<u>EVALUATION OF THE IMPACT OF THE END STAGE RENAL DISEASE QUALITY INCENTIVE PROGRAM ON THE ELDERLY</u>

by

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A Dissertation
Submitted to the
Graduate Faculty
of
George Mason University
in Partial Fulfillment of
The Requirements for the Degree
of
Doctor of Philosophy
Public Policy

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DEDICATION

This is dedicated to my husband Mark. Your unflagging support and patience kept me going throughout this lengthy process. Words cannot describe my appreciation and love for you.

ACKNOWLEDGEMENTS

I would like to thank my advisor Dr. Naoru Koizumi, who has been with me from the start of the program, for her guidance, encouragement and kindness throughout these many years. Next, I would like to express my sincere appreciation to Dr. Sita Slavov and Dr. Gilbert Gimm for their participation on my committee and their insightful and invaluable suggestions and criticisms. Also, a special thanks to my external reader Dr. Ernest Moy.

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Arteriovenous... AV
Confidence Interval... CI
Centers for Medicare and Medicaid Services ....CMS
Clinical Performance Measure..CPM
End Stage Renal Disease ....ESRD
Erythropoietin Stimulating Agent ....ESA
Health, Education and Welfare ....HEW
Hemodialysis .... HD
In-Center Hemodialysis Consumer Assessment of Providers and System……………ICH-CAHPS
Kidney Allocation System .... KAS
Medicare Improvement for Patients and Providers..MIPPA
National Quality Forum .... NQF
Omnibus Budget Reconciliation Act ....OBRA
Organ Procurement and Transplantation Network ....OPTN
Peritoneal Dialysis .... PD
Public Health Service..PHS
Prospective Payment System ....PPS
Quality Incentive Program...QIP
Technical Expert Panel .... TEP
Urea Reduction Ratio... URR
Vascular Access Type... VAT
Veterans Association .... VA

ABSTRACT

EVALUATION OF THE IMPACT OF THE END STAGE RENAL DISEASE QUALITY INCENTIVE PROGRAM ON THE ELDERLY

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George Mason University, 2020

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As Medicare expenditures continue to increase, pay-for-performance programs have been implemented to curb costs and improve the quality of care. As the first federally mandated pay-for-performance program, the End Stage Renal Disease Quality Incentive Program links a portion of payment to a dialysis facility's performance on pre-established quality measures. More accurately described as a penalty program, the QIP does not provide financial rewards for attaining high scores on performance measures. The maximum payment reduction which Medicare can apply to any facility is two percent. Concerns about the effectiveness of the incentive program since its implementation in 2012 have been expressed. While the financial incentive is aimed to change provider behavior in order to generate patient health improvements and cost reductions, these outcomes have been questionable. Provider interventions are not easily attributable to patients' achieving the targeted measures, and unintended consequences of the incentive program are a challenge. For elderly dialysis patients, who experience different physiological changes and treatment goals than their younger counterparts, the incentive program may not be responsive to their individual needs and lead to unwanted outcomes. This dissertation describes the development and impact of the End Stage Renal Disease Quality Incentive Program

(ESRD QIP), a federally funded initiative to cost effectively improve delivery of patient care and patient health outcomes. An introductory first chapter chronicling the history of the ESRD program leading to its current status will be followed by the second chapter, which include the research questions and hypotheses. The third chapter is a systematic review, which synthesizes the available literature on the status of the ESRD QIP. Chapters 4 and 5 empirically examine longitudinal data of dialysis patients, facilities and neighborhood characteristics since the implementation of the ESRD QIP. Chapter 4 evaluates high and low scoring dialysis facilities, while Chapter 5 assesses patient health outcomes for ESRD QIP targeted and non-targeted measures. Chapter 6 discusses the principal findings and a critical discussion of the results. The dissertation will conclude with Chapter 7, which consists of the study significance, limitations and policy implications.

CHAPTER ONE

Introduction

As the first federally mandated pay-for-performance program, Medicare's End Stage Renal Disease Quality Incentive Program (ESRD QIP) heralded a new era of value-based programs paying providers for quality of care rather than quantity. Aiming to cost effectively improve quality of care for End Stage Renal Disease (ESRD) patients receiving outpatient dialysis treatments, ESRD QIP links a portion of payment to dialysis facilities based on dialysis patient outcomes.[1] Dialysis patients suffer from ESRD, an incurable chronic illness which results in permanent failure of the kidneys and requires hemodialysis, peritoneal dialysis or a transplant for survival.[2] The magnitude of this disease is reflected in the patient, caregiver and societal burden. Medicare, which is the primary insurer for the majority of ESRD patients, spends about $36 billion per year for ESRD patients. Even though these patients constitute less than 1% of the Medicare population, they account for 7.2% of the total Medicare spending and expenditures continue to significantly grow each year.[3] As a result of these mounting costs, Medicare has assumed an increasingly more pronounced position in fostering cost-effective quality ESRD care.

[1] Centers for Medicare & Medicaid Services (CMS), HHS, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers. Final Rule."
[2] National Institute of Diabetes and Digestive and Kidney Diseases, "United States Renal Data System. 2014 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[3] United States Renal Data System, "2016 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States," Chapter 11.

The main focus of the ESRD QIP is payment reform for outpatient hemodialysis facilities, which is the primary driver of cost for the ESRD population. To help minimize facility costs, the ESRD QIP was created and requires all dialysis facilities to participate.[4]

Under the ESRD QIP, Medicare payments to dialysis facilities can be reduced if a minimum performance score is not attained. The maximum payment reduction which the Centers for Medicare and Medicaid Services (CMS) can apply to any facility is two percent. The dialysis facility performance score is based on pre-established measures that aim to promote cost-effective quality care and improve ESRD population health by incentivizing providers to deliver care that meets or exceeds targeted measures.[5] However, the ESRD QIP does not give a bonus payment to facilities which achieve the targeted measures, but uses a financial penalty structure to potentially yield Medicare savings.[6]

Since the ESRD QIP's inception in 2012, computation of facility performance scores has become more complex as the number of quality measures continues to increase from the three original measures. As of 2020, dialysis facilities are evaluated by sixteen quality measures which CMS reports as most important to quality care and better patient outcomes.[7] Initially focused on laboratory measures, the ESRD QIP is gradually adding more patient centered domains such as pain assessment, depression screening and a survey about patient care experience at the dialysis facility.[8] While a wide-ranging set of measures can allow for a more comprehensive assessment of improvements in care, the increasing number of measures can be more burdensome for dialysis providers to report. The program's lack of parsimony and the provider's responsibility to improve

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[4] Damien et al., "Assessing Key Cost Drivers Associated with Caring for Chronic Kidney Disease Patients."
[5] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[6] Weiner and Watnick.
[7] Centers for Medicare & Medicaid Services, "Meaningful Measures Hub."
[8] Nissenson, "Improving Outcomes for ESRD Patients."

patient outcomes can make attributing specific provider behaviors to achieving sixteen different targeted measures a challenge.[9,10,11]

The ESRD QIP's sixteen targeted measures aim to improve health outcomes for the entire ESRD population. While ESRD patients share the same chronic disease, different age groups in the ESRD population experience the disease differently. Elderly patients (65 years and above) comprise the largest proportion of ESRD patients. Older ESRD patients are likely to be frail and have an increased number of comorbidities, which is correlated with poorer health outcomes. Compared to younger (less than 65 years old) ESRD patients, older ESRD patients experience a significant difference in health-related factors and ESRD prognosis.[12,13] While all ESRD patients endure a poorer health related quality of life compared to patients with other chronic illnesses, the elderly has a greater susceptibility to adverse outcomes.[14]

Over 80% of all dialysis facilities from the combined years of 2012 through 2020 have achieved the targeted measures that represent Medicare's quality care outcomes, and incurred no financial penalty.[15] However, discerning whether the program has been cost-effective and results in improved health across age groups remains unclear.[16,17] Focusing research on the clinical outcomes of the ageing ESRD population since the inception of the ESRD QIP program in 2012 is critical to better understanding the suitability and impact of the ESRD QIP measures. While the aim of the ESRD QIP is to cost-efficiently improve the health of ESRD patients receiving care in outpatient dialysis facilities, it may not be compatible with the singular needs of the elderly with ESRD. Healthcare interventions that are population based have been shown to increase health

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[9] Damberg, Sorbero, Lovejoy, Raaen, Mandel, "Measuring Success in Health Care Value-Based Purchasing Programs."
[10] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[11] Meyer et al., "More Quality Measures versus Measuring What Matters."
[12] Buckinx et al., "Burden of Frailty in the Elderly Population."
[13] Rosansky et al., "Treatment Decisions for Older Adults with Advanced Chronic Kidney Disease."
[14] Chen, Al Mawed, and Unruh, "Health-Related Quality of Life in End-Stage Renal Disease Patients."
[15] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[16] Wanchoo, Hazzan, and Fishbane, "Update on the End-Stage Renal Disease Quality Incentive Program."
[17] Saunders and Chin, "Variation in Dialysis Quality Measures by Facility, Neighborhood, and Region."

disparities of more vulnerable patients such as the elderly.[18] To examine whether a disparity exists, distinguishing the health outcomes between older adults and younger adults receiving care in dialysis facilities throughout the country will be important to evaluating the effectiveness of the ESRD QIP.

Therefore, the broad purpose of this dissertation is to critically examine the impact of the ESRD QIP and better understand the status of the quality of care for one of the most vulnerable subsets of the Medicare population. Greater understanding of dialysis patient's quality of care and health outcomes under the ESRD QIP can provide specific policy recommendations to improve dialysis patients' risk for disparate health outcomes. Cost-effectively improving dialysis patient health outcomes has been a long-standing problem for the ESRD Program, which is the national health insurance program for ESRD beneficiaries. Under the ESRD Program, the ESRD QIP is the most recent policy shift to address the dialysis facility cost problem. The historical evolution of the ESRD Program, along with various programmatic changes to address rising dialysis facility expenditures illuminates the events and conditions which gave rise to the ESRD QIP adoption. To better understand the current status of the incentive program, a historical component is a valuable tool to assist with insightful exploration of the policies crafted under the ESRD Program that had a similar aim as the ESRD QIP.[19]

Innovation of the Dialysis Machine

The cascade of events leading to the ESRD Program, previously identified as the Kidney Disease Entitlement, was preceded by considerable political activity and equally indispensable to the passage of this legislation was the medical development that made it possible. Heralding substantial changes in medical technology, the invention of the artificial human kidney machine

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[18] Frohlich and Potvin, "Transcending the Known in Public Health Practice."
[19] Stakenas and Mock, "Context Evaluation."

inaugurated a time when patients with acute kidney failure could live. The individual credited with inventing the dialysis machine is Willem Kolff, a young Dutch physician working in a rural hospital in the Netherlands. While treating war casualties during a 1938 German invasion, Kolff watched a youthful man slowly suffer and die from an accumulation of impurities polluting his blood. Powerless to treat the patient's failing kidneys, Kolff resolved to invent a mechanism that could replace the function of the kidneys and artificially remove waste products from the blood.[20]

Building an apparatus using materials from his home and the hospital at which he worked, in 1945 Kolff successfully resuscitated and restored to life the first kidney failure patient.[21] Soon after this success, Kolff sent his machines to medical institutions around the world, including the United States. Dissemination throughout the world fostered collaboration and spurred a universal endeavor from the medical profession to refine the dialysis machine for safer and long-term patient use.[22]

A technological advancement that improved Kolff's prototypical dialysis machine occurred during the unfolding of the Korean War to treat wartime casualties. Soldiers who sustained severe crush injuries had massive amounts of damaged tissue, which accumulated in the body as waste products, and resulted in kidney failure and lethal levels of potassium in the blood that threatened the heart.[23] An Army Medical Research and Development team, spurred by the need for innovation, explored the use of a newly developed dialyzer offering technical enhancements that improved upon effectiveness and safety; and allowed for easier assembly.[24] With continued success at saving soldiers' lives who would have otherwise died, the precedent for kidney dialysis use during military conflicts was established. The effectiveness of treating

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[20] Kolff, "First Clinical Experience with the Artificial Kidney."
[21] Elkinton, "Hemodialysis for Chronic Renal Failure."
[22] Kolff, "The Development of Renal Hemodialysis."
[23] Ing, Kjellstrand, and Rahman, *Dialysis: History, Development and Promise*.
[24] Edward A. Olson Company, *The Kolff-Brigham Artificial Kidney*.

soldiers with dialysis in the Korean War led to the establishment of an official military Renal Detachment supporting soldiers experiencing kidney failure during wartime efforts.[25]

Dialysis in the 1950s was a great technological achievement, and gradually evolved from an experimental therapy to an established protocol for kidney failure. The dialysis machines were able to restore the health of patients experiencing acute kidney failure, which is a rapid decline in kidney functioning. Kolff's dialyzer and all the subsequent prototypes developed during the 1950s treated patients with acute kidney failure, which developed over a few hours or days. The dialysis machines in existence during this time were ineffectual for the population of patients with ESRD, kidney failure that is long-term and irreversible, and requires repeated dialysis therapy.[26] These patients with ESRD need repeated courses of maintenance dialysis for the remainder of their lives to survive. Long-term dialysis therapy would have involved repeated access to the circulatory system, which causes irreparable damage to the arteries and veins, preventing future use of those vessels.[27] The demand for a technical advancement for ESRD patients was evident, and researchers were investigating methods that would enable maintenance dialysis for patients needing this life-long therapy.[28]

In 1960 a crucial technical solution was developed through the ingenuity of Belding Scribner and Wayne Quinton at the University of Washington. To enable multiple access to the circulatory system without damaging the veins or arteries, they created a curved Teflon tube, forming a shunt.[29] Prior to this invention, glass tubing was inserted into the vessel, which caused clotting, infection and permanent damage of the vessel. The Teflon shunt had a non-stick surface that prevented blood clotting and enabled repeated vascular access and subsequent long-term

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[25] Welch, "Deployment Dialysis in the U.S. Army."
[26] Kolff, "The Artificial Kidney-Past, Present, and Future."
[27] Scribner, "Medical Dilemmas."
[28] Konner, "History of Vascular Access for Haemodialysis."
[29] Konner.

dialysis.[30] This invention was first used at the University of Washington Hospital in the forearm of Clyde Shields. A middle-aged Boeing machinist dying from ESRD, Shields garnered national attention in March of 1960 after being the first person to receive a successful maintenance hemodialysis treatment. With a permanent vascular access surgically placed in his arm, this revolution in dialysis care allowed Shields to survive eleven more years.[31] For patients dying of ESRD, the invention brought the possibility of treatment to the untreatable, and the prospect of living became a reality.

Placement of Dialysis on the Legislative Agenda

In the early 1960s, attitudes and values forming within the political system of the United States about the life-saving therapy began to develop. Being a prohibitively costly treatment, dialysis was unaffordable to most ESRD patients. Private health insurance did not offer dialysis coverage, and for the few patients that could afford the cost, the high demand and low availability of machines was problematic.[32] In an attempt to remedy these problems, in 1962 Belding Scribner founded the Seattle Artificial Kidney Center. Scribner, an associate at the newly built University of Washington School of Medicine and inventor of the Teflon shunt, recognized the need for an outpatient center. With long-term maintenance dialysis now feasible, Scribner saw a critical need to establish an independent community-based outpatient dialysis center where maintenance dialysis could be provided.[33] Funding from the Hartford Foundation, one of the largest philanthropic medical research organizations during that time, and the Public Health Service (PHS) provided startup and initial operational costs for a limited number of patients. This support quickly dissipated, however, as successful treatment regimens allowed the patients to live longer than expected, utilizing more financial resources. The first twelve patients were covered by grants

[30] Lenzer, "Belding Scribner."
[31] Blagg, "The Early History of Dialysis for Chronic Renal Failure in the United States."
[32] Blagg.
[33] Blagg, "The Early Years of Chronic Dialysis."

and community support, then additional government subsidies and patient contributions were sought. Despite these efforts, patient selection became a more stringent process as the dialysis center's original resources were exhausted and supplementary financing was limited.[34]

Being the only outpatient dialysis center in the country at that time, the demand to receive treatment at the Seattle Artificial Kidney Center was great. At $15,000 per patient per year, unadjusted for inflation, the center was unable to cover medical personnel and dialysis equipment for all ESRD patients.[35] Thousands of people living throughout the country and dozens living near the center suffered from ESRD. However, only one in fifty were considered a viable candidate for dialysis.[36] While an overwhelmingly negative response to rationing dialysis was universal, limiting who received the life-saving treatment was a bleak but necessary practice. Absent increased funding for the production and entry of additional dialysis machines, the few dialysis centers that eventually followed the Seattle model were powerless to treat every patient in need. While the success of dialysis continued to garner attention in the medical community and across the nation, the number of facilities to treat ESRD patients was profoundly inadequate.[37]

News Coverage of Dialysis Rationing

With the advent of life-saving treatments and dialysis allocation limitations, news mediums began candidly exposing the stark realities and evocative stories of patients dying from ESRD. These narratives, along with enduring support from dialysis advocacy groups, brought attention to the public, Congress and state legislatures.[38] Pressure for government action and the ethical ramifications of inaction were highlighted in a 1962 *Life* magazine article depicting the rationing of dialysis at the Seattle Artificial Kidney Center. Being the sole outpatient dialysis

[34] Haviland, "Experiences in Establishing a Community Artificial Kidney Center."
[35] Alexander, "Medical Miracle and a Moral Burden of a Small Committee: They Decide Who Lives, Who Dies."
[36] Alexander.
[37] Rescher, "The Allocation of Exotic Medical Lifesaving Therapy."
[38] Rettig, "Special Treatment -- The Story of Medicare's ESRD Entitlement."

center in the country during that time, insufficient funding for maintenance dialysis provisions combined with the high demand of ESRD patients prevented treatment for all in need.[39] In response to the high demand and fiscal constraints, the article revealed that the Seattle center resorted to limiting access of dialysis treatment through a rationing system that was performed by a lay committee.[40]

Consisting of seven anonymous members: a minister, a housewife, a labor leader, a lawyer, a businessman and two physicians, the committee convened monthly. They selected the one or two ESRD patients for whom the clinic had an available machine, and those who were not chosen died.[41] A somber event, the rationing process transpired in a small library room of a nurse's residence hall in downtown Seattle, just a few hundred feet from the clinic. Not too long after the committee started meeting, their ethically problematic system of deciding who lives and who dies was exposed to the nation in *Life* magazine. An extensive article depicted the grim process of selecting ESRD patients who would live based on age, sex, marital status, number of dependents, income, emotional stability to endure treatment, educational background, income, net worth, occupation, past performance and future potential, and patient references. Narrowing the selection was based on a conjecture about the patient's potential burden or contribution to society. This included whether the patient had the will to endure a life on dialysis.[42]

The ethical ramifications in the *Life* magazine article of allocating limited resources was echoed a year later in a *Wall Street Journal* article. It underscored the moral implications and probed a provocative question which government officials and physicians were grappling "How much is a human life worth?"[43] This article reinforced the problematic nature of limiting life-

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[39] Alexander, "Medical Miracle and a Moral Burden of a Small Committee: They Decide Who Lives, Who Dies."
[40] Rettig, "Special Treatment -- The Story of Medicare's ESRD Entitlement."
[41] Jonsen, "The God Squad and the Origins of Transplantation Ethics and Policy Symposium Article."
[42] Alexander, "Medical Miracle and a Moral Burden of a Small Committee: They Decide Who Lives, Who Dies."
[43] Lawson, "Medical Irony."

saving treatment, and a strong impetus for the government to intervene. It brought attention to White House staff members, who contacted the Department of HEW to better understand the policy implications of providing treatment to all patients in need.[44] While inertia for sweeping reform to the healthcare system by initiating a costly government kidney program existed, pressure continued to incrementally mount. The *Wall Street Journal* article highlighted the magnitude of the problem describing that up to 10,000 ESRD patients were dying annually because funding for treatment was lacking.

Part of the incredulity of this, which the article emphasizes, and was subsequently a rationale for passing the ESRD Program, was that dying patients who were given treatments could return to work.[45] One justification for federally supporting this costly treatment was the anticipation that dialyzed patients would provide public contributions, and future potential benefits which dying ESRD patients could not.[46] By the mid-1960s less than 800 patients were receiving dialysis despite over 10,000 patients requiring the treatment. Limited clinic space and funding precluded many dying patients from receiving this life-saving therapy.[47] The economic and ethical value of maintaining the health of thousands of people was a strong motivation to initiate a government program for this population. However, still considered an experimental therapy, the life prolonging effects of a potentially lower quality of life and high expenditures stymied government action.[48] The inertia was met with widespread publicity through the media and advocacy groups about the ethical ramifications of such decisions, which gradually brought pressure on legislators to act.[49]

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[44] Blagg, "The Early History of Dialysis for Chronic Renal Failure in the United States."
[45] Lawson, "Medical Irony."
[46] Scribner, "Medical Dilemmas."
[47] Kolff, "The Development of Renal Hemodialysis."
[48] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[49] Blagg, "The Early History of Dialysis for Chronic Renal Failure in the United States."

