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Research Article

Assessing the Impact of a Renal Care Management Program on Disease Progression: An Observational Cohort Study

Ashley Crossman*, Jiang Tao, Wade Bannister, Rahul Dhawan and Kevin Plosser

Director at Optum Health, USA

***Corresponding author**

Ashley Crossman, Director at Optum Health, 5733 N 18th Place, Phoenix, AZ 85016, USA, Tel: 480-221-6076

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Abstract

Introduction: There are few observational studies evaluating the effects renal care management programs have on the transition from chronic kidney disease to end stage renal disease, marked by initiation of dialysis. This limits the understanding of the quantitative effectiveness of such programs.

Methods: A retrospective cohort study of CKD patients with or without access to a renal care management program was completed. Propensity score 1:1 matching was used to balance the comparison groups on demographic and clinical characteristics. Healthcare claims data was used to determine whether program access affected the rate of transition to dialysis and the likelihood of transitioning to dialysis.

Results: We followed the cohort of 5,912 patients (2,956 with access to a renal care management program and 2,956 without access to the program) during a two-year period. Those with access to the program transitioned to dialysis later than those without access to the program. Further, those with access to the program had a 22 percent reduced risk of initiating dialysis compared to those without access to the program.

Conclusions: Patients with stage 4 or 5 chronic kidney disease who have access to renal care management have a reduced risk of transitioning to dialysis as well as a later transition to dialysis compared to CKD patients without access to renal care management.

INTRODUCTION

Chronic kidney disease (CKD) is prevalent in roughly 15 percent of the population and is the sixth leading cause of death in the United States [1]. Kidney disease is largely irreversible, the progression from CKD to end stage renal disease (ESRD) is inevitable unless the patient receives a transplant or expires. This transition has a significant impact on a patients' morbidity and mortality as well as on the healthcare expenditures and resources.

CKD and ESRD both come with considerable expenses. In 2018, Medicare fee-for-service spending for those with CKD who did not have ESRD exceeded $81 billion, which represented over 22 percent of the Medicare fee-for-service spending. ESRD costs add an additional $49.2 billion, bringing the total for both CKD and ESRD to $130 billion, representing nearly 36 percent of total Medicare spending. Each stage of the disease incurs more expenses than the previous, with CKD stages 1/2 costing $20,275 per year, stage 3 costing $23,300, and stages 4/5 costing $31,487 annually. Once a patient progresses to ESRD that cost increases to $93,100 annually [1]. Prolonging this progression from CKD to ESRD can not only prolong the patient's quality of life and mortality, but can also save the patient, employer, and health plan significant amounts of money.

The progression from CKD to ESRD is not a predictable or uniform one; many people are able to live long, active lives while having CKD while others progress to ESRD more rapidly. Some research even suggests that the trajectory is not linear but rather follows a more staccato and unpredictable course [2]. Factors that have been shown to predict CKD progression include proteinuria, hypertension, diabetes, metabolic acidosis, and mineral bone disorder, most of which are modifiable with lifestyle and/or pharmacologic intervention [3]. Early diagnosis of CKD can lead to specific interventions addressing these factors and ultimately help slow the progression of the disease.

Disease management is a comprehensive, integrated approach to care delivery that is well suited for patients with complex chronic illnesses, such as CKD and ESRD. The overall goals of disease management programs are to improve clinical outcomes and contain the costs of care, with an emphasis on the coordination of care across the spectrum of the disease or condition. Components to a successful disease management program include: identifying patients early before the disease

progresses; having a medical director that is responsible for ensuring that all care is coordinated, evidence-based, and optimizes outcomes based on the most recent research; and ensuring that a disease management care RN has a central role in the program, helping to coordinate care, serve as a liaison between the patient, providers, and other elements of the health care system as well as ensuring the patient is adhering to the plan of care [4].

