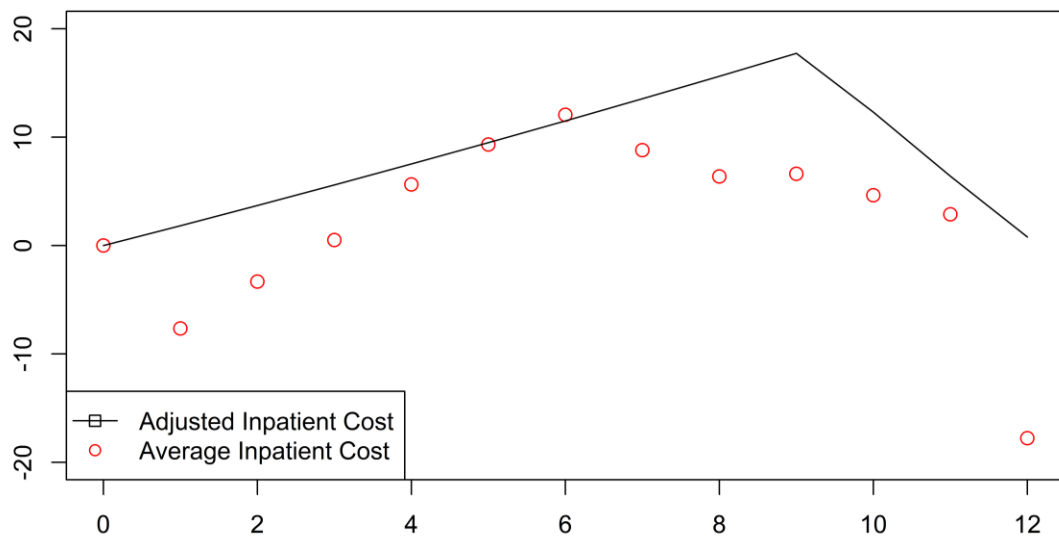
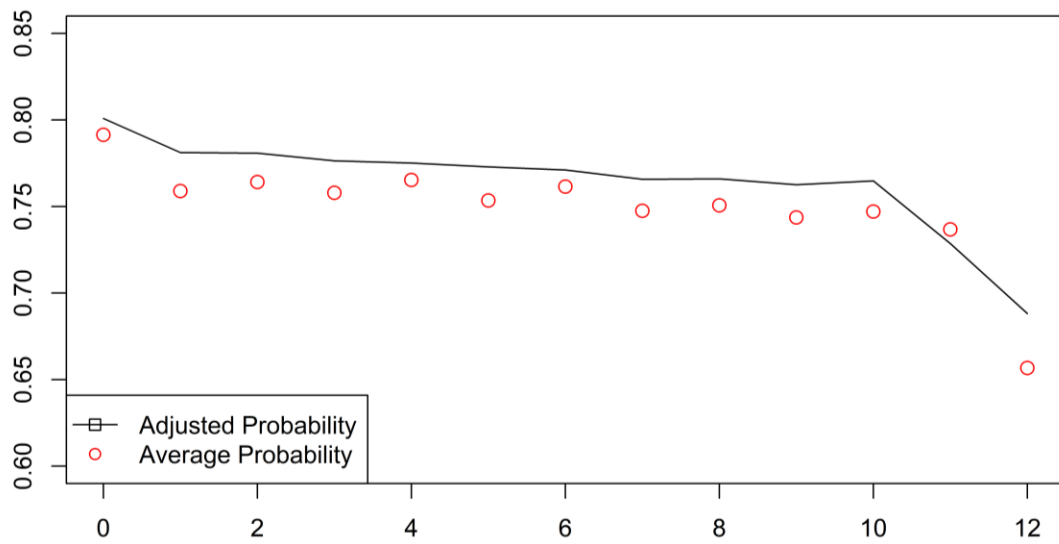


Figure 4f: Sensitivity Analysis – Probability of having non-zero Inpatient Cost



CONCLUSION

This study found that informing patients about kidney transplantation options is associated with increased odds of patients deciding to enroll in WL or receiving an LDKT. However, the effect of informing patients was less pronounced in for-profit dialysis centers compared with non-profit dialysis centers. Patient characteristics did not explain the observed difference, and the type of patients being informed was similar between for-profit and non-profit dialysis centers. Also, patients in for-profit dialysis centers had higher odds of being informed about transplantation options compared with patients in non-profit dialysis centers. Therefore, this study showed that information provided by for-profit dialysis centers was less effective and potentially lower quality than that provided by non-profit dialysis centers. The study highlights the need for developing guidelines to standardize transplantation information provided, in order to ensure similar informational quality across centers.