Initial Funding of Dialysis

In 1963 the technological advances that offered life-saving dialysis treatment to ESRD patients first received government funding from the PHS for eligible veterans.[50] The Veterans Administration (VA) opened about thirty dialysis units in VA hospitals throughout the country for any person who served in the military and suffered from ESRD. The prohibitive cost of the program, however, quickly generated concern and an official examination by the Bureau of the Budget for financial implications of the VA's action.[51] Attempting to control increasing expenditures, the Bureau of the Budget recommended that the VA and the PHS shift outpatient hemodialysis to home hemodialysis to increase the number of patients being dialyzed at home.[52] Dialyzing at home became more accessible and was significantly less costly. Home hemodialysis was greatly encouraged by Kolff and Scribner, who strongly advocated for more funding to be given to home hemodialysis than an outpatient hemodialysis center. The outcome of their appeal for sponsorship was a five-year funding period to initiate and validate the efficacy of educating and instructing ESRD patients about home dialysis.[53]

Similar to the economic implications of home dialysis today which payment reforms have attempted to address, shifting outpatient dialysis treatment to the home has been promoted as a cost-reduction mechanism since the beginning.[54,55] In the 1960s the Kidney Disease Control Program, which was a division under the Department of HEW and established by the PHS to provide funding for outpatient dialysis facilities was concerned about the high costs of hemodialysis in an outpatient setting. To promote a more cost-efficient treatment option, the

[50] Social Security Administration Agency, "Social Security History."
[51] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[52] Blagg, "The Early History of Dialysis for Chronic Renal Failure in the United States."
[53] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[54] Rivara and Mehrotra, "The Changing Landscape of Home Dialysis in the United States."
[55] Klarman, Francis, and Rosenthal, "Cost Effectiveness Analysis Applied to the Treatment of Chronic Renal Disease."

Kidney Disease Control Program gave fourteen home dialysis grants.[56] The push by the Department of HEW for home dialysis is significant because it links to a larger trend that continues to plague policy makers today. While home dialysis has always been the less expensive therapy, the current system predominantly incentivizes dialysis care in outpatient dialysis centers.[57]

To better understand the cost-benefit approach of alternative kidney disease programs, in addition to program planning and implementation, in 1968, PHS commissioned the Department of HEW to provide analysis of the potential legislation outcomes and the cost of funding it. The report described the average life expectancy of a patient on dialysis was nine years after dialysis initiation, and within the first year 15% of the population would not survive. The average age of a dialysis patient at the initiation of dialysis was 45 years.[58] The cost-benefit program analysis was based on the assumption that the cohort of dialysis patients would continue earning all or some portion of an annual income of which a healthy individual of similar age and gender would receive. The report estimated that 70% of patients receiving dialysis treatments would return to full employment, and the remaining 30% would be able to earn half of the expected income compared to a person of similar age and gender.[59] In 1968 the value of per person cost for the nine additional life years which dialysis was predicted to provide was $38,000 for home dialysis and $104,000 for outpatient dialysis. The assumption of researchers and policy analysts was that the number of patients receiving treatment in the home and at a facility would be approximately equal.[60] With an approximate prediction of the program cost, the feasibility and prospect of passing an ESRD entitlement legislation was becoming more likely.

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[56] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[57] Rivara and Mehrotra, "The Changing Landscape of Home Dialysis in the United States."
[58] LeSourd, Fogel, and Johnston, *Benefit-Cost Analysis of Kidney Disease Programs*.
[59] LeSourd, Fogel, and Johnston.
[60] Klarman, Francis, and Rosenthal, "Cost Effectiveness Analysis Applied to the Treatment of Chronic Renal Disease."

National Healthcare and Dialysis

For some in Congress, the momentum for a federally funded ESRD program proved a political opportunity to push for national health insurance, a plan that had persisted throughout the decades. After Medicare and Medicaid legislation passed in 1965, under the Social Security Act amendments, a reinvigoration to promote national health insurance followed. Attaching a kidney disease entitlement to Medicare and Medicaid, which was viewed as a small-scale version of national health insurance, seemed morally justifiable, feasible and a natural progression towards national health insurance.[61] The political landscape of the 1972 Kidney Disease Entitlement was preceded by mounting considerations about expanding government's role in healthcare, and an increasing belief amongst Democratic members of Congress that a federally sponsored healthcare system should exist. National healthcare had been an agenda for Democratic Presidents dating back to Franklin D. Roosevelt. Under his New Deal, social welfare programs like the Social Security Act, which provides pensions for the elderly and compensation for the unemployed, was passed.[62] Roosevelt was the first President to consider federal health insurance and aimed to include it in the Social Security Act, but temporarily abandoned the idea for fear it would prevent passage of Social Security.[63]

Decades later President Johnson amended the Social Security Act in 1965 to establish a health insurance program for the elderly. President Johnson's strategically packaged healthcare agenda in addition to his landslide victory gave momentum and legitimacy to achieve his vision for healthcare reform. By skillfully negotiating with congressional members and suppressing the expansive program spending estimates of economists, Johnson was able to pass one of the most significant pieces of healthcare legislation in history.[64] Upon signing the Medicare legislation of

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[61] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[62] Morone, "Presidents And Health Reform."
[63] Updegrove, *Indomitable Will: LBJ in the Presidency*.
[64] Blumenthal and Morone, *The Heart of Power: Health and Politics in the Oval Office*.

1965 under the Social Security Act, President Johnson credits Franklin D. Roosevelt for laying the foundation for the federally funded insurance plan for the elderly.[65] With Medicare passed, national health insurance seemed a feasible next step and policy debate for this legislation subsequently became a focus.

In the fall of 1971, twenty-one hearings of national health insurance proposals were delivered. While Senator Russell Long, the chairman of the most powerful committee in the Senate, did not favor the national health insurance proposals, he was a strong proponent of catastrophic health insurance. Senator Long, amongst other congressional members, wanted to expand Medicare for those experiencing a major health crisis.[66] This redirected the focus onto ESRD patients and provided a policy context for extending healthcare coverage to the entire ESRD population. The debate about affording government sponsored healthcare to the ESRD population was a microcosm of the bigger debate amongst Congressional members about the responsibility of the federal government to ensure Americans received healthcare coverage.[67] The value of national healthcare has been reiterated during the course of multiple presidencies starting with Franklin D. Roosevelt. While comprehensive healthcare reform has not been successful, an institutional pattern was set into motion and has led to incremental changes that reinforced this idea.

After the passing of the Medicare legislation in 1965, a reinvigoration to enact national healthcare intensified among some Congressional members. The belief that national healthcare was morally justifiable because healthcare was a basic right, reinforced the idea of passing such legislation in the near future.[68] Attaching a Kidney Disease Entitlement to the Medicare legislation seemed a natural progression towards this goal. At the time, the Kidney Disease

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65 Johnson, "Remarks with President Truman at the Signing in Independence of the Medicare Bill."
66 Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
67 Rettig, "The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease."
68 Sade, "Health Care Reform."

Entitlement proposal was viewed as a small-scale version of national healthcare, which would allow complete healthcare coverage for a small population of chronically ill patients requiring dialysis to survive.[69] Preceding the 1972 Kidney Disease Entitlement, mounting considerations about expanding government's role in healthcare, and an increasing belief amongst Democratic members of Congress that a federally sponsored healthcare system should exist.

Congressional Action

For politicians, the issue of ESRD was appealing for voting as no Congress person wanted to deny a person life-saving treatment. In early 1972, Indiana Senator Vance Hartke, a strong proponent of the National Kidney Foundation's (NKF) legislative agenda of providing financial assistance to those suffering ESRD, introduced an amendment to expand coverage for patients needing dialysis. Members of NKF, the powerful advocacy group, were directly involved in composing this amendment.[70] While Hartke's legislation failed to advance, a large-scale policy change was imminent. He was given another opportunity on a Saturday morning in September when an omnibus bill known as House Representative 1 (H.R.1), which encompassed the Nixon Administration's welfare reform proposals and other programmatic modifications was being considered on the Senate floor.[71]

H.R. 1 contained numerous welfare reform amendments to the Social Security Act and Hartke was proposing to add kidney disease to the amendment. He asked the powerful Senator Long, chairman of the Senate Finance Committee and advocate of catastrophic health insurance, to be a co-sponsor. Senator Long quickly became supportive after hearing testimony about hardworking Americans suffering from kidney failure but unable to afford the prohibitive cost of treatment. While he believed this was compelling testimony for passage of a kidney disease

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[69] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[70] Rettig, "Valuing Lives: The Policy Debate on Patient Care Financing for Victims of End Stage Renal Disease."
[71] Ball, "Social Security Amendments of 1972: Summary and Legislative History."

amendment, it was also a small-scale example of the catastrophic illness coverage which he promoted. Senator Long believe a Kidney Disease Entitlement program would serve as a preliminary assessment of the financial implications of catastrophic illness coverage.[72]

The H.R. 1 bill sent to the Senate in September of 1972 contained a provision that expanded Medicare to younger adults (less than 65 years) with disabilities, which was necessary for adding a Kidney Disease Entitlement. Dialysis patients are considered disabled, and therefore Medicare could be extended to them under the proposed entitlement. Upon arriving in the Senate, Senator Hartke proposed to amend the bill by adding kidney disease. On that Saturday morning with only fifty-five Senators present, Hartke was given the floor to propose adding a kidney disease amendment to the comprehensive Medicare reform.[73] He identified individuals undergoing dialysis treatment or awaiting kidney transplant as disabled, and therefore eligible to receive Medicare benefits.[74] These individuals, who were no longer able to work because of kidney failure, would now qualify under Medicare's work history requirements. During his testimony, Senator Hartke emphasized that individuals with kidney failure were hardworking Americans who could no longer be productive members of society.[75] After providing rationales for his Kidney Disease Entitlement, discussion and debate within the Senate ensued. In less than one hour, the Senate voted fifty-two to three in favor of the Hartke amendment. The three dissenting votes were two Republican Senators and one Democratic Senator.[76]

With overwhelming support of the modification by the Senators present, their version of the bill was subsequently sent to conference. The next step was a conference committee with the House Ways and Means to reconcile the two bills. The Senate Finance and the House Ways and

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72 Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
73 "Congressional Record September 30, 1972."
74 Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
75 "Congressional Record September 30, 1972," 33004.
76 Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."

Means Committees met on October 17th and in one day agreed upon the conference committee report, which included the Kidney Disease Entitlement.[77] The only alteration to the Kidney Disease Entitlement was a reduction in the timeframe of the patient's application to Medicare. The House proposed to reduce that period from six months to three months, which is how the law presently exists. The Senate concurred, and the entitlement program allowing kidney failure patients universal healthcare was attached to Medicare and sent to the President.[78] After reaching the desk of President Richard Nixon on October 30th, H.R. 1 was signed into law one week prior to the 1972 presidential election in which Nixon defeated Senator George McGovern.[79] The 1972 Social Security Amendments were, at that time, the single longest piece of legislation ever signed into law.[80] Including the kidney disease provision, this historic piece of legislation provides universal healthcare for the ESRD patient population, and became the only government program to give full benefits for patients of any age suffering from a specific disease.[81]

The Aftermath

For advocates and critics during that time, the amendment was considered the beginning of legislation that would pass national health insurance. If complete healthcare coverage could be mandated for one patient population, then shifting universal coverage to all patient populations seemed within the realm of possibility.[82] Expectations for national health insurance to prevail amongst the public and Congress during this decade were substantial. This perspective was one aspect that helped catalyze the passage of the Kidney Disease Entitlement. The impetus for congressional action was also impacted by public outrage over rationing of dialysis from the 1960s, prohibitive costs beyond a patient's ability to pay and a significant miscalculation of the

[77] Rettig, "Valuing Lives: The Policy Debate on Patient Care Financing for Victims of End Stage Renal Disease."
[78] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[79] Rettig.
[80] Rettig.
[81] Knauf and Aronson, "ESRD as a Window into America's Cost Crisis in Health Care."
[82] Caplan, "Kidneys, Ethics, and Politics."

predicted costs to Medicare.[83] The original cost estimates given to Congress were quickly proven to be unrealistic, and in 1973 generated a very publicized controversy. Once accurate cost estimates were provided, containing these excessive outlays for ESRD patients seemed unfeasible.[84]

In 1973, the first year of the ESRD program implementation, 64% of patients dialyzed in facilities, while the remaining ESRD patients dialyzed at home. With encouragement from legislators and healthcare analysts to promote home hemodialysis, the number of home hemodialysis patients was expected to increase over time. Less than three years later, however, the population of ESRD patients dialyzing at home decreased to 16% and has continued to decrease since then.[85] Currently, 87% of incident ESRD patients begin renal replacement therapy with in-center hemodialysis.[86] The decrease in home dialysis use since 1973 has been associated with various factors. Historically, the majority of nephrologists fail to present to patients with home dialysis as a treatment option.[87] This has been related to a lack of nephrologist training with home dialysis as a treatment, which prevents patient education on home dialysis therapies. In addition, providers receive greater profits for patients receiving in-center hemodialysis than home dialysis.[88,89] Patient barriers to using home dialysis also have also contributed to the decrease in home dialysis use. These include an uncertainty about their ability to become skilled at self-administering the therapy, and anxiety about the lack of provider support in the home.[90,91]

[83] Rothman, *Beginnings Count: The Technological Imperative in American Health Care*.
[84] Rettig, "Implementing the End Stage Renal Disease Program of Medicare," 8.
[85] Evans, Blagg, and Bryan, "Implications for Health Care Policy."
[86] United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[87] Mehrotra et al., "Patient Education and Access of ESRD Patients to Renal Replacement Therapies beyond In-Center Hemodialysis."
[88] Abra and Schiller, "Public Policy and Programs – Missing Links in Growing Home Dialysis in the United States."
[89] Chan et al., "Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report."
[90] Walker, Howard, and Morton, "Home Hemodialysis."
[91] Walker et al., "A Discrete Choice Study of Patient Preferences for Dialysis Modalities."

Underuse of home dialysis, which includes home hemodialysis and peritoneal dialysis, and the overall increase of the ESRD population using dialysis are two forces that have persisted since the ESRD program's inception.

The unforeseen and grossly inaccurate estimates of the Kidney Disease Entitlement program provided by the National Kidney Foundation to Senator Hartke helped with passage of the amendment.[92] In addition, increasing pressure from kidney disease interest groups, the media, the medical community, some congressional members and public awareness of death panels created a crisis atmosphere. What followed was a policy punctuation that revolutionized the established way of thinking about healthcare – near universal healthcare coverage for one subset of the population.[93] Had an accurate cost estimate been provided to lawmakers, passage of the entitlement would have been more difficult. While these unintended consequences have contributed to the significant increase in Medicare dialysis program expenditures, the program successfully achieved its intended effect. For patients needing life-sustaining treatment, the ESRD program continues to provide access to care for hundreds of thousands of patients who would have otherwise died.[94]

Evolution of the ESRD Program

Program Growth

Cost projections for the ESRD program in the late 1960s provided by the Committee on Chronic Renal Disease created by the Bureau of the Budget were considerably lower than the actual costs which soon followed. The projections of the committee, along with other federally funded cost-benefit analyses, were established by using inaccurate estimates of ESRD survival

[92] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[93] Goertz, *International Norms and Decision Making*.
[94] Eggers, "Medicare's End Stage Renal Disease Program."

rates and wage earnings.[95,96] Prior to the ESRD program enactment in 1972, renal dialysis was administered to young adults without comorbidities. Initially, older ESRD patients and those with additional comorbidities, such as heart disease or diabetes, were not eligible for dialysis treatment because they were deemed medically inappropriate to endure the rigors of dialysis. Aside from kidney failure, the analysts made a key assumption that ESRD patients would be young and healthy, and therefore possess earning potential that would afford future contributions adding to the total output of the economy. However, the cost projections were highly inaccurate based on the different patient population demographics prior to versus after the legislation passing.[97] After the legislation passed, age-based criteria to receive dialysis treatment ceased to exist and any patient with ESRD regardless of comorbidities had the right to receive dialysis treatment covered by Medicare. This resulted in a significant increase in older ESRD patients receiving Medicare benefits that continues today, and a shift of the ESRD population demographics, including gender, race, age and employment status.[98,99]

A report of ESRD patient characteristics receiving dialysis prior to the legislation passing in 1967, and approximately five years after its implementation in 1978, demonstrates the considerable changes. These include: an increase in the share of dialysis patients who were female from 25% to 50% and an increase in African Americans from 7% to 35%. College and post-graduate dialysis patients decreased from 25% to 7.5% and, conversely, those with a junior high education or less increased from 10% to 29%. In addition, the employment status of dialysis patients decreased from 42% to 18%, the age distribution significantly shifted from 7% of

95 LeSourd, Fogel, and Johnston, *Benefit-Cost Analysis of Kidney Disease Programs*.
96 Garner and Dardis, "Cost-Effectiveness Analysis of End-Stage Renal Disease Treatments."
97 Levinsky, "The Organization of Medical Care: Lessons from the Medicare End Stage Renal Disease Program."
98 Rettig, "The Implications of Cost-Effectiveness Analysis of Medical Technology."
99 United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."

dialysis patients 55 years or older to 46% of dialysis patients 55 years or older.[100] During these eleven years, the demographics shifted and the overall number of ESRD patients significantly increased. The explanation of this change was associated with older patients and those with multiple comorbidities being accepted as dialysis patients.[101] The unintended effect was a significantly increased ESRD population who were sicker and older, which generated considerably higher costs than projected.

Once dialysis treatment was initiated, the analysts surmised, patients would return to earning all or some portion of an annual income which a healthy individual of the similar age and gender would receive. Patients were considered disabled to receive the Medicare benefits; however, they would not be eligible for Social Security disability benefits if they were engaging in some form of work or substantial gainful activity. While all individuals receiving dialysis or a kidney transplant enroll in Medicare through Social Security to receive healthcare benefits, only a small portion were predicted to use the Social Security Disability Insurance benefits.[102,103] The cost-effectiveness analysis was based on the number of patients presently suffering from ESRD, the per capita cost of each renal replacement therapy and data from operating dialysis centers. The report estimated that after two years 50% of ESRD patients would have a functioning kidney transplant, 10% would have a second functioning kidney transplant, 20% would be on dialysis and 20% would have died.[104]

These predictions were soon found to be grossly incorrect and the after-effect of the program's implementation became a forerunner of the unpredictable and continual burgeoning of the ESRD Program cost and population. Today most patients are treated with outpatient

[100] Evans, Blagg, and Bryan, "Implications for Health Care Policy."
[101] Levinsky, "The Organization of Medical Care: Lessons from the Medicare End Stage Renal Disease Program."
[102] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[103] Ball, "Social Security Amendments of 1972: Summary and Legislative History."
[104] LeSourd, Fogel, and Johnston, *Benefit-Cost Analysis of Kidney Disease Programs*.

hemodialysis and the majority of dialysis patients do not maintain employment.[105] Employment status was important to budget analysts because ESRD patients' participation in the labor force and earnings were considered societal contributions that would offset the overall societal cost of the ESRD program. While ESRD patients continuing employment would not reduce Medicare's direct expenditures, when calculating the overall program costs to society, budget analysts assumed the cost per life-year gained would be minimized by rehabilitated ESRD patients returning to work.[106]

Another challenge which the report did not consider was the number of ESRD patients using outpatient hemodialysis, which has more restrictive treatment times, versus the number of patients choosing home hemodialysis. The analyses prior to the ESRD program passing recognized patients using outpatient hemodialysis would have less physical stamina to endure daily employment, and that dialysis centers' restrictive treatment times hindered ESRD patients from regular employment.[107] However, the assumption of researchers and policy analysts was that the number of patients choosing home hemodialysis, which allows flexible treatment times, and outpatient dialysis would be approximately equal. With home hemodialysis being significantly less costly, analysts believed the number of patients dialyzing at home would offset the costs of the number of patients dialyzing in-center.[108]

Since the implementation of the program in 1973, the average kidney failure patient's life expectancy and the overall population size has significantly increased.[109] The ESRD Program represents the onus and benefits of technological advancements: prohibitive costs for life-saving

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105 Hirth et al., "Chronic Illness, Treatment Choice and Workforce Participation."
106 Garner and Dardis, "Cost-Effectiveness Analysis of End-Stage Renal Disease Treatments."
107 Klarman, Francis, and Rosenthal, "Cost Effectiveness Analysis Applied to the Treatment of Chronic Renal Disease."
108 Rettig, "Special Treatment — The Story of Medicare's ESRD Entitlement."
109 Mozes, Shabtai, and Zucker, "Differences in Quality of Life among Patients Receiving Dialysis Replacement Therapy at Seven Medical Centers."

treatment to a small number of people.[110] On a patient and societal level, a significant problem of treating ESRD is the cost. In 2017, the annual Medicare cost for a patient with kidney failure receiving in-center hemodialysis is $84,550 and peritoneal dialysis, which is done in the home, is $69,919. While these costs are commensurate with patients suffering from chronic illnesses with a comparable severity level, the difference is that Medicare bears the bulk of charges for ESRD patients.[111] For those suffering comparable chronic illnesses to ESRD, expenses are borne by the Veterans Administration, state Medicaid, state kidney programs or private insurance.[112,113] ESRD Program costs since the inception of the program have significantly risen and approaches to control ballooning Medicare expenditures without compromising patient quality have been evaluated. Various payment models throughout the decades have offered different strategies to providing cost-effective and quality care.