METHODS

Study Population

The design is a retrospective cohort study of patients in the United States drawn from a national health plan claims database who were identified as having stage 4 or stage 5 chronic kidney disease on July 1, 2018. The treatment group consisted of commercial health plan members with access to Kidney Resource Services, a renal care management program, regardless of their engagement with the program (n = 2,956). To avoid participation bias, an intent-to-treat approach is used, resulting in a study group that is comprised of various levels of program engagement, including non-participation. The control group consisted of commercial health plan members who did not have access to the program (n = 2,956). The availability of the program to the patient was dictated by the patient's employer purchasing the program.

Members were traced from the beginning of the study period in July 2018 until whichever event occurred earliest: dialysis was initiated; patient received a kidney transplant; patient became Medicare Primary; patient deceased; or the end of the study period (June 2020).

The control group was selected by propensity score matching on demographic and clinical characteristics. Variables used to balance the two groups are shown in table 1. Sex, age, region of residence, risk score, and comorbid conditions were extracted from the members' healthcare claims. United States 2020 census data was used to measure median household income by zip code, education level by zip code, minority population by zip code, hospital beds by zip code, and PCP, specialist, nephrologist, and total physician concentration by zip code for each member. Cases and controls were matched 1:1 (Table 1).

Datasets and Variables

Analyses were conducted using data from a large national health plan claims database. Patients with stage 4 or 5 chronic kidney disease were identified through ICD-10 diagnosis codes N18.4 and N18.5 with a 24-month lookback period. Creatinine and eGFR laboratory results were also used to identify patients with a 12-month lookback period, using LOINC codes 2160-0, 33914-3, 48642-3, and 48643-1. The outcome, initiation of maintenance dialysis, was measured as the occurrence of three consecutive months of dialysis in the patients' claims.

Patient comorbidities were also evaluated using ICD-10 codes with a 24-month lookback period as of July 1, 2018 at the time that CKD was identified. Comorbidities include acute kidney failure, depression, diabetes, congestive heart failure, hypertension, proteinuria, atrial fibrillation, chronic obstructive pulmonary disorder, heart disease, hyperlipidemia, dyslipidemia, obesity, and nephrotic syndrome.

Statistical Methods

Kaplan-Meier curves were used to examine the effect of program access on the probability of transitioning to dialysis. Curves were compared between those who had access to the renal care management program and those who did not have access to the program using the log rank test.

In addition, a Cox proportional hazards model was used to measure the risk relationship between those who had access to the renal care management program and time to dialysis initiation while controlling for patient risk and patient characteristics. Additional outcomes assessed include mortality and inpatient hospital admissions. A significance level of 0.05 was used.

In both models, censoring points included receiving a kidney transplant, loss of medical coverage, death, and becoming a Medicare primary member.

RESULTS

A total of 5,912 patients were included in the study. 58.3 percent were male and 46 percent of were aged 55 to 64 as of July 1, 2018. Chronic kidney disease is commonly associated with extreme comorbidity across a wide range of physical and mental health conditions, as demonstrated by the current study population. Over 90 percent of the patients in the current study also have hypertension, and nearly 50 percent have diabetes. Congestive heart failure and proteinuria are also present in roughly one out of four patients. Almost 10 percent of patients had concomitant depression as well.

The Kaplan-Meier curves in Figure 1 show that members who had access to the renal care management program initiated dialysis later than members who did not have access to the program, a difference that is statistically significant at a p-value of 0.0118. The results indicate that among patients who transitioned to dialysis during the study period, those with access to the renal care management program transitioned 0.7 months later than those without access to the program.

Results of the fully adjusted Cox proportional hazards model are shown in Table 2. Members who had access to the program have a hazard ratio of 0.781, meaning that they had a 22 percent reduced risk of initiating dialysis compared to those without access to the program, after adjusting for patient risk and characteristics. Other factors that reduced the risk of dialysis initiation include depression (hazard ratio = 0.722), chronic obstructive pulmonary disease (hazard ratio = 0.689) and atrial fibrillation (hazard ratio = 0.713).