This study also showed that Medicare's PPS which was implemented in 2011 was associated with reduced total cost of 1-year care for new ESRD patients who received regular dialysis. However, the effect was not the same for all cost subcategories. Total outpatient and outpatient dialysis costs had declining trends over time before PPS. However, both cost categories had a significant increase right after PPS and the cost continued to decrease at a higher rate afterwards. Outpatient non-dialysis had an increasing trend over time before PPS; this category had a significant decrease immediately after PPS but continued to increase at a higher rate afterwards. Inpatient cost was growing before PPS, but the estimated cost significantly dropped right after PPS and started to decline afterwards. Probability of having a non-zero inpatient cost had a decreasing time trend before PPS, and the probability dropped

significantly after PPS. Hence, the study found that the PPS was associated with decreasing total cost of care. However, the effect was not the same for all cost subcategories. Nevertheless, PPS seems to have achieved the cost containment goal that it set out to achieve.

APPENDICES

Appendix: Table 1 -Sensitivity Analysis- Adjusted Odds Ratios Demonstrating the Effect of Patient, Dialysis Center, and Other Characteristics on Transplantation Status

	WL enrolled OR Estimate (95% CI) (Reference: Remaining on dialysis)	LDKT received OR Estimate (95% CI) (Reference: Remaining on dialysis)
Informed versus Uninformed Comparison:		
For For-profit	1.55 (1.49, 1.61)**	2.16 (1.90, 2.45)**
For Non-Profit	1.85 (1.69, 2.01)**	2.70 (2.05, 3.56)**
Patient Socio-Demographic Characteristics		
Age at study initiation	0.97 (0.97, 0.97)**	0.94 (0.94, 0.94)**
Gender (Reference: Male)		
Female	0.82 (0.80, 0.84)**	0.78 (0.74, 0.82)**
Race-ethnicity (Reference: Non-Hispanic White)		
Non-Hispanic Black	0.77 (0.75, 0.79)**	0.22 (0.20, 0.24)**
Hispanic	1.04 (1.01, 1.07)**	0.67 (0.62, 0.72)**
Non-Hispanic Other	1.09 (1.04, 1.13)**	0.38 (0.34, 0.42)**
Education	1.01 (1.01, 1.01)**	1.01 (1.01, 1.01)**
Logarithm of Income	1.52 (1.47, 1.57)**	2.46 (2.26, 2.66)**
Employment status at study initiation (Reference: Unemployed)		
Employed	1.63 (1.59, 1.67)**	2.45 (2.29, 2.63)**
Retired due to age	1.29 (1.24, 1.35)**	1.71 (1.50, 1.95)**
Retired due to disability	1.07 (1.04, 1.10)**	1.07 (0.98, 1.17)
Other	1.34 (1.29, 1.39)**	1.79 (1.64, 1.96)**
Insurance at study initiation (Reference: Medicare)		
Medicaid	0.88 (0.86, 0.91)**	0.74 (0.67, 0.82)**
Private insurance	1.77 (1.73, 1.82)**	2.89 (2.68, 3.11)**
Other	1.28 (1.23, 1.32)**	2.05 (1.86, 2.25)**
Uninsured	0.45 (0.40, 0.51)**	0.40 (0.27, 0.59)**
Patient Clinical Characteristics		
Nephrology care prior to study initiation (Reference: No)		
Yes	1.77 (1.73, 1.81)**	2.02 (1.90, 2.14)**
Missing	1.10 (1.06, 1.14)**	1.12 (1.01, 1.24)*
Primary cause of ESRD (Reference: Diabetes)		
Hypertension	0.99 (0.96, 1.02)	1.14 (1.04, 1.26)**
Glomerulonephritis	1.34 (1.30, 1.39)**	2.21 (2.01, 2.43)**
Polycystic kidney disease	1.75 (1.66, 1.84)**	2.13 (1.88, 2.41)**
Other	0.78 (0.75, 0.81)**	1.05 (0.94, 1.16)
Presence of hypertension at study initiation (Reference: No)		
Yes	1.18 (1.15, 1.21)**	1.13 (1.05, 1.21)**
Presence of diabetes at study initiation (Reference: No)		
Yes	0.95 (0.93, 0.98)**	0.74 (0.68, 0.81)**
Presence of CVD at study initiation (Reference: No)		
Yes	0.67 (0.66, 0.69)**	0.61 (0.57, 0.65)**
Presence of Cancer at study initiation (Reference: No)		
Yes	0.47 (0.44, 0.50)**	0.45 (0.38, 0.53)**
Presence of COPD at study initiation (Reference: No)		
Yes	0.55 (0.52, 0.58)**	0.45 (0.36, 0.57)**
Presence of Disability at study initiation (Reference: No)		
Yes	0.47 (0.45, 0.49)**	0.38 (0.32, 0.45)**
BMI at study initiation	0.97 (0.97, 0.97)**	0.95 (0.94, 0.95)**
GFR EPI at study initiation	0.98 (0.98, 0.99)**	0.98 (0.97, 0.99)**
GFR MDRD at study initiation	0.99 (0.99, 0.99)**	0.98 (0.97, 0.99)**
Patient Behavioral Characteristics		
Current smoker at study initiation (Reference: No)		
Yes	0.51 (0.49, 0.53)**	0.42 (0.37, 0.47)**
Alcohol dependent at study initiation (Reference: No)		
Yes	0.81 (0.75, 0.88)**	0.27 (0.18, 0.40)**