In the decades to follow, the ESRD population continued to increase. By 1991, the population of ESRD patients increased to 118,000, and nearly doubled again to 222,000 in 2000.[114] The sustained increase is predominantly associated with an increased survival rate and an increased rate of individuals suffering from the conditions that often result in ESRD.[115,116] The ESRD population size and program expenditures were unexpectedly high from the beginning, and the rate of increase for both continues to escalate. What started as a federal health insurance

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[110] Rettig, "Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972."
[111] United States Renal Data System, "2017 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[112] Trivedi, "Overview of Health Care Financing - Special Subjects."
[113] Rettig and Levinsky, "Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program."
[114] United States Government Accountability Office, "Problems Remain in Ensuring Compliance with Medicare Quality Standards: Dialysis Facility Compliance."
[115] United States Renal Data System, "2017 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[116] United States Government Accountability Office, "Problems Remain in Ensuring Compliance with Medicare Quality Standards: Dialysis Facility Compliance."

program costing a few hundred million dollars, has risen to over $36 billion in current dollars.[117] While prices in 2020 are about 515% higher than the average price in 1972, making a few hundred million dollars in 1972 equivalent to a few billion dollars today, the increase in expenditures has been considerable.[118] See Figure 1. This rapid growth in cost is largely associated with the increase in ESRD patients from 10,000 in 1972 to about 760,000 today.[119]

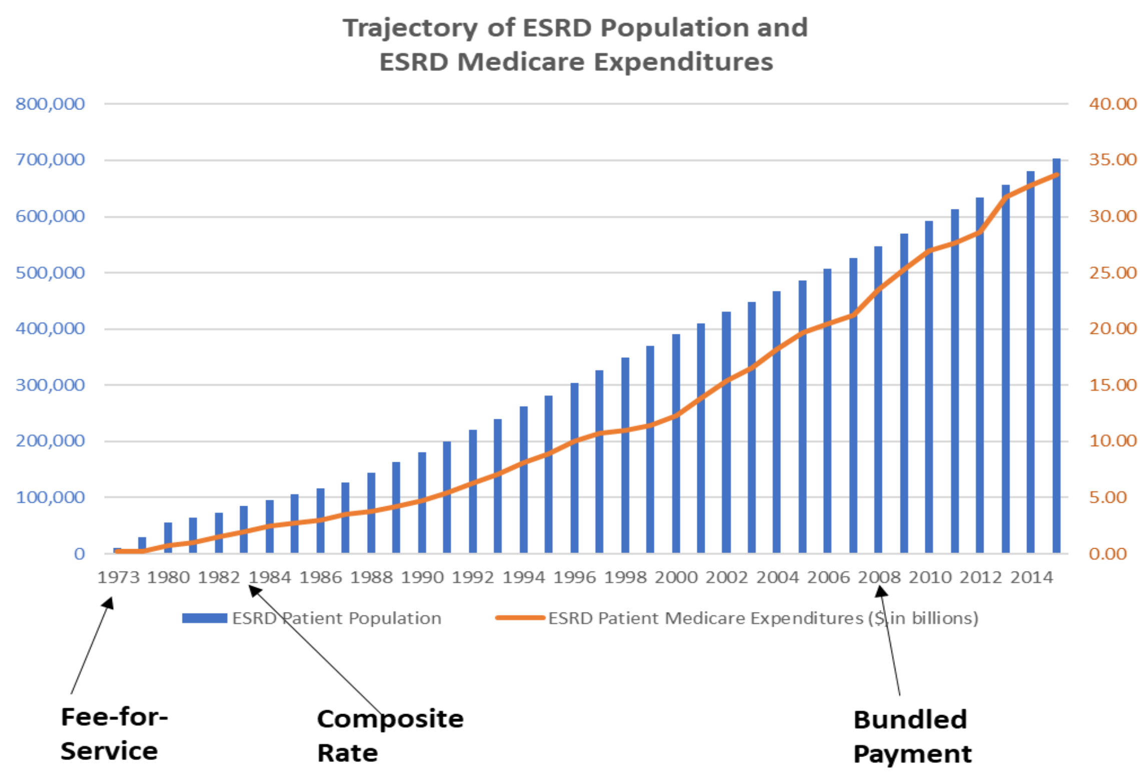

Figure 1. Trajectory of ESRD Population and Expenditures
Data Source: United States Renal Data System

[117] United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[118] Alioth LLC, "Inflation Calculator."
[119] United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."

Far exceeding initial cost projections, the ESRD program over the decades has persistently increased in expenditures. The unintended consequence that followed from the ESRD program legislation passage was precipitously increased the growth rate in the ESRD population using dialysis from accepting older and sicker patients; and subsequently a substantially more expensive ESRD program than estimated. Since the program's inception, the challenge of providing cost-effective quality care to a growing number of ESRD patients has been addressed by the implementation of various payment strategies aimed to incentivize dialysis healthcare providers and facilities to cut costs.

Payment Models

1973 Fee-for-Service Payment System

The payment model first used to reimburse healthcare providers for the costs of ESRD patient care was the fee-for-service model already being used in the traditional Medicare program covering the elderly. It employed a reasonable-charge basis for home and outpatient dialysis, which were provisions of reasonable charges established by the customary fee for a dialysis service in that geographic area and were decided by the insurance companies that managed Medicare claims.[120] To maximize profits by increasing the number of patients receiving dialysis treatment, providers and investors shifted dialysis care from the hospital to the outpatient setting, which was less expensive. However, over time, the fee-for-service model that paid dialysis providers for each dialysis related procedure in the outpatient setting created challenges to curbing costs. The fee-for-service model incentivized providers to increase billable dialysis services, which generated larger provider profits and Medicare expenses. As a result of the fee-for-service reasonable charge basis, a lack of cost containment existed.[121]

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[120] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."
[121] Taylor, "A Brief History on the Road to Healthcare Reform: From Truman to Obama."

In 1974, the average per person cost for ESRD was $16,487, which far surpassed the average per person cost for all other Medicare beneficiaries, which was $529.[122] The concern about the overall Medicare spending and the mounting ESRD program costs continued to intensify. After the first year of Medicare's ESRD program implementation, the cost was at an unprecedented $242 million, and as subsequent years passed, it continued to steeply rise. Five years later, in 1979, the costs escalated to over $1 billion.[123] While 24% of the total cost was attributable to per patient costs, 76% was attributable to the rise in the number of ESRD beneficiaries. In 1974 Medicare enrolled 16,000 ESRD beneficiaries, and by 1981 this number multiplied four-fold to 64,100.[124] The underuse of home hemodialysis, a less costly modality; the unprecedented and rapidly increasing number of ESRD patients; and an ESRD patient population that was older and in worse overall health than expected all contributed to the unintended and drastically increased costs during the program's first decade.

While overall program costs began to soar during the first five years of the program, the per patient cost adjusted by the medical Consumer Price Index decreased. This demonstrated increased productivity accompanied by cost containment that exceeded that of the medical community. By capping the fee-for-service for ESRD services at $138 per patient per treatment, Medicare was successful in containing per patient costs.[125] Even though ESRD per capita costs were contained, the overall program costs far outweighed the burden of the ESRD program on Medicare. With escalating healthcare expenditures and stagflation depressing the economy during this time, President Carter was prompted to focus on cost containment for Medicare and Medicaid. The Health Care Financing Administration, which was later named the Centers for Medicare and Medicaid Services, was established to administer the Medicare and Medicaid

[122] Gornick et al., "Thirty Years of Medicare."
[123] Evans, Blagg, and Bryan, "Implications for Health Care Policy."
[124] Eggers, "Trends in Medicare Reimbursement for End-Stage Renal Disease."
[125] Lowrie and Hampers, "The Success of Medicare's End-Stage Renal-Disease Program."

programs. By the end of the decade, the primary objective of the Health Care Financing Administration was to cut costs.[126,127] The dramatic increases in the ESRD program costs by the end of the decade, along with overall Medicare outlay increases, prompted a new strategy for Medicare and resulted in the next ESRD Program policy shift.

1981 Composite Rate Prospective Payment System

The dramatic increase in the ESRD program expenditures by the end of the 1970s was an exogenous pressure that brought about political attention to Medicare necessitating new policy solutions.[128] The 1981 Omnibus Budget Reconciliation Act (OBRA) ended the fee-for-service reasonable-charge basis payment approach that started in 1973.[129] The new ESRD payment model was a composite rate prospective payment system that paid a fixed amount for outpatient hemodialysis. To promote home hemodialysis, OBRA established fixed outpatient dialysis reimbursement rates by combining outpatient and home hemodialysis rates. One rate applied to outpatient hemodialysis and home hemodialysis, which was intended to incentivize dialysis facilities, who also managed home hemodialysis, to provide more home hemodialysis care.[130] Contrary to the assumption that home hemodialysis would increase to offset the costlier outpatient dialysis, an insignificant increase in home hemodialysis ensued.[131]

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[126] Midgley and Livermore, *The Handbook of Social Policy*.
[127] Bryan, "The Great Inflation."
[128] Boushey, "Punctuated Equilibrium Theory and the Diffusion of Innovationspsj_437 1."
[129] Rettig and Levinsky, "Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program."
[130] Eggers, "Trends in Medicare Reimbursement for End-Stage Renal Disease."
[131] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."

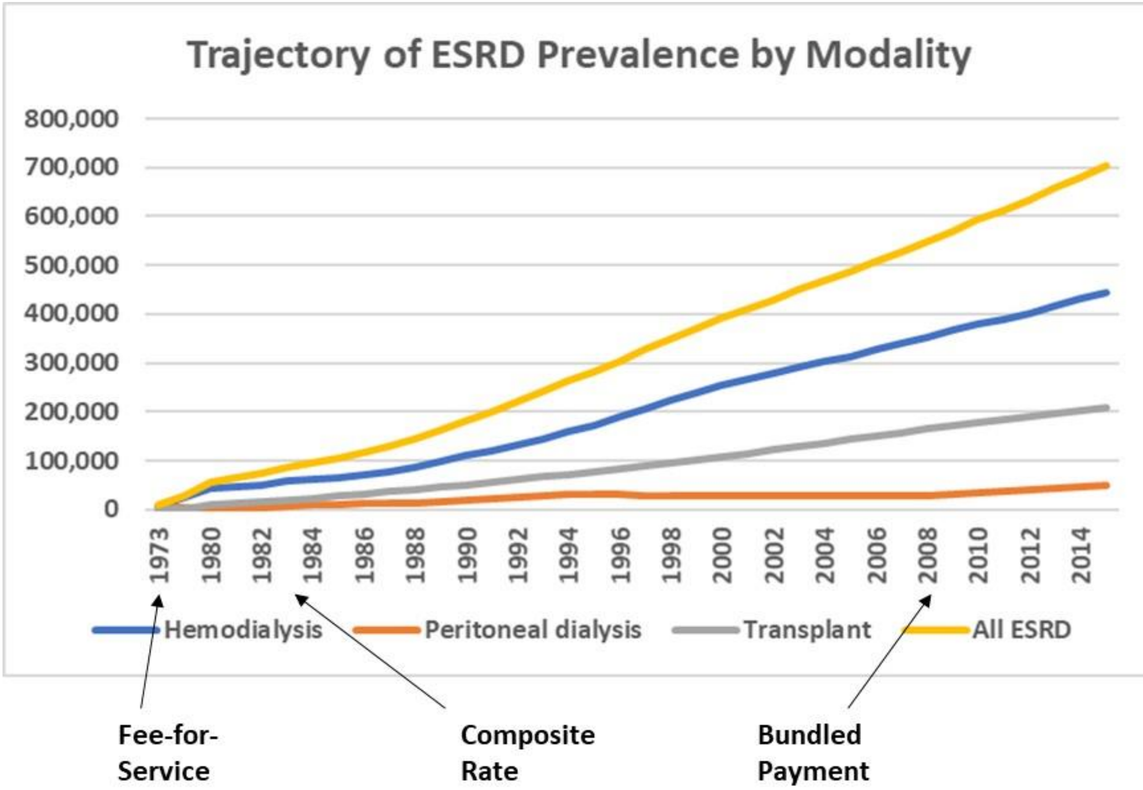

Figure 2. Trajectory of Type of Renal Replacement Therapy
Data Source: United States Renal Data System

While efforts to decrease costs by incentivizing home dialysis were not successful, provisions that curbed costs through other approaches did occur. The composite rate for dialysis established in OBRA's 1981 legislation and implemented in 1983 remained constant throughout the decade. Unlike all other aspects of Medicare, the ESRD program was not adjusted for inflation.[132] When the ESRD program was established, an inflation indexing component was never created and Congress afforded little direction about reimbursement. After the legislation passed, the initial objective was to promote swift building and expansion of dialysis facilities, and to incentivize providers to initiate services. The payment rate first established was high to foster

[132] Himmelfarb et al., "Cost, Quality, and Value."

development of new dialysis facilities. Without the benefit of market pricing because a private market did not exist, Medicare determined less than a decade later that the dialysis payment scale was set high. By the late 1970s and into the 1980s, Medicare administrators subsequently reduced the reimbursement rates.[133,134]

Over the years, this cost control mechanism gradually reduced reimbursements to providers. By 1989 reimbursements to dialysis providers were about 65% of 1983 levels, adjusting for inflation.[135] Compared to the initial ten years of the program, the composite rate in effect for over two decades reduced reimbursements to hospitals and dialysis centers, lowering per capita costs. As dialysis services were bundled into one composite rate, outpatient centers became significantly overextended in their ability to continue providing the same level of care with fewer funds. To accommodate this change, cost shift was necessary for the financial survival of dialysis centers.[136] Dialysis providers began to spend less and increase compensation through other means. One strategy of cost shifting was acquiring payments through employer-sponsored insurance plans, which was a provision included in OBRA.[137]

Medicare Secondary Payer Provision

Previous to OBRA, Medicare was the primary payer to dialysis facilities. After OBRA Medicare became a secondary payer if a patient had private insurance. The Medicare Secondary Payer provision, building economies of scale and decreasing dialysis facility input costs were three approaches that evolved after OBRA passed and throughout the 1980s were significantly expanded.[138] First, employer-sponsored insurance payers for those ESRD patients with private

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[133] Iglehart, "The American Health Care System."
[134] Rettig and Levinsky, "Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program."
[135] Himmelfarb et al., "Cost, Quality, and Value."
[136] Nissenson and Rettig, "Medicare's End-Stage Renal Disease Program."
[137] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."
[138] Eggers, "Medicare's End Stage Renal Disease Program."

insurance allowed more reimbursement to the dialysis facility than Medicare. This was an overall program cost reduction method for Medicare that followed from the Secondary Payer provision, and a means for dialysis facilities to increase compensation. The Secondary Payer provision required an ESRD patient's private insurance to be fully responsible for the payment of ESRD treatment and care for the first year prior to receiving Medicare. The length of time dialysis providers could charge private insurers was subsequently raised in 1997 to 30 months.[139]

Using Medicare as a secondary payer applies to approximately 15% of ESRD patients who have private insurance plans upon initiation of dialysis. Individuals with private insurance are charged by dialysis providers a significantly greater amount for a similar service than Medicare.[1] From an economic standpoint, supplanting lower Medicare reimbursements during initial treatment with higher private insurance reimbursement was essential for the continued existence of many outpatient dialysis centers, which charged private insurers about two to three times more than Medicare.[140] With private insurers reimbursing at higher rates than Medicare, selectively choosing profitable patients over Medicare patients is a concern. Dialysis payment policies do not contain regulatory mechanisms to prevent providers from recruiting privately insured patients. While providers report patients are not selected based on insurance status, the remunerations of private insurance payers have helped to sustain the ESRD program and facilitated the development of profitable dialysis businesses.[141] For-profit providers increased compensation using the Medicare Secondary Payer regulation, which helped counteract Medicare's cyclical per person reimbursement reduction.

[139] Eggers.
[140] Iglehart, "The American Health Care System."
[141] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."

Dialysis Industry Growth and Consolidation

A second result associated with offsetting Medicare's decreased per person reimbursement was accomplished more gradually. During the 1980s, growth in large sized for-profit chain outpatient dialysis centers occurred to take advantage of economies of scale. This included an increase in the number of dialysis centers, the number of dialysis machines in each center and the number of patients being dialyzed each day.[142] About 675 new dialysis facilities were constructed from 1980 to 1988 to accommodate the growing population of ESRD patients. Of those newly built facilities, 84% were larger for-profit centers.[143] While the predominant outpatient dialysis centers in 1980 were small in size and not-for-profit, by the end of the decade medium size for-profit facilities were the biggest dialysis provider category.

Another dynamic which led to the increase in number of larger dialysis centers was the time of day which a patient could receive treatment. When dialysis centers opened in the early 1970s, patients received treatments throughout a 24-hour period, which enabled more shifts to treat patients. As dialysis treatments shifted in the late 1970s from hospital-based to outpatient center-based, 24-hour dialyzing decreased dramatically as outpatient centers were inherently daytime operations. With night shift dialysis treatments no longer available, more facilities with a greater number of machines per facility were necessary to adjust for the decreased number of daily treatments shifts and an ever growing ESRD population.[144]

Per patient reimbursement has consistently declined over the decades, requiring a reduction in dialysis center operating costs for centers to subsist. The unanticipated effect was the consolidation of dialysis providers. Big chain dialysis corporations became prominent because

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[142] Rettig and Levinsky, "Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program."
[143] Iglehart, "The American Health Care System."
[144] Rettig and Levinsky, "Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program."

they were able to provide dialysis services at lower costs, while still ensuring profitability.[145] When the ESRD program was first instituted, non-profit facilities provided most dialysis care. However, a market of for-profit large volume clinics that provided hemodialysis swiftly gained momentum. Incentivized partly by the initial fee-for service model, filling dialysis clinics to maximum volume was a goal of for-profit facilities.[146] The non-price competitive dialysis market with Medicare as the predominant buyer created a consolidation of dialysis services that gradually developed in the first two decades of the program. By the 1990s the results were an acceleration toward building big chain companies.[147]

By the next decade, two large dialysis organizations, Fresenius Medical Care and DaVita Healthcare Partners, Inc., began to dominate the industry. Today these two companies continue to grow and currently account for about two-thirds of all dialysis facilities. The number of small non-profit dialysis companies, on the contrary, has demonstrated little to no increase.[148] Neither large nor small size dialysis facilities can apply market power and raise rates to improve profits because of the fixed Medicare reimbursement rate. However, large chain companies are advantaged by economies of scale, which affords a reduction in average overall costs per person.[149] For healthcare providers at large chain organizations with high patient volume dialysis centers, outpatient hemodialysis is a profitable industry. This profitability has stimulated policymaker opposition to maintaining or increasing per patient dialysis reimbursement rates. The declining reimbursement policy has contributed to pushing small dialysis centers into selling their

[145] Erickson et al., "Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition."
[146] Rettig and Levinsky, "Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program."
[147] Ozgen, "Does Chain Affiliation Make a Difference in Efficiency of Dialysis Providers in the USA."
[148] United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[149] Ozgen, "Does Chain Affiliation Make a Difference in Efficiency of Dialysis Providers in the USA."

companies to large chained corporations. The large chained centers overshadowed smaller centers, which could not take advantage of economies of scale.[150]

Reducing Input Costs and Making Profits

A third outcome which unfolded in response to offsetting the per patient reimbursement rate reduction was decreasing input costs. To ensure profit-making in an environment of inadequate reimbursements, outpatient dialysis centers were driven to reduce operating costs by reusing dialyzers, which posed risks for infection; decreasing the time a patient was dialyzed so more patients could be dialyzed each day; replacing nurses with technicians; increasing the number of patients each technician treated; and decreasing dietary and counseling services.[151] The reuse of dialyzers, which are the devices that remove toxins from the blood pose short and long-term risks. Reusing a dialyzer from one patient to the next and not properly cleaning it causes an immediate infection risk. In addition, the disinfectant agent and highly toxic systemic poison, formaldehyde, posed harm to patients over the long-term because of repeated exposure.[152]

To reduce costs, dialysis centers decreased the number of hours a patient was dialyzed to allow more patient treatments per day. However, this was associated with patient health risks and undermined quality care. Longer treatments offer more adequate removal of blood toxins but allowing more treatments per day offered dialysis facilities maximum profitability. The incentive for providers to maximize the treatments at the facility every day, conversely disincentivized a recommendation for home dialysis. Although home dialysis is less costly in the long term, for-profit dialysis centers aim to fill already owned dialyzers to maximize the number of treatments the facility can offer as opposed to providing new equipment for patients to initiate home

[150] Nissenson and Rettig, "Medicare's End-Stage Renal Disease Program."
[151] Rettig and Levinsky, "Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program."
[152] Iglehart, "The American Health Care System."

dialysis.[153] These conditions posed risks to patient safety and quality of care, however facilities continued to employ these practices to offset the composite rate reduction. Decreasing input costs, acquiring payments through employer-sponsored insurance plans and the growth in large sized for-profit outpatient dialysis centers were three significant adjustments that providers employed to ensure dialysis center profitability; and were the sequelae of OBRA's composite rate reduction.