Individuals who had stage 5 CKD at baseline had a significantly

Table 1: Baseline characteristics of the cohort by program access

	All Patients (n=5,912)	Program Access (n=2,956)	No Program Access (n=2,956)
Male sex, %	58.3	58.7	58.1
Mean risk score at baseline	10.8	11.23	10.45
Age at baseline, %			
18-54	35.3	34.9	35.6
55-64	46	46.5	45.7
65-74	15.5	15.6	15.4
75-84	2.7	2.4	2.9
85+	0.5	0.6	0.4
Region of residence, %			
Midwest	21.6	16.5	25.6
Northeast	23.6	34.8	14.5
South	41	37.2	44.1
West	13.8	11.5	15.8
Conditions at baseline, %			
CKD 5 at baseline	18.6	19.2	18.1
Stage 4 CKD 6 months prior to study period	61.7	61.4	61.9
Stage 5 CKD 6 months prior to study period	7.9	8	7.8
Acute Kidney Failure	12.8	12.6	13
Diabetes	48.8	49.7	48.2
Congestive Heart Failure	22.9	23	22.9
Hypertension	90.6	90.5	90.6
Atrial Fibrillation	8	7.8	8.1
Chronic Obstructive Pulmonary Disease	5.2	6	4.6
Proteinuria	26	26	26
Depression	8.2	8	8.5
Heart Disease	43.1	44.9	41.7
Hyperlipidemia	62.7	63.4	62.2
Dyslipidemia	59.1	59	59.3
Obesity	21.7	22.3	21.3
Nephrotic Syndrome	4.2	3.9	4.5
Education Level of Zip Code, High	49.2	47.7	50.4
Education Level of Zip Code, Median	39.4	40.7	38.4
Education Level of Zip Code, Low	11.4	11.6	11.2
Hospital Beds in Zip Code, High	5.3	5.6	5.1
Hospital Beds in Zip Code, Median	43.6	44.8	42.6
Hospital Beds in Zip Code, Low	51	49.5	52.3
Median Income of Zip Code, High	48	49.5	46.7
Median Income of Zip Code, Median	34.1	34.1	34.2
Median Income of Zip Code, Low	17.9	16.4	19.1
Minority Population in Zip Code, high	11.6	12.4	10.9
Minority Population in Zip Code, Median	52.1	50.3	53.5
Minority Population in Zip Code, Low	36.4	37.3	35.6
Nephrologists in Zip Code, High	59.5	60.7	58.6
Nephrologists in Zip Code, Median	32.8	31.8	33.6
Nephrologists in Zip Code, Low	7.6	7.4	7.8
PCPs in Zip Code, High	17.4	18.6	16.4
PCPs in Zip Code, Median	47.4	48.1	46.8
PCPs in Zip Code, Low	35.2	33.3	36.8
Physicians in Zip Code, High	30	34.2	26.5
Physicians in Zip Code, Median	43.2	41.2	44.8
Physicians in Zip Code, Low	26.8	24.6	28.7
Specialists in Zip Code, High	37.2	43.6	32.1
Specialists in Zip Code, Median	43.4	38.3	47.5
Specialists in Zip Code, Low	19.4	18.2	20.3
Surgeons in Zip Code, High	14.5	18.1	11.6
Surgeons in Zip Code, Median	37.8	39.4	36.5
Surgeons in Zip Code, Low	47.7	42.5	51.9