	WL enrolled OR Estimate (95% CI) (Reference: Remaining on dialysis)	LDKT received OR Estimate (95% CI) (Reference: Remaining on dialysis)
Drug dependent at study initiation (Reference: No)		
Yes	0.27 (0.24, 0.30)**	0.24 (0.16, 0.36)**
Dialysis Center Characteristics		
Number of dialysis stations	0.99 (0.99, 0.99)**	0.99 (0.99, 0.99)**
Regional ESRD Network (Reference: Network 14 - TX)		
Network 1 (CT, ME, MA, NH, RI, VT)	1.41 (1.28, 1.56)**	1.61 (1.36, 1.92)**
Network 2 (NY)	1.27 (1.17, 1.38)**	1.62 (1.38, 1.89)**
Network 3 (NJ, PR, VI)	1.05 (0.96, 1.15)	1.23 (1.04, 1.46)*
Network 4 (DE, PA)	1.49 (1.37, 1.62)**	1.35 (1.14, 1.60)*
Network 5 (DC, MD, VA, WV)	0.94 (0.87, 1.01)	1.10 (0.94, 1.29)
Network 6 (GA, NC, SC)	0.73 (0.68, 0.78)**	0.56 (0.48, 0.66)**
Network 7 (FL)	0.60 (0.55, 0.65)**	0.63 (0.53, 0.74)**
Network 8 (AL, MS, TN)	1.04 (0.96, 1.12)	1.04 (0.88, 1.23)
Network 9 (IN, KY, OH)	0.82 (0.76, 0.89)**	1.19 (1.03, 1.37)*
Network 10 (IL)	1.14 (1.05, 1.24)**	1.66 (1.41, 1.94)**
Network 11 (MI, MN, ND, SD, WI)	1.34 (1.24, 1.45)**	1.83 (1.58, 2.12)**
Network 12 (IA, KS, MO, NE)	0.93 (0.85, 1.02)	1.02 (0.86, 1.22)
Network 13 (AR, LA, OK)	0.72 (0.66, 0.79)**	0.68 (0.56, 0.83)**
Network 15 (AZ, CO, NV, NM, UT, WY)	0.88 (0.81, 0.95)**	1.03 (0.88, 1.20)
Network 16 (AK, ID, MT, OR, WA)	0.70 (0.63, 0.77)**	0.75 (0.62, 0.91)**
Network 17 (AS, Guam, HI, Mariana I, N. CA)	1.77 (1.63, 1.92)**	0.84 (0.70, 1.01)
Network 18 (Southern CA)	0.77 (0.72, 0.83)**	0.42 (0.35, 0.50)**
Other Variables		
Year of study initiation (Reference: 2005)		
2006	1.14 (1.08, 1.20)**	0.94 (0.84, 1.05)
2007	1.10 (1.04, 1.15)**	0.84 (0.75, 0.94)**
2008	1.08 (1.03, 1.14)**	0.80 (0.71, 0.90)**
2009	1.12 (1.06, 1.18)**	0.81 (0.72, 0.91)**
2010	1.10 (1.05, 1.16)**	0.72 (0.64, 0.81)**
2011	1.12 (1.07, 1.18)**	0.66 (0.59, 0.75)**
2012	1.14 (1.08, 1.20)**	0.65 (0.58, 0.74)**
2013	1.05 (0.99, 1.11)	0.58 (0.51, 0.66)**
2014	0.89 (0.85, 0.94)**	0.50 (0.44, 0.57)**
2015	0.77 (0.73, 0.81)**	0.47 (0.41, 0.53)**
2016	0.71 (0.68, 0.75)**	0.43 (0.38, 0.49)**

Note: * : Significant at P<0.05, ** : Significant at P<0.01

Abbreviations: ESRD - End-Stage Renal Disease; WL - Wait List; LDKT - Live Donor Kidney Transplant; CVD - Cardiovascular Disease; COPD - Chronic Obstructive Pulmonary Disease; BMI - Body Mass Index; GFR EPI - Glomerular Filtration Rate Epidemiology Collaboration; GFR MDRD - Glomerular Filtration Rate Modification of Diet in Renal Disease.

List of Abbreviations

ESRD – End Stage Renal Disease

PPS – Prospective Payment System

USRDS – United States Renal Data System

ITSA – Interrupted Time Series Analysis

WL – Wait List

LDKT – Live Donor Kidney Transplant

KT – Kidney Transplantation

CMS – Centers for Medicare and Medicaid Services

MIPPA – Medicare Improvements for Patients and Providers

ESA – Erythropoietin Stimulating Agent

PPPY – Per-Person-Per-Year

CPI – Consumer Price Index

OR – Odds Ratio

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