Per patient per year expenditures for all ESRD patients during this time, adjusted for medical care inflation, declined about 3% each year. Expenditures for non-ESRD Medicare beneficiaries, in contrast, increased about 3.5% each year.[154] Even with per patient costs decreasing, however, overall program outlays were significantly increasing. By the end of the decade, in 1990, expenditures for ESRD Medicare beneficiaries were about $5 billion and over the next decade increased to over $15 billion.[155] During the early 1990s the increase in overall ESRD program spending was driven by two factors. First, the continued expansion of the ESRD patient population occurred because older beneficiaries with chronic comorbidities were being placed on dialysis. Older sicker ESRD patients with comorbidities are medically complex and incur higher costs to Medicare because they require more medical attention including multiple medications, and frequent hospitalizations. The second factor which increased ESRD program spending was the introduction of supplemental coverage for a new medication to treat anemia, a common complication of ESRD.[156] Initially, Medicare paid for this new medication, an erythropoietin stimulating agent (ESA), using a capitated approach that was supplemental to the capitated payment model for dialysis services. With dialysis facilities receiving a flat rate of

[153] Hodge, "Let's Get Rid of the Dialysis Death Incentive."
[154] United States Renal Data System, "1994 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[155] United States Government Accountability Office, "Problems Remain in Ensuring Compliance with Medicare Quality Standards: Dialysis Facility Compliance."
[156] United States Government Accountability Office.

reimbursement for any dose between 1 and 10,000 units, providers were incentivized to give patients lower doses so the medication could be used amongst more patients.[2] To correct the problem of patients being under dosed, an incremental payment strategy change occurred to improve efficiency. The change occurred at a marginal level without disrupting the fundamental structure of the ESRD payment model.[3] Leaving in place the original capitated payment model for dialysis services, in 1991 the capitated payment approach for ESAs shifted, and a fee-for-service for ESAs was implemented.[157]

With a fee-for-service approach, the more units of ESA per patient per week used, a greater amount in per patient reimbursement was given by Medicare to the facility. The payment approach swiftly increased the program costs and time spent on patient care. This approach incentivized providers to order more ESAs and provide unnecessary higher doses to patients.[158] In addition, the company which created and sold the drug provided discounts to large dialysis centers ordering larger quantities of the drug. With the continued decrease in the real value reimbursement rate for per patient dialysis, providers were even more incentivized to prescribe additional units of ESAs.[159] Additionally problematic was the evidence indicating an association between an increased risk for mortality and a higher than recommended dosing of ESAs among ESRD patients with anemia.[160]

By 1994, payment for an average dialysis treatment session was approximately $130, which was a 60% decrease in real dollars from the initial 1974 program payment of $138. Monthly capitation payments to ESRD physicians for an ESRD patient's routine care was

[157] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."
[158] Kleinke, "Re-Naming And Re-Gaming."
[159] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."
[160] Brookhart et al., "Comparative Mortality Risk of Anemia Management Practices in Incident Hemodialysis Patients."

additionally maintained below inflation.[161] With a reduced composite rate, dialysis providers looked to generate revenue through billing Medicare for excessive amounts of ESAs, which was reimbursed through a fee-for-service system. Becoming the single biggest medication expenditure for the entire Medicare program by 2005, ESA outlays for ESRD patients on dialysis were estimated to be over $2 billion.[162] This unintended, exogenous stimulus redirected political attention on a new aspect of problems in the ESRD program.[163]

2008 Bundled Payment System

The development of new medications, specifically the ESAs, which are the standard of care for ESRD patients on dialysis, required a separate category for dialysis care claims. Since these new drugs were not in existence when the composite rate was established in 1981, they were separately added to dialysis services on a fee-for-service basis. As new drugs developed, new billable categories, separate from the composite rate, were added.[164] Concerned about the excessive fees for separately billable drugs, particularly ESAs, Medicare created a bundled payment that includes almost all dialysis services, supplies and medications.[165] This policy shift occurred in 2008 under the Medicare Improvements for Patients and Providers Act (MIPPA), which allowed four years to shift payments for ESRD services to a bundled payment system.[166]

MIPPA was a complex piece of legislation that also contained the ESRD Prospective Payment System (PPS) and the Quality Incentive Program (QIP) to promote cost-effective quality care in outpatient dialysis facilities.[167] These ESRD provisions became the most significant

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[161] Gornick et al., "Thirty Years of Medicare."
[162] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."
[163] Boushey, "Punctuated Equilibrium Theory and the Diffusion of Innovationspsj_437 1."
[164] Collins, "From the Field: Composite vs Bundle Confusion."
[165] Charytan, "Bundled-Rate Legislation for Medicare Reimbursement for Dialysis Services."
[166] Centers for Medicare & Medicaid Services, "Roadmap for Implementing Value Driven Healthcare in the Traditional Medicare Fee-for-Service Program."
[167] Centers for Medicare & Medicaid Services, "CMS Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System (CMS 1651-F)."

changes to the dialysis payment system since 1983, when the fixed composite rate payment system was first implemented.[168] Specifically, disease education and awareness; dialysis facility quality incentives; and dialysis treatment and services are now covered under the new bundled payment system.[169]

ESRD Prospective Payment System

The bundled payment system, established under MIPPA's Prospective Payment System (PPS), consolidates all dialysis services such as drugs, laboratory tests and maintenance dialysis that occurs during one episode of care.[170] The bundled payment items and services covered under Medicare Part B at that time included: dialysis treatment and routine services, such as equipment, nursing and laboratory tests; injectable medications; oral drugs that have injectable equivalents; and oral-only ESRD medications.[171] Updates every few years to the PPS, including adjusting quality measures continue to occur. The shift to value-based care from the fee-for-service system began an ongoing process of incremental modifications that are continually adjusting to changes in clinical research of health outcomes.[172]

The bundled payment system aims to incentivize healthcare providers in dialysis facilities to deliver cost-efficient care that reduces unnecessary expenditures, especially with the use of ESAs. By increasing levels of hemoglobin, ESAs correct anemia which affects almost all ESRD patients. Prior to the bundled service, injectable medications like ESAs were billed separately. Dialysis facilities compensated for the decreasing composite rate reimbursements over the years by increasing the administration of these separately billed injectable medications.[4] However,

[168] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."
[169] 110th Congress, Medicare Improvements for Patients and Providers Act, Sections 152 and 153.
[170] 110th Congress, Medicare Improvements for Patients and Providers Act.
[171] Centers for Medicare & Medicaid Services, "CMS Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System (CMS 1651-F)."
[172] Centers for Medicare & Medicaid Services (CMS), HHS, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers. Final Rule."

using ESAs more frequently were found to be correlated with adverse health outcomes, and higher levels of hemoglobin from ESA therapy were more dangerous than a lower target level. Patients with higher levels of hemoglobin from ESAs were found to have an increased risk of cardiovascular complications and mortality.[173] Based on clinical data, the United States Food and Drug Administration issued a African American box warning for ESAs to caution about the potential for serious adverse health events.[174] In addition to the African American box warning, the bundled payment subsequently helped to address the overuse of ESAs.

With ESAs included in the bundled payment and the dosing recommendation lowered, providers became incentivized to reduce ESA use. Equally problematic as the overuse of ESAs, the underuse of ESAs can lead to acute episodes of anemia requiring blood transfusions and hospital level care. However, the dialysis facility is not financially responsible for correcting an acute episode of anemia requiring a hospitalization.[175] Examining trends in ESA dosing, intravenous iron use and hemoglobin levels before and after the policy that added ESAs to the bundled payment, analysts found an abrupt decrease in the use of ESAs, and a decrease in hemoglobin levels. Hemoglobin levels are associated with anemia and underdosing of ESAs. In addition, an increase in intravenous iron was noted, which can help treat anemia. This medication is less expensive than ESAs and is covered by Medicare.[176] With the advent of the bundled payment system, providers became incentivized to under prescribe ESAs, and were not penalized if the patient required a hospitalization as a result.

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[173] Foley, Curtis, and Parfrey, "Erythropoietin Therapy, Hemoglobin Targets, and Quality of Life in Healthy Hemodialysis Patients."
[174] Singh, "The Controversy Surrounding Hemoglobin and Erythropoiesis-Stimulating Agents."
[175] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."
[176] Fuller et al., "International Comparisons to Assess Effects of Payment and Regulatory Changes in the United States on Anemia Practice in Patients on Hemodialysis."

Medicare predicted that with a bundled payment less services and medications, specifically ESAs, would be used. Therefore, after the bundled payment was established, Medicare decreased it by 2% to adjust for these efficiencies.[177] Conversely, with more services and drugs covered under the bundled payment at a reduced rate, dialysis facility providers were further incentivized to cut costs by underproviding medications, especially ESAs.[178] A study examining the effects of the PPS on ESA and blood transfusion use found that the mean ESA dose per patient per month administered at each dialysis facility decreased and was correlated with an increase in blood transfusions, which are covered by Medicare. Requiring a hospital visit, blood transfusions for ESRD patients rose from 14 % in 2009 to 26 % in 2011.[179] The result of under prescribing ESAs, and the subsequent increase in hospitalizations are associated with poor clinical outcomes and increased Medicare costs.

ESRD Quality Incentive Program

Anticipating the potential problem created by the bundled payment system under which dialysis providers are incentivized to reduce costs by underproviding treatments, MIPPA established the ESRD Quality Incentive Program (QIP) for providers of ESRD services, to incentivize dialysis facilities to provide better quality care to patients.[180] Implemented in 2012, the ESRD QIP builds on previous attempts to cost-effectively improve dialysis care and deter dialysis facilities from withholding medications and services to maximize profits under the bundled payment system.[181] Reducing payments to facilities that do not achieve specific clinical standards, the ESRD QIP is the first program in Medicare to link reimbursement to performance

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[177] Wish, Johnson, and Wish, "Rebasing the Medicare Payment for Dialysis."
[178] Hirth, "The Organization and Financing of Kidney Dialysis and Transplant Care in the United States of America."
[179] Wetmore et al., "Effects of the Prospective Payment System on Anemia Management in Maintenance Dialysis Patients."
[180] Centers for Medicare & Medicaid Services, "CMS Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System (CMS 1651-F)."
[181] Department of Health and Human Services, "Medicare Program; End-Stage Renal Disease Prospective Payment System."

by reducing payments to dialysis facilities that fail to comply with specific performance measures.[182]

To better appreciate whether financial incentives are effective, comprehensive databases of ESRD QIP data provides a beneficial opportunity to critically evaluate this original value-based program. Medicare's Dialysis Facility Compare Website contains ESRD QIP targeted measure outcomes of dialysis facilities nationwide and the United States Renal Data System comprises a nationwide data system collecting descriptive epidemiology of ESRD patients.[183,184] Within the Dialysis Facility Website, Medicare created a Five Star Rating System which helps dialysis facilities compete on targeted measure attainment and assists patients with making a decision about the dialysis center from which they want to receive treatment.[185] The Dialysis Facility Comparison website offers information about patient outcomes that overlap with the ESRD QIP measures.[186] These websites offer a wealth of information on dialysis patients and will help with evaluating whether the ESRD QIP positively impacts dialysis patient health outcomes.

More accurately described as a penalty program, the QIP does not provide financial rewards for attaining high scores on performance measures. The penalty program is structured to allow a facility to either receive a reduction in Medicare reimbursements or maintain the standard reimbursement amount.[187] To determine whether a penalty will be incurred, a comparison period, a performance period and a pay period are employed. During the comparison period dialysis facility data is collected. The clinical indicators gathered include type of access, adequacy of dialysis, hemodialysis bloodstream infections, hypercalcemia, hospital readmission rates,

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[182] Centers for Medicare and Medicaid Services, "ESRD Quality Incentive Program Overview."
[183] Centers for Medicare and Medicaid Services, "Dialysis Facility Compare."
[184] United States Renal Data System, "USRDS Home Page."
[185] Erickson et al., "Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition."
[186] Centers for Medicare and Medicaid Services, "Dialysis Facility Compare."
[187] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"

transfusion rates and patient satisfaction.[188] The comparison period is followed by the performance period in which dialysis facilities must perform the same or better than the comparison period to prevent future payment reductions. When the performance period ends, CMS evaluates the facility's performance based on the comparison period and creates a Total Performance Score for each facility. For facilities not achieving or exceeding the targeted measures established during the comparison period, a payment reduction of up to two percent for the pay year is incurred.[189]

ESRD QIP Measures

From 2012 to 2020 the number of measures has increased from three to sixteen. Beginning with easily retrievable measures, the ESRD QIP clinical measures of 2012 and 2013 consisted of targeted hemoglobin levels and a urea reduction ratio (URR),[190] which is the percent of waste removed from the body after a patient is dialyzed. In 2014 the number of measures increased and the method of scoring became more complex.[191] The clinical measures were hemoglobin, URR and vascular access type (VAT), which is the category of a device that attaches a dialysis machine to a patient's bloodstream and can include a fistula or catheter. At this time reporting measures, which only require that the dialysis facility report the clinical outcomes, were also added. These included bloodstream infection, mineral metabolism that targets phosphorus levels, and the In-Center Hemodialysis Consumer Assessment of Providers and Systems (ICH-CAHPS).[192] Medicare began adding patient reported measures in 2014 to enhance the value and robustness of the measures, and to consider the value of patient satisfaction and quality of life issues. The first patient reported measure was the ICH-CAHPS, which has changed from a

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188 Gupta and Wish, "Do Current Quality Measures Truly Reflect the Quality of Dialysis?"
189 Centers for Medicare & Medicaid Services, "ESRD QIP Payment Year 2018 Program Details."
190 Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
191 Fishbane et al., "Changes to the End-Stage Renal Disease Quality Incentive Program," June 2, 2012.
192 Centers for Medicare & Medicaid Services, "ESRD QIP Summary: Payment Years 2012 - 2016."

reported measure to a clinical measure. In 2018 Medicare added ICH-CAHPS to the clinical measure list in an effort to capture a patients' perspective about satisfaction with their dialysis care.[193]

In 2015 the clinical measures were hemoglobin, VAT and dialysis adequacy, which measures how much waste is removed from the blood after dialysis with consideration to the volume of water in a patient's body contains. Reporting measures included bloodstream infection, ICH-CAHPs, mineral metabolism, and anemia management. Anemia management involves hemoglobin and hematocrit levels in addition to erythropoiesis-stimulating agent dosage, which is a medication that helps make red blood cells. The targeted clinical measures changed in 2016 with the addition of hypercalcemia, which measures whether high levels of calcium are in the blood, and bloodstream infections. The 2016 reporting measures were the same as 2015, except that 2016 changed bloodstream infections from a reported measure to a targeted clinical measure.[194] The 2017 targeted clinical measures were the same as 2016, except Medicare excluded hemoglobin levels and added a Standardized Readmission Ratio, which is the ratio of the number of observed versus unplanned 30-day hospital readmissions.[195]

In 2018 Medicare added to the clinical measures: the ICH-CAHPS and Standardized Transfusion Ratio, which is the risk adjusted dialysis facility blood transfusion event count among patients. The reporting measures added: a pain assessment and follow-up; Clinical Depression Screening and follow-up; and influenza vaccination. The 2018 reporting measures excluded ICH-CAHPS from 2017 because the survey was added to the 2018 clinical measures. The 2019 measures remained the same as 2018, except that bloodstream infection is categorized

[193] Centers for Medicare & Medicaid Services, "ESRD QIP Payment Year 2018 Program Details."
[194] Centers for Medicare & Medicaid Services, "ESRD QIP Summary: Payment Years 2012 - 2016."
[195] Centers for Medicare & Medicaid Services, "Centers for Medicare & Medicaid Services End-Stage Renal Disease Quality Incentive Program Payment Year 2017 Final Measure Technical Specifications."

under ‘safety’ measures instead of clinical measures.[196] For Pay Year 2020, the targeted measures were the same as 2019 except a Standardized Hospitalization Ratio was added to the clinical measures; and serum phosphorus and ultrafiltration rate were added to the reporting measures. See Table 1. The finalized measures specified through 2022 demonstrate that the number and complexity of measures will continue to change and the computation of performance scores will become more complex.[10,197]

Table 1. End Stage Renal Disease Quality Incentive Program Summary

Pay Year	2012	2013	2014	2015	2016	2017	2018	2019	2020
Clinical Measures	Hgb > 12 g/dL Hgb < 10 g/dL URR > 65%	Hgb > 12 g/dL URR > 65%	Hgb > 12 g/dL URR > 65% Vascular Access	Hgb > 12 g/dL Dialysis Adequacy Vascular Access	Hgb > 12 g/dL Vascular Access Dialysis Adequacy Bloodstream Infection Hypercalcemia	Readmission Ratio Vascular Access Dialysis Adequacy Bloodstream Infection Hypercalcemia	Readmission Ratio ICH CAHPS Transfusion Ratio Vascular Access Dialysis Adequacy Bloodstream Infection Hypercalcemia	Readmission Ratio ICH CAHPS Transfusion Ratio Vascular Access Dialysis Adequacy Hypercalcemia	Readmission Ratio ICH CAHPS Transfusion Ratio Vascular Access Dialysis Adequacy Hypercalcemia Hospitalization Ratio
Safety Measures								Bloodstream Infection Dialysis	Bloodstream Infection
Reporting Measures			Bloodstream Infection ICH CAHPS Mineral Metabolism	Anemia Management Bloodstream Infection ICH CAHPS Mineral Metabolism	ICH CAHPS Mineral Metabolism Anemia Management	ICH CAHPS Mineral Metabolism Anemia Management	Mineral Metabolism Anemia Management Pain Assessment Depression Screen Influenza Vaccine	Mineral Metabolism Anemia Management Pain Assessment Depression Screen Influenza Vaccine	Serum Phosphorus Anemia Management Pain Assessment Depression Scree Influenza Vaccine Ultrafiltration Rate
Performance Period	2010	2011	2012	2013	2014	2015	2016	2017	2018
Comparison Period	N/A	N/A	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016	2017

Data Source: The Centers for Medicare and Medicaid Services

The ESRD QIP patient data is compiled by Medicare in publicly downloadable datasets. The downloadable datasets contain dialysis facility Total Performance Scores, payment reductions and facility level survey data and clinical outcomes. The ESRD QIP performance scores are available on the Dialysis Facility Compare website, which also includes a star rating system for facilities across the country. Using a five star-rating system, aggregated dialysis facility data is publicly reported by Medicare on the Dialysis Facility Compare website. This data includes some of the ESRD QIP data and additional clinical measures. The Dialysis Facility

[196] Centers for Medicare & Medicaid Services, “ESRD QIP Summary: Payment Years 2016 - 2020.”
[197] Cavanaugh, “Patient Experience Assessment Is a Requisite for Quality Evaluation.”

Compare star-ratings are a summary of how a dialysis center performs on clinical measures and patient surveys compared to the national average. Each dialysis facility receives a rating between one and five stars. A five-star rating indicates a facility has quality of care that is deemed 'much above average' compared to other dialysis facilities. A one or two-star rating means that clinical outcomes for that facility was below average.[198,199] Information about dialysis facility patient outcomes and delivery of care is publicly reported to foster transparency and promote patient and provider decision-making. The star-rating system and the ESRD QIP were designed to provide details about how dialysis facilities deliver care with the overall objective to cost-effectively improve patient outcomes.[200]

Critiques of the Program Design

A growing body of literature reviewing the ESRD QIP express concern about its effectiveness.[201,202] While policymakers and some researchers believe the ESRD QIP has the potential to improve dialysis patient care, whether the measures are meaningful, improve patient outcomes and are reflective of provider interventions is uncertain.[203,204,205] Multiple articles cite challenges with the measures and question whether patients' achieving these performance standards derive meaningful benefits. Evidence that achieving the targeted measures translates into better delivery of care and a collective improvement in dialysis patient outcomes has yet to

[198] Kidney Epidemiology and Cost Center, "Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release."
[199] Pozniak and Pearson, "The Dialysis Facility Compare Five-Star Rating System at 2 Years."
[200] Centers for Medicare & Medicaid Services, "Dialysis Facility Compare."
[201] Gupta and Wish, "Do Current Quality Measures Truly Reflect the Quality of Dialysis?"
[202] Chan et al., "How to Use Quality Improvement Tools in Clinical Practice."
[203] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[204] Moss and Davison, "How the ESRD Quality Incentive Program Could Potentially Improve Quality of Life for Patients on Dialysis."
[205] Wanchoo, Hazzan, and Fishbane, "Update on the End-Stage Renal Disease Quality Incentive Program."

be proven.[206,207,208,209,210,211] Critics of the measures argue that applying population-based metrics may undermine a patient-centered approach to care. A "one-size-fits-all" model of care can create barriers to addressing the individual needs of each patient. This is especially problematic for more vulnerable subsets of the dialysis population, such as the frail elderly, who often have unique needs with treatment goals different from their younger counterparts.[212,213,214,215] For example, target hemoglobin levels, an ESRD QIP measure, have been shown to be more effective when considering a patient's age. The individual pathophysiology of a dialysis patient with anemia in association with target hemoglobin levels, medication treatment and overall patient outcomes is complex.[216,217] Population-based metrics may fail to address the unique physiological processes associated with each person suffering from individualized patient care and may compromise quality of care.