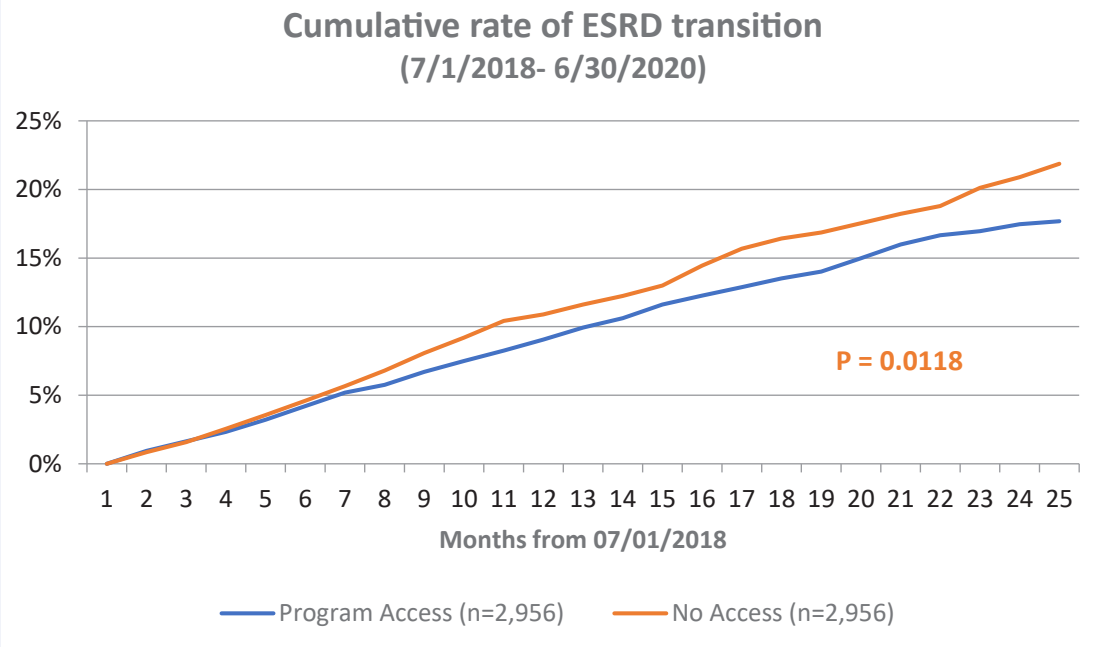

Figure 1 Cumulative rate of ESRD transition.

Table 2: Fully adjusted model for transition to dialysis

Parameter	Parameter Estimate	Standard Error	p Value	Hazard Ratio
Access to program	-0.247	0.081	0.002	0.781
Male	-0.028	0.069	0.688	0.973
Risk Score	0.009	0.003	0.007	1.009
Age at baseline				
18-54	-11.068	122.074	0.928	0
55-64	-10.586	122.074	0.931	0
65-74	-10.304	122.074	0.933	0
75-84	-9.652	122.075	0.937	0
Region of residence				
Midwest	-0.039	0.126	0.756	0.962
Northeast	0.035	0.132	0.788	1.036
South	-0.159	0.112	0.153	0.853
Conditions at baseline				
CKD 5 at baseline	1.177	0.083	<.0001	3.245
Stage 4 CKD 6 months prior to study period	0.172	0.087	0.048	1.188
Stage 5 CKD 6 months prior to study period	0.085	0.129	0.51	1.089
Acute Kidney Failure	0.486	0.088	<.0001	1.625
Diabetes	0.379	0.075	<.0001	1.461
Congestive Heart Failure	0.312	0.086	0	1.366
Hypertension	0.451	0.164	0.006	1.57
Atrial Fibrillation	-0.339	0.146	0.02	0.713
Chronic Obstructive Pulmonary Disease	-0.372	0.175	0.034	0.689
Proteinuria	0.302	0.071	<.0001	1.352
Depression	-0.326	0.136	0.016	0.722
Heart Disease	0.092	0.078	0.239	1.096
Hyperlipidemia	0.178	0.095	0.061	1.195
Dyslipidemia	-0.146	0.09	0.106	0.864
Obesity	-0.003	0.079	0.969	0.997
Nephrotic Syndrome	0.165	0.128	0.197	1.18

Table 3: Clinical outcomes by renal care management access

Outcome	Program Access (n=2,956)	No Program Access (n=2,956)	p-value
Mortality Rate	1.80%	2.00%	0.524
Inpatient Hospitalization Rate	23.20%	29.90%	<.0001
Average number of inpatient admissions	0.46	0.56	<.0001

increased risk of transitioning to dialysis, with a hazard ratio of 3.245. Other significant risk factors include acute kidney failure (hazard ratio = 1.625), diabetes (hazard ratio = 1.461), congestive heart failure (hazard ratio = 1.366), hypertension (hazard ratio = 1.57), and proteinuria (hazard ratio = 1.352).