A measure that is meaningful to patients and produces improved patient outcomes can be revealed through methodologically rigorous evidence-based research. Inclusion of measures in the ESRD QIP is an area of debate because the studies used to select the measures are not methodologically robust and lack a proven link to improved patient outcomes.[218,219,220] For

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206 Gupta and Wish, "Do Current Quality Measures Truly Reflect the Quality of Dialysis?"
207 Fishbane et al., "Changes to the End-Stage Renal Disease Quality Incentive Program," June 2012.
208 Gabbay and Meyer, "Incentives for Caution: The in-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey and Experience of Care."
209 Chan et al., "How to Use Quality Improvement Tools in Clinical Practice."
210 Cavanaugh, "Patient Experience Assessment Is a Requisite for Quality Evaluation."
211 Moss and Davison, "How the ESRD Quality Incentive Program Could Potentially Improve Quality of Life for Patients on Dialysis."
212 Williams, "Health Policy, Disparities, and the Kidney."
213 Woo and Lok, "New Insights into Dialysis Vascular Access."
214 Kliger, "Quality Measures for Dialysis."
215 Kalloo, Blake, and Wish, "A Patient-Centered Approach to Hemodialysis Vascular Access in the Era of Fistula First."
216 Mimura, Tanaka, and Nangaku, "How the Target Hemoglobin of Renal Anemia Should Be?," 2015.
217 Fuertinger et al., "Prediction of Hemoglobin Levels in Individual Hemodialysis Patients by Means of a Mathematical Model of Erythropoiesis."
218 Weiner and Lacson, "Fluid First or Not So Fast: Ultrafiltration Rate and the ESRD Quality Incentive Program."
219 Hogan, "ESRD QIP: The Good, the Not So Good, and the Mysterious."
220 Flythe et al., "Ultrafiltration Rates and the Quality Incentive Program."

example, calcium level became a targeted measure because observational studies demonstrated that low serum calcium levels are associated with mortality. However, no interventional trial supports a specific threshold of a calcium level that is associated with improved patient outcomes.[221,222] In addition, correcting low calcium levels have been associated with a greater risk for vascular calcification and bone disease.[223] Basic quality measures such as levels of calcium, hemoglobin and dialysis adequacy are data points that are easily retrievable and can reflect dialysis provider interventions. These metrics which most facilities are attaining, however, have little evidence-based association with improved patient health outcomes such as decreased hospitalizations.[224]

Targeted hemoglobin levels, which became one of the first QIP measures, were established because low levels are a common occurrence in ESRD patients and have been associated with an increased risk for cardiovascular events and mortality.[225,226] However, studies have demonstrated that increased hemoglobin levels do not necessarily improve all dialysis patient health outcomes. The recommended level of hemoglobin correction can benefit relatively healthy dialysis patients but for those with cardiovascular disease, a common occurrence in elderly ESRD patients, an increased hemoglobin level is not associated with a better outcome.[227,228] Low hemoglobin is a common problem in the ESRD population and disproportionately impacts elderly patients. For patients who are 65 years and older, use of

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221 Rivara and Mehrotra, "The Changing Landscape of Home Dialysis in the United States."
222 Centers for Medicare & Medicaid Services, "CMS ESRD Measures Manual."
223 O'Neill, "Targeting Serum Calcium in Chronic Kidney Disease and End-Stage Renal Disease."
224 Gupta and Wish, "Do Current Quality Measures Truly Reflect the Quality of Dialysis?"
225 Pascual et al., "Regression of Left Ventricular Hypertrophy after Partial Correction of Anemia with Erythropoietin in Patients on Hemodialysis."
226 Foley et al., "The Impact of Anemia on Cardiomyopathy, Morbidity, and Mortality in End-Stage Renal Disease."
227 Maekawa et al., "Influence of Atherosclerosis on the Relationship between Anaemia and Mortality Risk in Haemodialysis Patients."
228 Foley, Curtis, and Parfrey, "Erythropoietin Therapy, Hemoglobin Targets, and Quality of Life in Healthy Hemodialysis Patients."

medication to correct hemoglobin levels is associated with increased blood transfusions, which is costly and can lead to further complications.[229,230] Optimal hemoglobin levels for different age groups may vary, and therefore incentivizing providers to achieve the QIP's targeted hemoglobin level for all dialysis patients may increase health disparities in older adults.

Another measure that fails to demonstrate an association with patient outcomes is the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS). As a patient survey measure that aims to capture the quality of health care from the patient's perspective, ICH CAHPS is currently the highest weighted measure. While the ESRD QIP places considerable importance on the patient experience, whether a patient's perceived quality of care translates into better health outcomes is unknown.[231,232,233,234] The infrastructure and corroboration for selecting quality measures that are scientifically proven to improve patient outcomes is lacking. In addition to challenges with technical specifications, invalid documentation of measures has created poor quality of data. The standardized transfusion ratio, which is the number of nationwide dialysis patient blood transfusions, was added to the ESRD QIP in 2016, to help reduce the national upward trend of dialysis patient transfusion administration. Blood transfusions increase the risk of blood borne infections, allergic reactions and the potential for increased anti-human leukocyte antigen antibodies resulting in reduced access to donor kidney matching for transplantation. Furthermore, a blood transfusion is a scarce resource, and when not

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[229] Juárez-Cedillo et al., "Prevalence of Anemia and Its Impact on the State of Frailty in Elderly People Living in the Community."
[230] Winkelmayer et al., "Trends in Anemia Care in Older Patients Approaching End-Stage Renal Disease in the United States (1995-2010)."
[231] Dalrymple, "Understanding ICH CAHPS as a Measure of Health Care Quality."
[232] Richardson and Grobert, "ICH-CAHPS."
[233] Wood et al., "Evaluation of the Consumer Assessment of Healthcare Providers and Systems In-Center Hemodialysis Survey."
[234] Weidmer et al., "Development and Evaluation of the CAHPS® Survey for In-Center Hemodialysis Patients."

freely donated from the blood bank, is costly. The standardized transfusion ratio became 22% of the 2019 total dialysis facility performance score.[235,236]

The validity of this measure has been questioned in relation to a shift from the International Classification of Diseases, Ninth Revision (ICD-9) taxonomy to the International Classification of Diseases, Tenth Revision (ICD-10) taxonomy, which document diagnoses and procedures in hospital settings and includes 256 blood transfusion documentation codes.[237] Transitioning from ICD-9 to ICD-10 was associated with a misrepresentation of blood transfusion documentation in the hospital setting. Specifically, a dramatic reduction in blood transfusion documentation occurred after the ICD-10 was implemented. While the cause of this decrease is uncertain, hospitals may lack a financial incentive to record blood transfusions. The inclusion of blood transfusions in the bundled payment and as a targeted measure may have reduced blood transfusion documentation.[238,239,240] Therefore, the data used for the ESRD QIP standardized transfusion ratio may not accurately describe the use of dialysis patient blood transfusions.

For targeted measures that are selected, the goal is ultimately improved patient outcomes. This is achieved by means of a provider delivering care that meets or exceeds ESRD QIP performance standards. In addition to challenges with the ESRD QIP measure design and proper documentation, another issue that may undermine the effectiveness of the program is patient level factors. The incentive program design depends on an imperfect gauge of the degree of effort and

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[235] University of Michigan Kidney Epidemiology and Cost Center, "Report for the Standardized Transfusion Ratio NQF #2979."
[236] Centers for Medicare & Medicaid Services, "Blood Transfusion Coverage."
[237] Weinhandl and Kubisiak, "Changes in Transfusion Coding Among Hospitalized Medicare Beneficiaries after Implementation of ICD-10."
[238] Chou et al., "Bundled Payments."
[239] Weinhandl and Kubisiak, "Changes in Transfusion Coding Among Hospitalized Medicare Beneficiaries after Implementation of ICD-10."
[240] Weinhandl, Kubisiak, and Wetmore, "Low Quality of International Classification of Diseases, 10th Revision, Procedural Coding System Data Undermines the Validity of the Standardized Transfusion Ratio: Time to Chart a New Course?"

quality attributed by the provider that is associated with achieving a targeted measure. Other factors, such as patient level and dialysis facility level characteristics, contribute to achieving targeted measures.[241] While the ESRD QIP places the responsibility of achieving patient targeted measures on the provider, patients play a role in the status of their health and subsequent clinical outcomes. Home medication adherence, adequate physical activity, proper diet, and risk-modification behaviors such as avoidance of smoking and drinking alcohol impact dialysis patient functionality, quality of life and clinical outcomes.[242,243,244,245]

Critics of the ESRD QIP question whether the extent to which complex measures, such as a fistula placement, are attributable to the provider. Factors associated with a patient receiving a fistula can include age, life expectancy, comorbidities, risk for complications, timing of referral, healthcare accessibility and volume of fistula placements at the surgical center.[246,247,248,249] Provider interventions can help lead to attainment of ESRD QIP measures, however the outcomes can be mediated by patients and system level factors. Separating the programmatic effect from confounding variables is a challenge, especially with the ESRD QIP, which affords no control group to draw meaningful conclusions exists.[250] Contextual elements can impact outcomes for this vulnerable subset of chronically ill patients suffering poorer health outcomes relative to the general population.

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[241] Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
[242] Adams, "Improving Health Outcomes with Better Patient Understanding and Education."
[243] Johansen, "Exercise in the End-Stage Renal Disease Population."
[244] Tsuruya et al., "Dietary Patterns and Clinical Outcomes in Hemodialysis Patients in Japan."
[245] Liebman et al., "Smoking in Dialysis Patients."
[246] Gupta and Wish, "Do Current Quality Measures Truly Reflect the Quality of Dialysis?"
[247] Woo and Lok, "New Insights into Dialysis Vascular Access."
[248] O'Hare et al., "Impact of Surgeon and Surgical Center Characteristics on Choice of Permanent Vascular Access."
[249] MacRae et al., "Arteriovenous Vascular Access Selection and Evaluation."
[250] Damberg, Sorbero, Lovejoy, Raaen, Mandel, "Measuring Success in Health Care Value-Based Purchasing Programs."

ESRD in the Elderly

Older ESRD patients consume the greatest amount of hemodialysis resources and is the largest segment of the ESRD population. The increasing number of older kidney failure patients is transforming the demographic makeup of the ESRD program.[251] Of all ESRD age groups, the highest prevalence of ESRD patients are 65 to 74 years old. In addition, dialysis patients $\geq$75 years old are the largest subset of ESRD patients initiating dialysis, and those 65-74 years old are the second fastest growing incident population.[252] Elderly dialysis patients are generally associated with having poor sleep quality, depression and a poor health related quality of life. After dialysis initiation, functional and cognitive decline in this age group significantly accelerates.[253] Complications of elderly ESRD patients receiving hemodialysis differ from their younger cohorts because of the natural aging process. Elderly patients have a greater risk for functional and cognitive impairments and frailty compared to their younger ESRD cohorts. Challenges for the elderly are compounded by the innate consequences of ESRD and the burden associated with hemodialysis.[254] Therefore, examining how the ESRD QIP affects the elderly is important.

A focus on the effects of the ESRD QIP on elderly ESRD hemodialysis patients is important for several reasons. Healthcare for elderly patients is associated with a large proportion of Medicare expenditures and can alter the productivity and economic status of families and caregivers. Caring for older patients is distinct from other age groups because the elderly consumes greater amounts of resources, encounter more ethical dilemmas about life-saving interventions, and suffer more pervasive physical and mental illnesses.[255] As the number,

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[251] Stevens, Viswanathan, and Weiner, "CKD and ESRD in the Elderly."
[252] United States Renal Data System, "2017 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[253] al, "Sleep Quality, Depression, and Quality of Life in Elderly Hemodialysis Patients. - PubMed - NCBI."
[254] Anand, Tamura, and Chertow, "The Elderly Patients on Hemodialysis."
[255] National Research Council., "The Health of Aging Populations."

proportion and longevity of elderly ESRD patients on dialysis grows, a central question is whether this population has been benefitting from the QIP program and how elderly performance measures have compared to younger ESRD patients at different dialysis facilities.

The serious medical and psychosocial challenges of ESRD caused by enduring no cure, symptom management, dialysis treatment demands and an unpredictable illness trajectory creates distress for patients and families. Physical, psychological and spiritual distress affects care needs and is different for every patient and family.[256] This is especially the case with elderly compared to younger ESRD patients who often experience a greater burden of symptom distress and complications associated with ESRD and dialysis treatment.

Elderly ESRD patients have an increased burden of age-related complications. This includes cognitive impairments, functional impairments and frailty.[257] Frailty accelerates the natural decline in functioning as a person ages and is associated with an increased risk for disability, hospitalization and death. The clinical presentation of frailty includes weight loss, extreme fatigue, delirium, falls and frequent infection.[258,259] A Dialysis Morbidity and Mortality Study (DMMS) study demonstrated that almost 70% of all ESRD patients met the criteria for frailty, and older patients had the highest prevalence and greatest severity of frailty symptoms.[260] For older ESRD patients compared to younger ESRD patients, these complications create a more dramatic deleterious effect on health.

Dialysis treatment adds another dimension to the challenges of ESRD. For elderly patients, hemodialysis is universally offered. This has been associated with a considerable number of frail elderly ESRD patients receiving aggressive treatment as they near the end of

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[256] Safford, Allison, and Kiefe, "Patient Complexity."
[257] Jassal and Watson, "Dialysis in Late Life."
[258] "Frailty in Older People."
[259] Tamura, Tan, and O'Hare, "Optimizing Renal Replacement Therapy in Older Adults."
[260] Johansen et al., "Significance of Frailty among Dialysis Patients."

life.[261] Even though the benefit of dialysis treatment decreases with age, a growing number of elderly patients are initiating dialysis. Most elderly patients select hemodialysis as a renal replacement therapy and are more likely to suffer frailty than their peritoneal dialysis counterparts.[262,263] Even though peritoneal dialysis patients report more satisfaction with their treatments and a greater quality of life, the modality is underutilized for all age groups and used least frequently in the elderly.[264] For elderly patients, the lack of peritoneal dialysis use is frequently associated with functional impairments or cognitive dysfunction preventing the self-dialysis care.[265] Therefore, most elderly ESRD patients use hemodialysis, which is a physically and mentally demanding treatment.

Nephrologists significantly diverge in their approach to initiate dialysis in the elderly. Studies demonstrate dialysis and other intensive procedures performed on elderly ESRD patients are not based on individual patient characteristics, but rather associated with regional differences. In areas with greater health care spending, elderly ESRD patients in the last months of life are less likely to discontinue dialysis and receive hospice, and more likely to die in the hospital.[266,267] Discussing end-of-life decisions with ESRD patients and families plays an important role in the care of a family and patient. The treatment goals and decisions of elderly ESRD patients often diverge from younger ESRD patients and the elderly often fail to receive communication about prognosis and advance care planning.[268,269]

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[261] Thorsteinsdottir, Swetz, and Tilburt, "Dialysis in the Frail Elderly — A Current Ethical Problem, an Impending Ethical Crisis."
[262] Johansen et al., "Significance of Frailty among Dialysis Patients."
[263] O'Hare et al., "Regional Variation in Health Care Intensity and Treatment Practices for End-Stage Renal Disease in Older Adults."
[264] Rubin et al., "Patient Ratings of Dialysis Care with Peritoneal Dialysis vs Hemodialysis."
[265] Sakacı et al., "Clinical Outcomes and Mortality in Elderly Peritoneal Dialysis Patients."
[266] Wong, Kreuter, and O'Hare, "Treatment Intensity at the End of Life in Older Adults Receiving Long-Term Dialysis."
[267] O'Hare et al., "Regional Variation in Health Care Intensity and Treatment Practices for End-Stage Renal Disease in Older Adults."
[268] Saeed et al., "Outcomes of In-Hospital Cardiopulmonary Resuscitation in Maintenance Dialysis Patients."
[269] Holley, "Advance Care Planning in CKD/ESRD."

Initiating dialysis in the elderly, especially for those ≥75 years old affords a small probability of improved quality of life or long-term survival.[270] The rigors of dialysis are more deleterious on the health of frail elderly patients. When compared to elderly patients initiating dialysis and those choosing conservative management, the dialysis group expends more of their remaining life years in the dialysis clinic or hospital. In addition, while in the hospital the elderly are two to three times more likely to die.[271] A small number of dialysis patients execute 'do not resuscitate' orders even though 74% of cardiopulmonary resuscitation interventions in this population ends in death. For those that survive, increased functional and cognitive deficits frequently ensue.[272] Frailty and comorbidities are notable predictors for a higher mortality risk, and more frequently occur in elderly patients.[273]

Elderly patients on dialysis are a rapidly growing segment of the ESRD population with singular healthcare needs and preferences. Compared to younger ESRD patients, elderly patients have a greater risk for frailty, lower hemoglobin levels, calcium disorders, and difficulty with maturing a fistula. In addition, this vulnerable population is more likely than younger ESRD patients to have functional and cognitive impairments.[274] Ensuring dialysis care for the elderly is responsive to their specific needs is critical for improving quality of life and patient outcomes.

For some older ESRD patients, utilization of dialysis, a physically and psychologically demanding treatment, can result in inadequate and inappropriate treatment outcomes. In general, elderly dialysis patients have a different baseline health status and needs than their younger counterparts. However, elderly dialysis patients are measured by the same clinical standards as

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[270] Rosansky, "The Sad Truth about Early Initiation of Dialysis in Elderly Patients."
[271] Carson et al., "Is Maximum Conservative Management an Equivalent Treatment Option to Dialysis for Elderly Patients with Significant Comorbid Disease?"
[272] Saeed et al., "Outcomes of In-Hospital Cardiopulmonary Resuscitation in Maintenance Dialysis Patients."
[273] Qureshi et al., "Inflammation, Malnutrition, and Cardiac Disease as Predictors of Mortality in Hemodialysis Patients."
[274] Anand, Tamura, and Chertow, "The Elderly Patients on Hemodialysis."

their younger dialysis peers. While the ESRD QIP aims to improve care for all ESRD patients, the elderly is a unique subset of this population that may require different measures of quality care. As the ESRD QIP evolves, new quality measures are added every year. However, whether the targeted outcomes improve individual patient health outcomes has yet to be answered.[275,276] Considering that the ESRD QIP metrics continue to change each year, the lack of research on the program evaluation and the singular needs of the elderly is timely, important and requires attention.

Policy Problem Statement

Since the inception of the ESRD program, legislators have been grappling with approaches to control program spending and provide quality care. Almost 50 years later, these challenges continue to plague ESRD Medicare providers, payers and patients.[277,278] As Medicare's first pay-for-performance program, the ESRD QIP was created to improve dialysis patient health outcomes and penalize dialysis providers for inadequate patient performance on predefined measures. Research to determine the impact of the ESRD QIP on ESRD dialysis patient outcomes since its inception is lacking. Early studies were performed, however an examination of performance and health outcome trends from the program beginning to the current day does not exist. While changes to the payment model are aimed to reduce ESRD expenditures and improve health outcomes, little is known about the trajectory of individual measures and facility penalties, and how the ESRD QIP has impacted Medicare beneficiaries by age group.

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[275] Moss and Davison, "How the ESRD Quality Incentive Program Could Potentially Improve Quality of Life for Patients on Dialysis."
[276] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[277] Rettig and Levinsky, "Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program."
[278] Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."

To help address quality care for this large group of costly beneficiaries, the ESRD QIP aims to reduce costs, improve patient care by encouraging providers to achieve a set of patient standards, and deter dialysis facility providers from withholding medications and services to maximize profits under the bundled payment system.[279,280] Since the program's inception, researchers have raised questions concerning the ESRD QIP's quality measures and evaluation of the program's effectiveness in improving patient outcomes.[281,282,283,284,285,286,287] Dialysis care is complex and developing policy to provide medical treatments within budget constraints have been a continual challenge. Over the decades, attempts to curb spending for the growing ESRD population, especially for patients using outpatient hemodialysis, have yet to reach a solution. With older and sicker patients joining the program, the prevalence and incidence of ESRD patients continues to considerably grow, as does the total spending. Regulatory adjustments have been implemented however the unrelenting expansion of Medicare outlays continues to drive legislators toward updating or creating new payment models that will limit spending and provide quality care.[288]

The incidence and prevalence of patients suffering from ESRD has increased significantly since the inception of the ESRD program and continues to grow largely because of the rising rates of comorbidities such as diabetes and high blood pressure. With the increase of patients being diagnosed with ESRD, the proportion of patients receiving dialysis continues to

[279] Department of Health and Human Services, "Medicare Program; End-Stage Renal Disease Prospective Payment System."
[280] Centers for Medicare and Medicaid Services, "ESRD Quality Incentive Program Overview."
[281] "Innovative ESRD Care and Payment Models."
[282] Steward, "The Relationship Between Bloodstream Infections and Hemodialysis Catheters in Hospital-Based Hemodialysis Units."
[283] Schiller, "The Medical Director and Quality Requirements in the Dialysis Facility."
[284] Pollak, Lorch, and Pollak, "Perpetuating Sub-Optimal Care: CMS, QIPs, and the Hemoglobin Myth."
[285] Lee and Zenios, "An Evidence-Based Incentive System for Medicare's End-Stage Renal Disease Program."
[286] Krishnan et al., "Guiding Principles and Checklist for Population-Based Quality Metrics."
[287] Kliger, "Quality Measures for Dialysis."
[288] Knauf and Aronson, "ESRD as a Window into America's Cost Crisis in Health Care."

rise. Dialysis treatments are intensive treatment resources that underscore federal fiscal healthcare challenges and individual patient quality of life. Even though individual treatment costs remain relatively low, overall ESRD program expenditures continue to dramatically increase largely because of an expanding and sicker ESRD population.

ESRD morbidity, mortality, individual suffering and loss of productivity represent a significant and increasing burden on individuals suffering from the disease and on the healthcare system. The number of incident ESRD cases is approximately 124,000 and each year this number expands by an additional 20,000 patients.[289] Today, over 700,000 individuals in the United States suffer from ESRD and that number is growing every year.[290] The expansion is driven by patients living longer and an ever-increasing prevalence of individuals with diabetes and high blood pressure, which leads to ESRD and requires dialysis or renal transplantation to survive.[291] To live, individuals with ESRD require dialysis or transplantation. While transplantation affords the best health outcomes and is the least costly treatment alternative for ESRD patients, the supply of donor kidneys is considerably inadequate to match the demand.[292] The remaining options for treatment are hemodialysis, which is used by about 90% of dialysis patients, and peritoneal dialysis.[293] Second to transplantation, peritoneal dialysis, is the least costly of renal replacement therapies. Since the inception of the ESRD program, budgetary analyses and policy makers believed costs would be curbed by the number of ESRD patients receiving transplants and the number of patients using peritoneal dialysis instead of hemodialysis.[294,295] However, hemodialysis continues to be use by the majority of ESRD patients.

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[289] United States Renal Data System, "2017 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[290] United States Renal Data System.
[291] Ronco et al., "Renal Replacement Therapy in Acute Kidney Injury."
[292] Ronco et al.
[293] Tonelli et al., "Systematic Review."
[294] Hirth et al., "Chronic Illness, Treatment Choice and Workforce Participation."
[295] LeSourd, Fogel, and Johnston, *Benefit-Cost Analysis of Kidney Disease Programs*.

ESRD dialysis patients are required to adhere to a burdensome treatment schedule along with fluid and dietary restrictions. Changes in bodily appearance occur such as a catheter in the abdomen or a fistula in the arm, which are used for treatment access. The majority of patients experience a significant reduction in energy levels and constant fatigue. The fatigue which ESRD patients experience is associated with anemia, coexisting comorbidities, malnutrition, an increase of waste compounds in the blood, medication side effects, sleep problems, lack of dialysis adequacy, and the physical demand of dialysis.[296] For patients dependent on dialysis as their renal replacement therapy, a considerable amount of time is used to receive treatment, which is associated with lethargy and restricts everyday activities. Most ESRD patients cannot perform daily routine activities because of the fatigue and the duration of dialysis sessions during the week days.[297] The day-to-day life of an ESRD patient receiving renal replacement therapy is drastically changed because of the extent of the treatment and the physical and psychosocial challenges which patients experience. While patient survival outcomes have improved, more dialysis patients are experiencing multiple comorbidities and age-related complications.[298,299]

Better understanding the ESRD QIP health outcome trends, especially how it affects older dialysis patients is important for several reasons. The elderly population is the fastest growing segment of patients initiating dialysis. Specifically, dialysis patients $\geq$75 years old are the largest subset of ESRD patients initiating dialysis. In addition, those 65-74 years old have the highest prevalence rate and are the second fastest growing population. Secondly, studies have demonstrated the quality of care and quality of life for elderly dialysis patients nearing death is poor. Almost half of all ESRD patients will die in a hospital. While the purpose of dialysis is to

[296] Jhamb et al., "Fatigue in Patients Receiving Maintenance Dialysis."
[297] Finnegan-John and Thomas, "The Psychosocial Experience of Patients with End-Stage Renal Disease and Its Impact on Quality of Life."
[298] Jassal and Watson, "Dialysis in Late Life."
[299] Lee et al., "The Number of Comorbidities Predicts Renal Outcomes in Patients with Stage 3–5 Chronic Kidney Disease."

restore kidney functioning and maintain life, elderly ESRD patients often become more disabled and suffer greater physical burden after dialysis initiation. Survival has increased over the decades, however, for those 75 and older morbidity frequently complicates the benefit of living longer. This subset of patients experiences the lowest life expectancy and the greatest costs of care.[300]

The performance-based incentives disproportionately impact the elderly, a vulnerable population with singular needs. While about half of the ESRD population are 65 and older, the failure of targeted measures being tailored to the needs of the elderly is a problem.[301,302] To maximize the intended policy impact without jeopardizing the health outcomes of the elderly, reexamining quality measures to focus on the generalizability to all age groups is warranted. Resources to support better ESRD quality of care and efficiency may incur greater expenditures than the savings actually attained. Therefore, the impact of the ESRD QIP should be evaluated and supported based on program efficiency, which is associated with overall patient costs and individual health outcomes.

The original Medicare Kidney Disease Entitlement goal of rehabilitating the ESRD population while incurring nominal societal costs never garnered traction. Attempts to curb spending for the growing ESRD population, especially for patients using outpatient hemodialysis, have yet to reach a solution. Regulatory adjustments have been implemented however the unrelenting expansion of Medicare outlays continues to drive legislators toward updating or creating new payment models that aim to limit spending and provide quality care. However, with older and sicker patients joining the program, the prevalence and incidence of ESRD patients

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300 Tamura, Tan, and O'Hare, "Optimizing Renal Replacement Therapy in Older Adults."
301 Stevens, Viswanathan, and Weiner, "CKD and ESRD in the Elderly."
302 United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."

continues to considerably grow, as does the total spending.[303] Over the past decades, clinical outcomes have not made great strides. More importantly, quality of life continues to be suboptimal and mortality rates have not significantly improved.[304] This is especially true for older ESRD patients, who have the highest ESRD incident rate. For these elderly patients, dialysis initiation often increases suffering and creates a financial burden on the family and healthcare system.[305] Elderly ESRD patients receiving dialysis experience a considerable burden of treatment symptoms and high mortality rates. Therefore, understanding the intersection between the demands of hemodialysis and geriatric challenges is warranted.

[303] Knauf and Aronson, "ESRD as a Window into America's Cost Crisis in Health Care."
[304] Norbert Lameire, Wim Van Biesen, and Raymond Vanholder, "Did 20 Years of Technological Innovations in Hemodialysis Contribute to Better Patient Outcomes?" *Clinical Journal of the American Society of Nephrology* 4, no. Supplement 1 (December 1, 2009): S30–40, https://doi.org/10.2215/CJN.04000609.
[305] United States Renal Data System, "2017 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."

CHAPTER TWO

Research Questions and Hypotheses

Since the ESRD QIP was implemented in 2012, dialysis facilities failing to attain targeted patient outcomes have been penalized with payment reductions. Whether the program produced the intended outcomes of improving patient outcomes is uncertain. To develop an understanding of program's effectiveness, this dissertation aims to synthesize the existing literature on the ESRD QIP, and examine facility and patient level data before and after the program's implementation. The research questions will examine the predictors and characteristics of dialysis facilities that receive payment reductions; and how health outcomes vary by age. The following are the research questions that will be examined in this dissertation:

1. Does the ESRD QIP literature demonstrate whether the program has been successful at achieving its goals of cost-effective quality care?

2. What facility and neighborhood level characteristics influence the likelihood of a payment reduction under the ESRD QIP since its implementation in 2012? How does the dialysis facility's star-rating that began in 2015 compare to a facility's ESRD QIP penalty status?

3. Do dialysis patient targeted clinical outcomes vary by age since the 2012 ESRD QIP implementation? Do dialysis patient non-targeted clinical outcomes vary by age since the 2012 ESRD QIP implementation?

Chapter three of this dissertation is dedicated to answering the first objective as it systematically reviews the literature on the ESRD QIP. The systematic method employed for the review involves collecting and critically appraising research studies, along with synthesizing the findings. This method is discrete from the quantitative analysis used for the remaining research objectives. Chapter four of this dissertation will address objectives two and three.

As the ESRD QIP continues to mature and add new measures, a systematic review synthesizing research on the effectiveness of the ESRD QIP is needed. Preliminary searches of PubMed and CINAHL have confirmed that no systematic review has been published on this topic. Filling this unexplored opportunity of research is critical because of ESRD program expenditures, the amount of resources allocated to the QIP administration, the existence of health disparities and the vulnerability of this patient subset.[306,307,308] For question one, I hypothesize that the collective empirical evidence of the ESRD QIP will range from positive to negative. Existing opinion articles and reviews describe the ESRD QIP as having structural problems with the potential for an exacerbation of health disparities and minimal impact to patient health and cost reduction.[309,310,311] While the Centers for Medicare and Medicaid Services (CMS) designed the program to promote quality care, whether patient health outcomes are improving has yet to be determined. According to CMS, the facility's achievement of quality patient care is signaled by the attainment of the program's targeted measures which precludes receiving a penalty. The majority of facilities do not receive payment reductions; therefore, these facilities are meeting or

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306 Williams, "Health Policy, Disparities, and the Kidney."
307 Government Accountability Office, ""Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable MedicalEquipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS," November 2018.
308 National Academies of Sciences, Engineering, and Medicine et al., *Accounting for Social Risk Factors in Medicare Payment*.
309 Gupta and Wish, "Do Current Quality Measures Truly Reflect the Quality of Dialysis?"
310 Hogan, "ESRD QIP: The Good, the Not So Good, and the Mysterious."
311 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."

exceeding standards indicative of quality care. However, whether attaining targeted measures translates into improved patient health outcomes and reductions in cost is unknown.[312,313]

The number of federally assisted healthcare programs that employ financial incentives to reward or penalize providers has continued to increase over the last decade. While the evidence that these types of programs are successful is limited, the overall literature shows that the research does not strongly support or oppose such payment schemes.[314,315] Research demonstrating positive results has generally presented small improvements with recommendations to adjust the incentive program's design for better success.[316,317,318] Conversely, some research also demonstrates that these programs are ineffective in improving patient health outcomes, and conclude that unintended consequences can negatively impact sicker more vulnerable patients.[319,320,321] Evaluating incentive programs such as the ESRD QIP can be difficult because it is a federally mandated program in which the vast majority of dialysis facilities are required to participate. Therefore, a comparison group not subjected to the ESRD QIP are few. Methodological weaknesses are inherent in such research and for these incentive programs, the clarity of what constitutes a successful incentive program is unclear making policy analysis a further challenge.[322] Based on this evidence, I surmise that the ESRD QIP will have similar results. I hypothesize that my systematic review of the ESRD QIP will results in a small number of

[312] Centers for Medicare and Medicaid Services, "ESRD Quality Incentive Program Overview."
[313] Hogan, "ESRD QIP: The Good, the Not So Good, and the Mysterious."
[314] Scott et al., "The Effect of Financial Incentives on the Quality of Health Care Provided by Primary Care Physicians."
[315] Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
[316] Figueroa et al., "Association between the Value-Based Purchasing Pay for Performance Program and Patient Mortality in US Hospitals."
[317] Jha et al., "The Long-Term Effect of Premier Pay for Performance on Patient Outcomes."
[318] Shih et al., "Does Pay-for-Performance Improve Surgical Outcomes?"
[319] Roland and Dudley, "How Financial and Reputational Incentives Can Be Used to Improve Medical Care."
[320] Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
[321] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[322] Damberg, Sorbero, Lovejoy, Raaen, Mandel, "Measuring Success in Health Care Value-Based Purchasing Programs."

research articles that modest methodological rigor and demonstrate mixed results with no clear clinical impact.

For the first part of question two, I hypothesize that dialysis facilities in poorer neighborhoods and with a greater proportion of elderly will be more likely to receive facility payment reductions. Facilities that receive payment reductions are often associated with treating patients that have poorer health. Elderly dialysis patients are generally of poorer health because they are more likely to be disabled, have a greater number of comorbidities and experience frailty.[323] In addition, elderly patients have a greater risk for low hemoglobin levels and insufficient vasculature that can prevent the maturation of a fistula.[324,325] Hemoglobin levels and fistulas are ESRD QIP targeted measures that can be more difficult to achieve for elderly patients. In addition, elderly ESRD patients tend to have more frequent hospitalizations, receive more intensive procedures and are more likely to be living in a skilled nursing facility. These services, especially when nearing end-of-life ae associated with more intensive care and poorer health outcomes.[326] Therefore, dialysis facilities with a greater proportion of elderly may score lower on measures, and the facility may be more likely to receive a payment reduction.

For the second part of this question, I predict that dialysis facilities receiving no ESRD QIP penalty are more likely to be characterized by a higher star-rating; and lower star-rating facilities will more likely have receive a penalty. While an aim of the ESRD QIP is to improve health care delivery and patient outcomes, the star-rating program similarly awards facilities a one to five-star scale rating based on patient outcomes and surveys. This simple and patient-friendly reporting system aims to better inform a patient about the quality of care provided at a

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[323] Broyles, McAuley, and Baird-Holmes, "The Medically Vulnerable."
[324] Steensma and Tefferi, "Anemia in the Elderly."
[325] Lomonte et al., "The Vascular Access in the Elderly."
[326] United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."

dialysis facility.[327,328] In addition, both reporting systems involve similar metrics. A little over half of the metrics used in the ESRD QIP overlap with the star-rating system.[329] Therefore, the variation in ESRD QIP penalty status and the variation in the star-rating should be congruent. That is, dialysis facilities performing well on the ESRD QIP should perform well on the star-rating reporting system, and facilities receiving a payment penalty should be more likely to receive a lower star-rating.

For question three, I hypothesize that elderly patients who are old (65-74 years old) and oldest old (75+ years old) will be less likely to achieve targeted measures, and the program will have little impact on non-targeted measures. I hypothesize that end-of-life care measures for older dialysis patients will unlikely change over time. However, older dialysis patients will be more likely to receive end-of-life care measures compared to younger dialysis patients. Under the ESRD QIP, I believe that the elderly will have more challenges achieving the targeted measures. Physiological differences between older and younger individuals exist as part of the ageing process, and the elderly are more likely to experience multiple chronic conditions.[330] While the ESRD QIP has not integrated aging into its model, researchers believe that older adults need healthcare that is tailored to their ageing and disease process, and that considerations of age should be integrated into a healthcare delivery model.[331]

Furthermore, development of the ESRD QIP targeted measures were not based on randomized control trials. This precludes having a high degree of confidence that a causal relationship between achieving a targeted measure and an improved patient health outcome

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[327] Kidney Epidemiology and Cost Center, "Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release."
[328] Pozniak and Pearson, "The Dialysis Facility Compare Five-Star Rating System at 2 Years."
[329] Kidney Epidemiology and Cost Center, "Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release."
[330] Golinowska et al., "Health Promotion Targeting Older People."
[331] "Population Health Management for Older Adults: Review of Interventions for Promoting Successful Aging Across the Health Continuum - Rifky Tkatch, Shirley Musich, Stephanie MacLeod, Kathleen Alsgaard, Kevin Hawkins, Charlotte S. Yeh, 2016."

exists.[332] The published literature has also not indicated that the ESRD QIP targeted measures have improved overall patient health outcomes. These targeted measures were based on population studies and do not afford patient-centered care tailored to individual characteristics and treatment goals.[333,334] Therefore, I predict that the elderly will perform poorer than their younger counterparts on the targeted and non-targeted measures, and that the health of neither age groups will be significantly impacted by achieving these measures.

Theoretical Framework

The evaluation of quality care is dependent upon the theoretical and operational definition of what quality means. To quantify the concept of quality, a tangible representation must be afforded. Seeing a need for a classification of methods that assesses quality, in 1966, Avedis Donabedian created a universal framework for quality healthcare.[335] According to Donabedian, the quality of care can be structured under three categories: structure, process and outcomes. The three categories are dependent and connected by a framework that operates as an organizational source. While structure, process and outcomes are not quality per se, the framework allows for an ordered approach to defining quality.[336]

Laying the foundation for the evaluation and monitoring of quality of healthcare in the United States, Donabedian's structure process and outcomes framework has been widely used by quality assurance committees and in the literature about quality care research.[337,338] Process and outcome measures are currently used by the National Quality Forum (NQF) which promotes healthcare quality by measuring performance and public reporting. The NQF reviews and

[332] Kovesdy and Kalantar-Zadeh, "Observational Studies vs. Randomized Controlled Trials: Avenues to Causal Inference in Nephrology."
[333] Kliger, "Quality Measures for Dialysis."
[334] Krishnan et al., "Guiding Principles and Checklist for Population-Based Quality Metrics."
[335] Suñol, "Avedis Donabedian."
[336] Donabedian, "The Quality of Care."
[337] Lohr, "Medicare."
[338] McDonald et al., *Conceptual Frameworks and Their Application to Evaluating Care Coordination Interventions*.

recommends measures that are used in over twenty federal public reporting and pay-for-performance programs, including the ESRD QIP.[339] Another entity that implements process and outcomes is the National Committee for Quality Assurance. It examines the extent to which health plans and providers recommend evidence-based care and recognizes organizations that offer better quality of care.[340]

CMS currently uses quality measures to assess process and outcome data for Medicare beneficiaries in various Medicare programs such as the performance of dialysis facilities on the Dialysis Facility Compare Website.[341] Evidence-based clinical practice guidelines for dialysis patients were among the first to be created. CMS began using the practice guidelines in 1997 to develop dialysis facility performance measures with the ESRD Clinical Performance Measures (CPM) Project. This project created a data gathering and reporting system for dialysis healthcare providers that established the basis for the ESRD QIP.[342] Currently the ESRD QIP process measures are created by a clinical technical expert panel (TEP) and based on risk-adjusted observational studies that demonstrate a relationship between the quality measure and the intended health outcome.[343]

Measuring dialysis facility performance on pre-established clinical measures under the ESRD QIP is appropriate if achieving the targeted outcomes is connected to improved patient health outcomes. When the creation of the dialysis facility quality measures for public reporting was in its nascent stages, the potential quality measures being identified were obtained from published literature and a small number of patient focus groups.[344,345] Few observational studies

339 National Quality Forum, “NQF: Improving Healthcare Quality.”
340 Gupta and Wish, “Do Current Quality Measures Truly Reflect the Quality of Dialysis?”
341 Centers for Medicare and Medicaid Services, “Dialysis Facility Compare.”
342 Gupta and Wish, “Do Current Quality Measures Truly Reflect the Quality of Dialysis?”
343 Centers for Medicare & Medicaid Services, “CMS ESRD Measures Manual.”
344 Frederick et al., “Developing Dialysis Facility-Specific Performance Measures for Public Reporting.”
345 Weiner and Watnick, “The ESRD Quality Incentive Program—Can We Bridge the Chasm?”

and no randomized control trials were performed to elicit whether the ESRD QIP quality measures improve patient health outcomes.[346,347] Whether a patient's health outcome is principally a consequence of a specific quality measure is unclear because of uncontrolled extraneous factors that can influence the relationship between the quality measure and the intended outcome. Inferring causality between a process and outcome is problematic unless a randomized controlled experiment is performed.[348]

While clinical requirements are a widely accepted standard for quality, focusing on specific metrics can preclude a holistic approach to care. Caring for patients holistically involves individualized care that addresses prevention, coordination of care, rehabilitation and patient preferences. The singular needs of each patient and the collective value of care to the ESRD population is necessary to effectively evaluate the quality of care.[349] Donabedian asserts the process of interactions between patients and providers, and how providers deliver care is necessary to understand prior to attributing a value judgment about how provider interventions contribute to patient health outcomes.[350] Including individualized care and the patient-provider relationship as quality care indicators adds to the complexity of defining quality. Focusing on specific targeted measures can cause a provider to ignore other healthcare measures and prevent a holistic approach to care.[351,352]

The majority of dialysis facilities achieve the targeted quality outcomes, however, the relationship between dialysis facility performance and improved patient health outcomes remains elusive. Understanding the current state of the ESRD QIP can help critically address areas for

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[346] Fishbane et al., "Changes to the End-Stage Renal Disease Quality Incentive Program," June 2, 2012.
[347] Bothwell et al., "Assessing the Gold Standard — Lessons from the History of RCTs."
[348] McAuliffe, "Measuring the Quality of Medical Care."
[349] Donabedian, "The Quality of Care."
[350] Donabedian, "Evaluating the Quality of Medical Care."
[351] Thomson et al., "Unintended Consequences of Incentive Provision for Behaviour Change and Maintenance around Childbirth."
[352] Zamanzadeh et al., "Effective Factors in Providing Holistic Care."

improvement associated with patient satisfaction, health and cost-efficiency. To describe the various components of the ESRD QIP including exogenous factors that impact the program, provider behavior and patient health outcomes; and describe the relationships among the components, a conceptual framework is proposed.[353] See Figure 3 for Donabedian's Quality Assessment Conceptual Framework applied to the Quality Incentive Program. Informed by Donabedian's structure, process and outcomes framework for assessing quality care, this conceptual framework provides a visual description of provider, patient and system level impacts on the QIP and patient health outcomes. Donabedian's model will be useful to help identify factors affecting the success of the QIP since its implementation in 2012 when dialysis facilities began receiving penalties.