Education level, hospital access, minority prevalence, and nephrologist/specialist/PCP/surgeon access did not impact the results.

The results of the clinical outcomes by access to renal care management are shown in Table 3. Patients with access to the program had a significantly lower hospitalization rate, with a 6.7 percent difference between the groups. Patients with program access had an average of 0.46 inpatient admissions during the 24 months, compared to 0.56 for those with no program access. While the mortality rate was lower among the patients who had program access, the difference was not statistically significant.

DISCUSSION

In this study, we have shown that the cumulative rate that CKD patients transition to dialysis happens faster among patients without access to the renal care management program compared to those that do have access. Specifically, nearly 22 percent of patients without access the program transition to dialysis by 24 months, compared to less than 18 percent of patients with access to program.

We have also quantified the risk of CKD patients transitioning to dialysis among those with access to the renal care management program and those without access to the program, after controlling for patient risk and characteristics. The risk of transitioning to dialysis is significantly higher among patients without access to the renal care management program a 22 percent increase in risk.

CKD patients with comorbidities are also at a greater risk of transitioning to dialysis. Diabetes increases the risk of transition by 46 percent while congestive heart failure increases the risk by 37 percent. The renal care management program helps patients navigate the complexities of treating these complex comorbidities. For example, the program's nurses educate patients on the benefits of following up with specialists and ensure communication between various specialties taking care of the patient. The program also includes certified diabetic educators who help patients identify causes of uncontrolled diabetes, improving diabetes medication compliance, and therefore reducing the risk of progression of CKD [5].

CKD patients who have an episode of acute kidney failure have a 63 percent increased risk of transitioning to dialysis. By working with patients to educate them of benefits of close nephrology follow up, facilitating transportation to appointments and performing medication reconciliation post discharge, the program can identify causes of acute kidney injury. In addition, the program works to stop persistent insults to kidneys by identifying nephrotoxic medications especially in the setting of acute kidney injury and educating patients and providers regarding safer alternatives. The COVID-19 pandemic has further added to the complexity of care and the program is a valuable benefit for patents who are navigating the complexities of this additional burden of disease [6].

Some comorbidities are shown to have a protective effect on the risk of transitioning to dialysis, however. Atrial fibrillation chronic obstructive pulmonary disease, and depression are showing protective effects against progression to dialysis among CKD patients in our analysis. More research is needed to determine why these comorbidities have a potential paradoxical protective effect on the current study population.

In addition to delaying kidney disease progression, access to renal care management programs also impacts clinical outcomes such as hospitalization rates. Nearly 30 percent of patients without access to renal care management had at least one inpatient hospitalization during the 24-month study period, compared to only 23 percent of patients with access to the program. Future research is needed to look at additional clinical outcomes that might be impacted.

One limitation of this study relates to the nature of routine healthcare claims data, which is limited in information outside of medical procedures. This makes it difficult to identify factors such as lifestyle, diet, exercise, and genetic factors that might influence a patient's progression from chronic kidney disease to end stage renal disease. Another limitation of the study is the limited scope. For instance, the patients' current treatment regimen for chronic kidney disease is not considered. It is possible that other treatments or medications are contributing to the delay in dialysis transition in addition to access to the renal care management program. A further limitation is that the Kidney Resource Services renal care management program was the only plan included in the study, which limits the potential representation of the program benefits to other renal care management plans.

In conclusion, we have shown that CKD patients with access to the renal care management program transition to dialysis at a slower rate compared to those without access to the program. We have also quantified the risk of transitioning to dialysis for those with access to the program compared to those without access to the program while controlling for patient risk and characteristics. Further work is needed to understand additional

factors that could be in effect, as well as what specific aspects of the renal care management program are the most influential at helping to prolong the transition to dialysis among CKD patients.

STATEMENT OF ETHICS

This study was granted an exception by the institute's committee on human research under the following IRB exemption category: "Secondary use of existing data in a limited data set. The data will be recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects. The investigator will not contact or attempt to re-identify the subjects. Based on the Exemption criteria, informed consent and HIPAA authorization from the research subjects are not required."

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