[353] Handler A, Issel M, and Turnock B, "A Conceptual Framework to Measure Performance of the Public Health System."

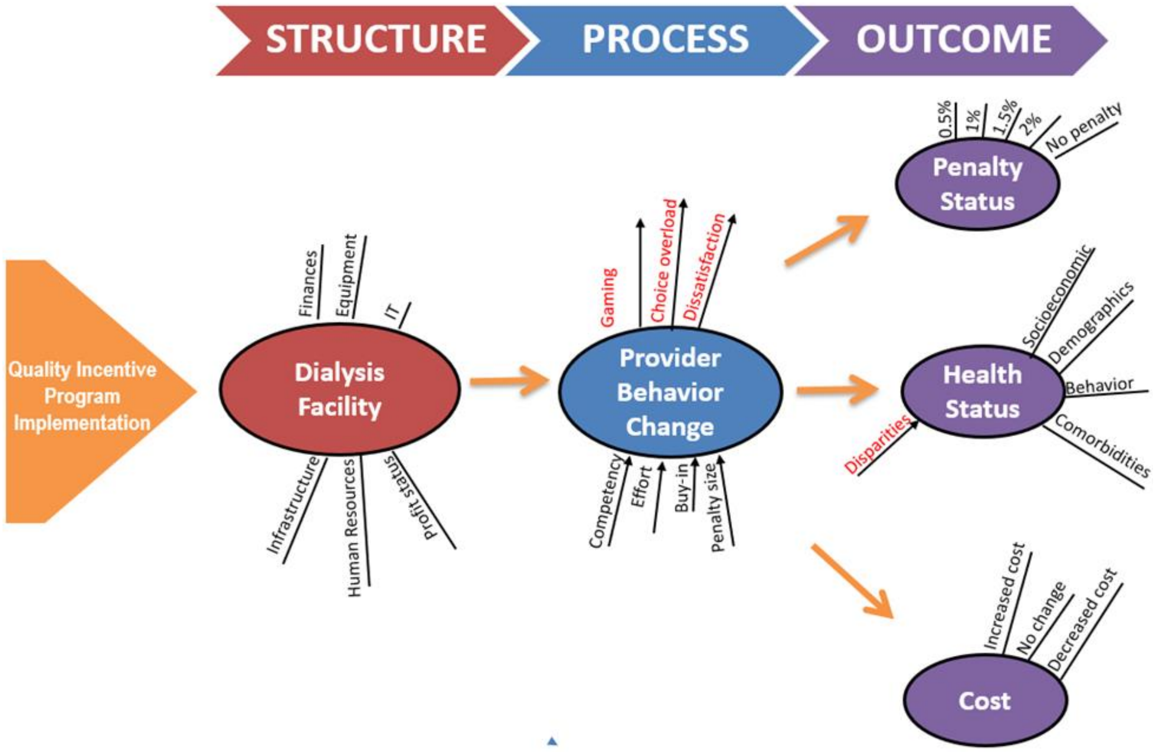

Figure 3. Donabedian's Conceptual Framework applied to the ESRD QIP
Donabedian's Structure-Process-Outcomes Paradigm[354]

Evaluating the quality of dialysis care begins with structure, which assesses the dialysis facility delivery system. Structure is the context for which dialysis care is provided, which includes the physical, social and economic environment within that system.[355] The dialysis facility provides the foundation for the QIP and involves the dialysis facility and its characteristics. This includes the financial situation of the facility, profit status, chain affiliation, dialysis facility infrastructure, equipment, human resources and the data system and technical support.[356] Infrastructure includes type of dialysis services offered, times of day the facility is open, the number of dialysis stations and the facility size in addition to hygiene, safety, and

354 Donabedian, "The Quality of Care."
355 Donabedian, "Evaluating the Quality of Medical Care."
356 Santana et al., "How to Practice Person-Centred Care."

cleanliness of the environment. This may involve waste management services and sterilization protocols.

Equipment involves available medications, medical devices and equipment in proper working condition with scheduled maintenance. Human resources include the trained medical staff that deliver dialysis care. This involves the frequency a physician visits the facility and has a patient interaction, the number of technicians and registered nurses, and the patient to provider ratio.[357] It also includes the skill level of each provider, certifications of healthcare providers and accreditation of the dialysis facility, organization and communication of training provided at the facility, and required refresher and enhancement training. The data system and technical support is the information technology system that maintains records of patient care, including incidents and accidents. It enables providers to participate in the QIP by accessing and reporting patient data to Medicare.[358] The existence of structure creates an environment where processes occur as planned.

The process context examines the provider behavior changes in his or her interaction and care delivered to the patient. The provider behavior change domain is behavior adjustments that lead to improved patient outcomes and achievement of QIP targeted measures. Provider behavior change is impacted by the degree of competency. This includes a provider's technical skill level, communication skills, knowledge of the disease, monitoring, diagnosing potential problems and proficiency with patient education. These components, including provider behavior change, can improve patient clinical outcomes and impact the effectiveness of achieving targeted performance measures. The behavior of a provider and the aim to achieve the targeted outcomes is influenced by the incentive to avoid a penalty. When an incentive is framed as a loss instead of a gain, the

[357] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[358] Rettig and Levinsky, "Structure of the Provider Community."

behavioral response is considerably different because loss aversion is significantly more preferred than securing an equivalent gain.[359] The QIP is a pay-for-performance program that endeavors to motivate providers to change behavior through a penalty-based incentive arrangement. While studies demonstrate that individuals are more responsive to economic losses than rewards, disadvantages are associated with a punitive approach and incentive designs in general.[360,361] Unintended consequences associated with provider behavior and patient outcomes occur, especially within the context of the economic behavioral structure of the QIP that is penalty based.[362]

Three major unintended consequences of the incentive program are related to provider behavior change. The first unintended consequence is provider dissatisfaction associated with external incentives weakening self-determination and professional autonomy. Dissatisfaction about being compelled to focus on specific patient targeted measures, and the time expended to collect and report those measures can impede intrinsic motivation to provide quality care. In addition, providers of penalized dialysis facilities may feel discounted and dissatisfied when compared to facilities that receive no penalty.[363,364] This may result in provider non-compliance, especially if the incentive is in the form of avoiding a penalty instead of receiving a reward.[365] Based on behavior modification social psychology, the incentive to avoid a penalty does not create new improved behavior, but informs an individual about what not to do. If a provider delivers care to a patient that results in a patient failing to achieve a targeted measure, then this

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[359] Kahneman and Tversky, “Prospect Theory.”
[360] Matjasko et al., “Applying Behavioral Economics to Public Health Policy.”
[361] Kahneman and Tversky, “Prospect Theory.”
[362] Marcotte et al., “Into Practice.”
[363] Freedman and Murea, “Target Organ Damage in African American Hypertension.”
[364] Eijkenaar, “Key Issues in the Design of Pay for Performance Programs.”
[365] Rosenthal and Frank, “What Is the Empirical Basis for Paying for Quality in Health Care?”

decreases the likelihood that in the future the provider will engage in the specific behavior that was associated with the patient not achieving the targeted measure.[366]

While a provider may avoid a behavior that causes a penalty, this assumes that a causal relationship exists between specific provider behaviors and patients' achieving targeted measures. The incentive program design depends on an imperfect gauge of the degree of effort and quality attributed by the provider that is associated with achieving a targeted measure. Other factors, such as patient and dialysis facility level characteristics, contribute to achieving targeted measures.[367] While the QIP places the responsibility of achieving patient targeted measures on the provider, patients play a role in the status of their health and subsequent clinical outcomes. For example, home medication adherence, adequate physical activity, proper diet, and risk-modification behaviors such as avoidance of smoking and drinking alcohol impact dialysis patient functionality, quality of life and clinical outcomes.[368,369,370,371] Provider interventions can encourage healthy behaviors, however patients who participate in risky behaviors can negatively impact achieving targeted clinical measures. Failure to achieve targeted measures and being forced to focus on specific measure outcomes can be associated with provider dissatisfaction.

A study of over 10,000 dialysis patients from 173 geographically varied dialysis facilities throughout the United States examined the influence of provider versus patient characteristics in the targeted urea reduction ratio (URR) of $\geq$65%, which is a QIP measure. Patient factors were found to account for 88% of the variance, while provider factors accounted for 12% of the variance in attaining the URR targeted outcome. The most significant factor associated with failing to attain $\geq$65% was patient nonadherence related to dialysis treatment shortening time.

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[366] Martin and Pear, *Behavior Modification*, 122–30.
[367] Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
[368] Adams, "Improving Health Outcomes with Better Patient Understanding and Education."
[369] Johansen, "Exercise in the End-Stage Renal Disease Population."
[370] Tsuruya et al., "Dietary Patterns and Clinical Outcomes in Hemodialysis Patients in Japan."
[371] Liebman et al., "Smoking in Dialysis Patients."

Other nonadherence factors related to URR target measure achievement were increased weight gain between dialysis sessions, poor phosphorus control and skipping dialysis treatments. In addition, dialysis patients who frequently shortened their dialysis treatment time were more likely to be young African American men with greater body surface area.[372] This study demonstrates that specific provider behaviors cannot be easily attributed to attaining the URR targeted measure designated by the QIP. When a patient outcome is not easily attributable to a provider behavior, then differences in patient outcomes cannot be attributable to differences in provider behavior.[373] Being held accountable for patient characteristics that are not modifiable by provider intervention can lead to unjustifiably penalizing providers for caring for more vulnerable patients who fail to achieve targeted measures.[374] Unfair penalizing and the burden of participating in the incentive program can bring about provider dissatisfaction.

A second provider category of negative unintended consequences is gaming, which occurs when providers manipulate the process of achieving a targeted measure without actually attaining the desired goal. For example, a provider may underperform during the comparison period to have an artificially low threshold during the performance period. A provider may also miscode a healthcare service, which can negatively impact quality of care by ignoring the opportunity to address poor quality of care.[375] Gaming can also involve the selection of patients based on the probability that the patient will achieve the targeted measures. Younger healthier patients are more likely to achieve targeted measures and therefore "cherry-picking" patients who are more likely to have better clinical health outcomes is a potential problem. Dialysis providers may try to protect themselves from older sicker dialysis patients by appealing to younger and

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[372] Tangri et al., "Both Patient and Facility Contribute to Achieving the Centers for Medicare and Medicaid Services' Pay-for-Performance Target for Dialysis Adequacy."
[373] Baker and Chassin, "Holding Providers Accountable for Health Care Outcomes."
[374] Tangri et al., "Both Patient and Facility Contribute to Achieving the Centers for Medicare and Medicaid Services' Pay-for-Performance Target for Dialysis Adequacy."
[375] Rosenthal and Frank, "What Is the Empirical Basis for Paying for Quality in Health Care?"

healthier patients. In a national survey of dialysis healthcare providers prior to the implementation of the QIP, most respondents reported that they perceived cherry-picking to be a common practice in the dialysis population.[376] The preferred type of patient is compliant with diet and exercise, has less comorbidities, is younger and has private insurance.[377] While this was a perception of cherry-picking and not a reality, incentive programs such as the QIP create an environment that may incentivize providers to select patients who are more likely to achieve the targeted measures. The selection of younger healthier patients is problematic because it can decrease health benefits for the collective dialysis population.[378]

The third main provider unintended consequence is the problem of choice overload and multitasking. Avoidance of a penalty may cause a provider to disregard unmeasured clinical outcomes.[379] In an effort to achieve the targeted measures, the provider may focus only on achieving targeted measures while neglecting other aspects of care. The incentive to attain specific process measures can preclude improving overall patient health outcomes and quality of life, safe delivery of care, and patient satisfaction with health services rendered.[380] Neglect of patient-centered care can be exacerbated, when additional targeted measures are required. As the number of targeted measures increases, the significance a provider places on each measure is diminished. If the impact of a measure or measures on the total performance is considered to be inconsequential, then provider effort may be deficient and patient outcomes may not improve.[381]

The targeted measures in the QIP have increased significantly, the scoring system has become more complicated and the method for reporting is more time consuming. Whether the 2% payment reduction maximum that is given two years after the provider delivers care has been

[376] Desai et al., “Is There ‘Cherry Picking’ in the ESRD Program?”
[377] Desai et al.
[378] Rosenthal and Frank, “What Is the Empirical Basis for Paying for Quality in Health Care?”
[379] Rosenthal and Frank.
[380] Smoldt and Cortese, “Pay-for-Performance or Pay for Value.”
[381] McDonald et al., “Chapter 2: Literature Review and Conceptual Framework.”

sufficient to change behavior is unclear.[382,383] The provider may be less inclined to achieve targeted measures when multiple measures exist and the penalty is not delivered immediately following the behavior. A penalty is more likely to be effective if it targets a specific behavior instead of various behaviors, and is delivered immediately following the behavior. The less time between the behavior and the penalty, in addition to the degree of the penalty is associated with more likelihood of behavior change.[384] The QIP maintains the provider behavior change can foster improved clinical outcomes. However, unintended consequences associated with provider behaviors remains a major area of conflict within the incentive program.[385]

Provider behavior and clinical activities that comprise the process construct are followed by the outcome, which is the third construct from which implications can be formulated regarding quality of care for the QIP. Figure 1 identifies three outcome domains: the penalty status which indicates whether the dialysis facility achieved the patient targeted measures; cost of care which indicates whether the QIP initiative has been cost-effective; and health status which indicates how the QIP has impacted patient health outcomes.[386] Quantifying the components of the outcome measures includes the consideration of patient characteristics, which impact patient health outcomes. The age of a patient, behavioral risks, physical attributes, morbidity, socioeconomic status, compliance with diet and medications, race, ethnicity and patient preference collectively impact clinical health outcomes.[387,388,389] Various studies have demonstrated that patient determinants can impact clinical outcomes independent of provider interventions. For example,

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382 Schiller, "The Medical Director and Quality Requirements in the Dialysis Facility."
383 Fishbane et al., "Changes to the End-Stage Renal Disease Quality Incentive Program," June 2, 2012.
384 Martin and Pear, *Behavior Modification*, 122–30.
385 Thomson et al., "Unintended Consequences of Incentive Provision for Behaviour Change and Maintenance around Childbirth."
386 Christianson, Leatherman, and Sutherland, "Financial Incentives, Healthcare Providers and Quality Improvements: A Review of the Evidence."
387 Krousel-Wood, "Practical Considerations in the Measurement of Outcomes in Healthcare."
388 Nocella et al., "Structure, Process, and Outcomes of Care in a Telemonitoring Program for Patients with Type 2 Diabetes."
389 Donabedian, "The Quality of Care."

patient age and comorbidity status are associated with poor survival, and African Americans are more likely to have lower URRs, which is a targeted measure.[390,391] Another study demonstrated that older age, poverty level and lower education levels are sociodemographic factors associated with overall poor performance on dialysis clinical outcomes.[392] Dialysis patient health outcomes are expected to improve when the QIP targeted outcomes are achieved.[393] However, the health outcomes of patients are frequently shaped by factors independent of provider control. While outcome measures ultimately validate the effectiveness of the QIP, identifying whether a provider behavior directly affects a patient outcome can be challenging.

A major unintended consequence of the incentive program that impacts patient outcomes is the exacerbation of existing patient disparities. Achieving targeted measures can depend on patient characteristics and can be challenging for providers with certain mixes of patients. For providers with patients who are more disadvantaged and have lower baseline outcomes, more work is required to achieve the targeted measures. Focusing on targeted measures and ignoring patient care that is not measured can potentially increase disparities for those conditions in patients needing the most comprehensive disease management.[394] In addition, providers that receive payment reductions for patients not achieving targeted measures may be in most need of more financial resources. Reducing payment to providers with vulnerable populations can increase health care disparities.[395] Studies evaluating ESRD QIP have demonstrated that disparities amongst the ESRD population may be increasing. Dialysis facilities receiving a

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[390] Lowrie et al., "The Urea [Clearance x Dialysis Time] Product (Kt) as an Outcome-Based Measure of Hemodialysis Dose."
[391] Roy et al., "Evaluation of Unplanned Dialysis as a Predictor of Mortality in Elderly Dialysis Patients."
[392] Zaslavsky et al., "Impact of Sociodemographic Case Mix on the HEDIS Measures of Health Plan Quality."
[393] Handler A, Issel M, and Turnock B, "A Conceptual Framework to Measure Performance of the Public Health System."
[394] Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
[395] Friedberg et al., "Effects of Health Care Payment Models on Physician Practice in the United States."

payment reduction were more likely to be poorer and in African American neighborhoods.[396,397] For the socioeconomically disadvantaged, disparities can be exacerbated in the environment of an incentive program, especially if cherry-picking exists and fewer financial resources are given to facilities with the most vulnerable patients.[398]

Policy Implications

The ESRD QIP is a value-based program that rewards a dialysis provider with an incentive payment and is part of Medicare's larger reform efforts to pay providers for quality rather than quantity. Soon after the ESRD QIP was implemented, Medicare echoed these efforts in hospitals, nursing facilities, home health and physician groups. These domains of care now employ value-based programs, and similar to the ESRD QIP, Medicare maintains that the payment model will reduce costs and improve patient outcomes.[399] As value-based programs become more widespread, examining the evidence of data collected is critical to understanding whether such a program improves care and reduces costs.

With pressure to reduce costs and improve quality care from a growing number of ESRD patients, federally sponsored healthcare incentive programs have been increasingly common within the United States and across different countries. While differences in per ESRD patient spending have shown to be negligible and associated with each country's overall per person healthcare expenditures, the small variations in costs and patient outcomes were not correlated with the type of incentive program employed in each country.[400] Similar to the literature on incentive programs in the United States, Canada has demonstrated no clear evidence that these

[396] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[397] Saunders and Chin, "Variation in Dialysis Quality Measures by Facility, Neighborhood, and Region."
[398] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[399] Centers for Medicare & Medicaid Services, "Value Based Programs."
[400] Dor et al., "End-Stage Renal Disease and Economic Incentives."

type of programs cost-effectively deliver better care. In addition, the incentive programs are believed to contribute to an increased risk of poor outcomes for vulnerable populations.[401,402]

Patients are not uniformly distributed at each facility and providers treating sicker patients may be delivering quality care but unable to achieve the targeted measures. Providers treating sicker patients are more likely to be financially penalized even though these sicker patients have a greater need for more resources, not less.[403] While risk adjustment lessens the impact of potential adverse selection, it can be complex for providers to incorporate and may not be enough inducement to deter providers from selecting healthier patients.[404] Risk adjustment is not widespread as the United States and the United Kingdom use other approaches to allow providers an equal chance at successfully achieving the targeted measures. The ESRD QIP excludes patients based on certain characteristics, such as age, and the United Kingdom allows patients who are non-compliant to be omitted.[405,406] In addition, literature reviews on both country's incentive programs have revealed similar results. The extent of research on the topic is limited and neither countries demonstrate an association between the incentive program and improved patient outcomes.[407,408]

The ESRD QIP has taken important steps to assess and report on dialysis quality of care, however, the extant literature on the impact of the program is lacking. Analysis of dialysis facility, health outcomes of different age groups and program expenditures from QIP inception to the current year has not been performed. This is important because research has demonstrated that

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401 Kyeremanteng et al., "An Analysis of Pay-for-Performance Schemes and Their Potential Impacts on Health Systems and Outcomes for Patients."
402 Eijkenaar, "Key Issues in the Design of Pay for Performance Programs."
403 Eijkenaar.
404 Christianson, Leatherman, and Sutherland, "Financial Incentives, Healthcare Providers and Quality Improvements: A Review of the Evidence."
405 Eijkenaar, "Key Issues in the Design of Pay for Performance Programs."
406 Centers for Medicare & Medicaid Services, "CMS ESRD Measures Manual."
407 Christianson, Leatherman, and Sutherland, "Financial Incentives, Healthcare Providers and Quality Improvements: A Review of the Evidence."
408 Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"

population-based healthcare interventions increase disparities for the population subset that is at higher risk for adverse health outcomes. The elderly patients are a vulnerable subset of the ESRD population, and whether the QIP adversely impacts this segment of the population is unknown. Research has demonstrated that healthcare utilization and cost vary for different age groups with older ESRD patients having the highest expenditures. Given both the high cost of ESRD treatment for dialysis patients to the federal government and the significant toll it takes on the health of older adults, research to better understand how the QIP affects older versus younger ESRD patients is needed. This problem has important implications regarding policies that direct individualized treatment strategies and patient centered decision-making for the elderly. As the ESRD QIP continues to expand, it is critical to understand whether the targeted measures are cost-efficiently improving patient health outcomes across all age groups.

CHAPTER THREE

Introduction

The End Stage Renal Disease (ESRD) Program is a federal health insurance program for individuals suffering from ESRD. According to the Centers for Medicare and Medicaid Services (CMS), the objectives of the program are designed to encourage self-care dialysis and kidney transplantation and clarify reimbursement procedures to achieve effective cost control.[409] Under the ESRD Program, the ESRD Quality Incentive Program (QIP) was created to target delivery of care improvements in outpatient dialysis facilities. The care of ESRD patients in outpatient dialysis facilities have been historically problematic. As the most-costly aspect of the ESRD Program with numerous reports of poor patient care, dialysis facility services have been identified as areas in need of improvement. In response to these issues, the ESRD QIP was established.[410,411,412]

The ESRD QIP is the first federally mandated pay-for-performance program that links reimbursement to a dialysis facility's performance on patient targeted measures by reducing payments to dialysis facilities that fail to comply with these performance standards.[413] In evaluating the incentive program, collecting and analyzing the best research information that exists can help inform actions taken in the health policy-making setting. As an effective decision-making tool, a systematic review is an important instrument to methodically summarize the

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[409] Centers for Medicare & Medicaid Services, "ESRD General Information | CMS."
[410] Office of the Inspector General, "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs."
[411] Brown, "External Quality Review of Dialysis Facilities: A Call For Greater Accountability."
[412] Nobahar and Tamadon, "Barriers to and Facilitators of Care for Hemodialysis Patients; a Qualitative Study."
[413] Centers for Medicare and Medicaid Services, "ESRD Quality Incentive Program Overview."

evidence of this health policy.[414] Therefore, the objective of this chapter is to critically evaluate and synthesize the literature that evaluates the ESRD QIP. Whether the program has been successful at achieving its goals of cost-effective quality care is unknown, and therefore a systematic review of the program is timely and relevant.

Objectives

The aim of this review is to critically evaluate and synthesize the ESRD QIP literature to examine whether the program has been successful at achieving its goals of cost-effective quality care. The following are key questions from which the literature was sought:

- What are the facility and neighborhood characteristics of high and low performing dialysis facilities?
- What is the impact of the ESRD QIP program on targeted? Are changes in patient outcomes attributed to the program?
- What is the impact of the ESRD QIP program on non-targeted patient outcomes? Are changes in patient outcomes attributed to the program?

Methods

Eligibility criteria, information sources and search strategy

A systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines was conducted.[415] In December 2019, a comprehensive search of PubMed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science (Clarivate) and Google Scholar was performed. Study selection criteria was determined a priori and included manuscripts limited to the English language and empirical

[414] Gopalakrishnan and Ganeshkumar, "Systematic Reviews and Meta-Analysis."
[415] Liberati et al., "The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Healthcare Interventions."

studies from 2012 to the present. This timeframe was selected because in the ESRD QIP was implemented in January of 2012.

Exclusion criteria included: news articles; books; letters; commentaries; opinion pieces and proposals. Retained articles included peer-reviewed studies that examine the relationship between any of the following: dialysis facilities, dialysis providers, QIP measures and patient outcomes. Observational study designs, before-and-after studies, prospective and retrospective cohort studies, cross-sectional and longitudinal studies will also be considered for inclusion. Reference lists of the retained articles were also screened to identify additional relevant articles to be included in this review. In order to capture the status of the ESRD QIP, articles not involving an empirical evaluation of the ESRD QIP were excluded. A Health Science Librarian specialist provided support for the development of this search strategy to confirm the most comprehensive key terms were used. The full search strategy for each database can be found in Table 2.

Table 2. Search Strategy

Database	Search Terms	Output
CINAHL (EBSCOhost)	((((((("incentive*") OR "incentive program")) AND (("dialysis") OR "hemodialysis")) AND (("end stage renal disease") OR "kidney failure"))) OR ((((("end stage renal disease quality incentive program") OR "end stage renal disease quality incentive") OR "esrd qip") OR "esrd quality incentive") OR "esrd payment system")))	53
Web of Science	((((((("incentive*") OR "incentive program")) AND (("dialysis") OR "hemodialysis")) AND (("end stage renal disease") OR "kidney failure"))) OR ((((("end stage renal disease quality incentive program") OR "end stage renal disease quality incentive") OR "esrd qip") OR "esrd quality incentive") OR "esrd payment system")))	40
PubMed	"hemodialysis")) AND (("end stage renal disease") OR "kidney failure"))) OR ((((("end stage renal disease quality incentive program") OR "end stage renal disease quality incentive") OR "esrd qip") OR "esrd quality incentive") OR "esrd payment system"))) OR (((("Kidney Failure, Chronic"[Mesh]) OR "Renal Dialysis"[Mesh])) AND "Reimbursement, Incentive"[Mesh])	72
Google Scholar	"End Stage Renal Disease Quality Incentive Program" -"federal register"	117

Data collection process

Data was managed using Zotero software (Version 5.0.76). All references were imported into Zotero and duplicates were removed. All abstracts and titles were screened to check for inclusion agreement and articles. Articles considered potentially relevant were retrieved and the full text was read. These full text articles were assessed for eligibility and carefully reviewed to checked against the inclusion criteria. After this screening, the remaining articles were extracted into an excel data-extraction sheet by author, date, purpose, sample size, methods, results, discussion and limitations. After identifying the articles to be included in the review, all publications by each author were screened to ascertain additional articles for inclusion.

Quality Assessment

To evaluate the reliability of the articles retained, the Appraisal tool for Cross-Sectional Studies (AXIS) was used to evaluate the study design, risk of bias and reporting quality. The twenty-item tool, which follows a "yes," "no," or "do not know/comment" scoring system, assisted with the systematic interpretation of each article. For each of the twenty questions, contextual information is provided to enable a clear understanding of each questions importance in evaluating the article. AXIS is a guide for appraising each study based on the following items: clarity of aims; study design appropriateness; sample size justified; target population defined and sampling frame representative of target population; selection bias and non-responders addressed; measurement validity and reliability achieved; study design appropriate and sufficiently described; comprehensive description of results, including internal consistency; discussions and conclusion justified; and limitations and conflicts of interest addressed.[416] Scoring of the twenty-item tool responses was divided into four equal segments. The highest score corresponds to >15 of the criteria achieved, the second highest score corresponds to 11-15 of the criteria achieved;

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[416] Downes et al., "Development of a Critical Appraisal Tool to Assess the Quality of Cross-Sectional Studies (AXIS)."

the next lowest score corresponds to 6-10 of the criteria achieved; and the lowest score corresponds s to 1-5 of the criteria achieved. Using AXIS, I appraised and recorded the score of each article. To ensure intra-reliability, assessments of the manuscripts were performed three times at different points in time to ensure consistency in ratings.

Results

Study selection

The combined output from CINAHL, Web of Science, PubMed and Google Scholar was 252 articles. One article was ascertained through scanning the reference list of a retained article. Once duplicate articles were removed, 108 articles remained and were screened. Of those articles, 43 were excluded because they were non-empirical and/or did not include the topics of dialysis facilities, dialysis providers, QIP measures or patient outcomes. Themes of the excluded articles that were non-empirical included chronic kidney disease care, the validity of the ESRD QIP quality measures, inequities in dialysis care, nephrologists' opinions about dialysis care goals, non-ESRD QIP policy changes for dialysis care, and ESRD QIP payment rule changes. Empirical studies that were excluded addressed undocumented immigrants, economic evaluations of pre-ESRD care, pre-dialysis care clinical outcomes, dialysis pay for performance programs in countries outside of the United States, and Medication reimbursement policy for dialysis patients.

After the 43 articles were excluded, 65 articles remained for full-text screening. Of those 65 articles, 54 were excluded because they were not empirical research evaluating the ESRD QIP. For example, one article included empirical research about a dialysis patients' targeted weight achievement. However, this is not an ESRD QIP measure, nor does it evaluate how weight achievement is related to the ESRD QIP.[417] After removing those 54 articles, a total of 11 articles

[417] Flythe, Assimon, and Overman, "Target Weight Achievement and Ultrafiltration Rate Thresholds."

satisfied the criteria for inclusion. See Figure 3, which displays a graphical representation of the process using a PRISMA flow diagram.

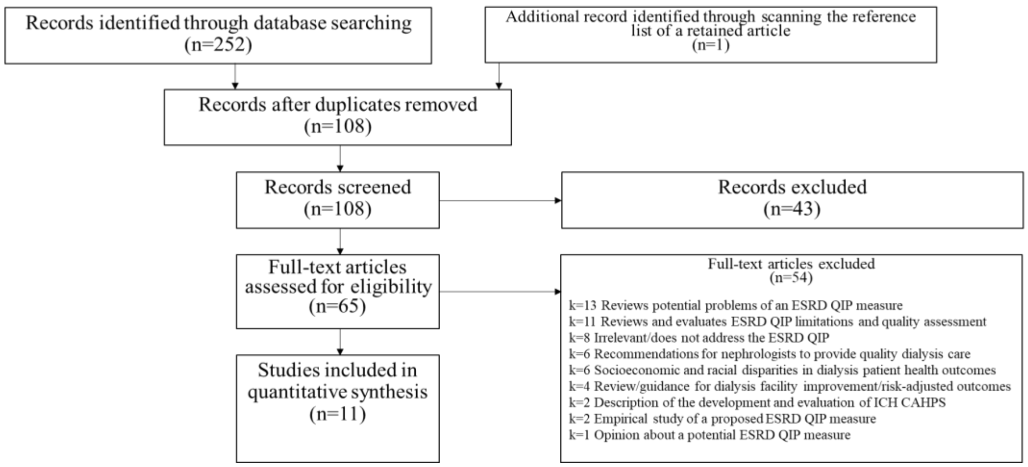

Figure 4. Prisma Flow Diagram

Study characteristics

All studies employed a cross-sectional design; therefore, AXIS was an appropriate tool to evaluate the reliability of the studies retained. These studies included regression analyses, spatial autocorrelation, econometric analyses, Spearman's correlation coefficient, chi square, Wilcoxon and t tests. Table 3 provides a summary of the 11 included studies.

Table 3. Summary of Included Studies

Authors	Purpose	Study Design	Total Sample Size	Results

Ajmal et al. (2019)	To examine the association between freestanding dialysis facility size and QIP scores.	Cross-sectional analysis comparing 2015 QIP scores across levels of facility size adjusting for facility, patient and community characteristics.	5,193 dialysis facilities	Facilities achieving higher QIP scores: operating >10 dialysis stations than those operating fewer; South & NE; not offering peritoneal dialysis; affiliated with chains; spending more hours per dialysis session; higher proportion of Hispanic patients; patients with access to pre-end-stage renal disease nephrologist care. Facilities scoring lower: higher African American patient population; higher patient travel distances.
Almachraki et al. (2016)	To compare the relationship between dialysis facility SES (poverty and rurality), performance and provider type (chain size and tax status).	Spatial autocorrelation was calculated for each county to determine if poverty in a given county was concentrated or an outlier; chi square tests for categorical data; adjusted logistic regression.	6,506 dialysis facilities	ESRD QIP penalties varied as a function of poverty and facility setting. Large dialysis organizations account for a disproportionate fraction of facilities serving patients in rural and high-poverty areas.

Bao et al. (2017)	To identify facility characteristics & practice patterns and their association with QIP measures and hospitalization risk	Econometric analyses to estimate the association between facility characteristics & practice patterns and their association with dialysis process measures & hospitalization risk. Performed Seemingly Unrelated Regression estimations of QIP measures against practice patterns with facility characteristics as controls.	4,571 dialysis facilities with 4,758 facility level observations for 2012 and 5,006 facility level observations for 2013	Dialyzer reuse is positively associated with QIP measures and greater hospitalization risk. Late shifts lower levels of dialysis adequacy and higher hospitalization risk. A higher nurses-to-patient ratio improves anemia management, whereas higher physician-to-patient ratio increases the likelihood of poor anemia control. Station-to-patient ratio improves dialysis adequacy and hospitalization risk.
Brady et al. (2018)	To explore the association between dialysis facility ICH CAHPS scores from 2015-16 and patient, facility & geographic characteristics.	Cross-sectional analysis/ multivariable mixed effects linear regression models with geographic random effects used to examine associations of ICH-CAHPS scores with patient/dialysis facility/ geographic characteristics and to identify the amount of total between-facility variation in ICH CAHPS scores explained by these categories.	2,939 dialysis facilities	For-profit operation, free-standing status, and large dialysis organization designation were associated with less favorable patient-reported experiences of care (ICH CAHPS scores). Patient experience scores varied geographically, and African American and Native American populations report

				less favorable experiences.
Dad et al. (2018)	To explore patient characteristics associated with non-response to the ICH CAHPS survey administered in 2012.	Cross-sectional analysis using multivariable logistic regression models predicting non-response.	213 Dialysis Clinic Inc. facilities; 3,369 patients completed the survey and 5,372 patients were non-responders.	Non-responders were more likely to be men, non-white, younger, single, dual Medicare/ Medicaid eligible, less educated, non-English speaking, inactive on the transplant list, longer ESRD vintage, lower BMI, lower serum albumin, worse functional status, more hospitalizations, more missed treatments, more shortened treatments.

Kshirsager et al. (2017)	Examine the association of area-level poverty, race and ethnicity with dialysis clinic star ratings & QIP Total Performance Score.	Ordered logistic regression for star ratings and linear regression for the QIP. Spearman's correlation coefficient between star rating and QIP score.	6,032 dialysis facilities	Lower star ratings are associated with the proportion of individuals of African American race and geographic region (NE). Minimal influence on the rating included poverty, Hispanic, profit status and size of clinic. Star ratings and QIP Scores similar results.
Kshirsager et al. (2018)	Examine the relationship of ICH-CAHPS survey results with QIP scores & star ratings for dialysis clinics in 2016.	Used ICH-CAHPS domains as independent variables in separate regression models; calculated odds ratios from ordered logit model for star ratings, calculated β coefficients from linear regression model for QIP. Analyses repeated using 2015 data to check consistency/ robustness of the findings.	3,176 dialysis facilities	Positive association between ICH CAHPS Scores and QIP Scores & Star ratings. ICH-CAHPS domains pertaining to the dialysis facility/transmission of information had greater strength of association than domains related to nephrologist satisfaction.
Kutner et al. (2017)	Investigate depression scores & 4 QIP measures in relation to ability to work reported by a cohort of working-age individuals receiving outpatient dialysis.	Observational study using medical record reviews and patient interviews; Chi-square test for categorical variables and t-test or Wilcoxon test for continuous variables.	14 Dialysis facilities; 528 working age dialysis patients (patient baseline data from 2009-11)	Prevalence of depression was higher among patients who said they were not able to work. The proportions of patients who met the QIP targets (Kt/V, Hgb, mineral metabolism) were similar regardless

				of whether the patients reported they could work or not work. Catheter use and depression were frequent among patients not able to work.
Qi et al. (2019)	Evaluate differences in characteristics between facilities that received a 2018 QIP penalty & those that did not. Determine if facility performance is associated with race/ ethnicity/Medicaid enrollment/median neighborhood household income/ rurality.	Cross sectional data. Multivariable linear regression to evaluate facility demo-graphics/neighborhood qualities and performance score. Multivariable logistic regression to examine relationship between these predictors and receiving a penalty.	6,314 Dialysis Facilities	Facilities located in zip codes with low median household income and serving high proportions of African American or dually enrolled patients had poorer QIP performance.
Saunders et al. (2017)	Examine association of dialysis facility qualities with 2012 QIP payment reductions & change in performance measures to determine the programs potential impact on dialysis care quality and disparities.	Cross sectional data. Generalized linear mixed effects model to examine associations between each outcome & facility quality: facility type, length of operation, # of stations/neighborhood/ demographic (% African American and % of population below FPL).	5,089 Dialysis Facilities	Large improvement in anemia management. Facilities in largely African American communities had greatest reduction in % of patients overtreated for anemia and a modest increase in % of patients with adequate dialysis. Despite this, these communities had lower performance

				scores. For profit facilities were less likely to receive a payment reduction and less likely to be in the largest payment reduction group.
Zhang et al. (2016)	Examine the association between 2014 facility QIP Scores and facility/ neighborhood/region-related factors.	Multiple linear regression used to describe the association between facility score and facility/ neighborhood/ region covariates.	4,086 Dialysis Facilities	No significant association between performance (QIP Scores) & poverty. Neighborhoods with higher proportion of African Americans have significantly lower scores. For-profit facilities have higher scores than nonprofit facilities. Large size facilities have lower scores. West region has the highest scores. Facilities in the NE region had the worst scores.

Of the eleven studies, nine studies addressed patient, facility, neighborhood and/or regional characteristics associated with a dialysis facility's ESRD QIP performance outcomes. The outcome variables were individual targeted measures and total performance score or penalties incurred.[418,419,420,421,422,423,424,425,426] Three studies examined challenges with ICH CAHPS. One of those studies assessed the association of ICH CAHPS with the ESRD QIP Total Performance Score, and two of the studies evaluated the association of ICH CAHPS with patient, facility and neighborhood characteristics.[427,428,429] One of 11 studies assessed the relationship between ESRD QIP measures and the perceived ability of dialysis patients to work.[430]

AXIS Critical Appraisal

After employing the critical appraisal tool to measure the quality of the cross-sectional studies that evaluated the ESRD QIP, manuscripts were found to have various strengths and weaknesses, including a variety of analytic designs of varying methodological rigor. See Table 4 for the 20-item tool and percent of manuscripts attaining each criterion.

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[418] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[419] Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
[420] Bao and Bardhan, "Antecedents of Patient Health Outcomes in Dialysis Clinics: A National Study."
[421] Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
[422] Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
[423] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
[424] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[425] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[426] Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."
[427] Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
[428] Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
[429] Kshirsagar et al., "Patient Satisfaction Is Associated with Dialysis Facility Quality and Star Ratings."
[430] Kutner and Zhang, "Ability to Work among Patients with ESKD."

Table 4. Percent of Articles Meeting AXIS Criteria

Q	AXIS criteria	% (n) meeting criteria
	Introduction	
1	Were the aims/objectives of the study clear?	91% (10)
	Methods	
2	Was the study design appropriate for the stated aim(s)?	100% (11)
3	Was the sample size justified?	91% (10)
4	Was the target/reference population clearly defined? (Is it clear who the research was about?)	91% (10)
5	Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	82% (9)
6	Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	73% (8)
7	Were measures undertaken to address and categorise non-responders?	36% (4)
8	Were the risk factor and outcome variables measured appropriate to the aims of the study?	82% (9)
9	Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	100% (11)
10	Is it clear what was used to determine statistical significance and/or precision estimates? (e.g. p-values, confidence intervals)	100% (11)
11	Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	100% (11)
	Results	
12	Were the basic data adequately described?	100% (11)
13	Does the response rate raise concerns about non-response bias? *	9% (1)
14	If appropriate, was information about non-responders described?	55% (6)
15	Were the results internally consistent?	92% (10)
16	Were the results presented for all the analyses described in the methods?	100% (11)
	Discussion	
17	Were the authors' discussion and conclusions justified by the results?	73% (8)
18	Were the limitations of the study discussed?	82% (9)
	Other	
19	Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results? *	46% (5)
20	Was ethical approval or consent of participants attained?	100% (11)

*These questions are reverse coded ('No' response to the question equates to the criteria being met)

Nine manuscripts were assessed to be high-quality studies with scores >15.[431, 432, 433,434,435,436,437,438,439] Two studies were assessed to be of moderate quality with scores between 10

431 Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
432 Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
433 Bao and Bardhan, "Antecedents of Patient Health Outcomes in Dialysis Clinics: A National Study."
434 Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
435 Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
436 Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
437 Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
438 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
439 Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."

and 15.[440,441] Two of the manuscripts scored “yes” to all items, and the lowest scoring studies answered “yes” to 11 of the items. All of the studies answered “yes” to 7 of the items. These included: appropriate study design; risk factors and outcome variables measured correctly; statistical significance clarified; methods sufficiently described; data described; results presented for analyses described; and ethical approval obtained.

The items least frequently attained included criteria addressing non-responders. These seven studies used secondary data analysis, and one of those studies used primary data analysis.[442,443,444,445,446,447,448] Non-response items are important because dialysis facilities failing to submit ESRD QIP data may have patients from a particular subset of the dialysis population, which can transfer baseline data away from that subset and provide an inaccurate representation of the target population.[449] Qi et al extracted data from 6,825 dialysis facilities and arrived at a sample size of 6,314 facilities because 276 dialysis facilities not receiving a performance score under the ESRD QIP were either too small or too new to receive a score, and 235 dialysis facilities had missing data among key predictors.[450]

While an interpretation of the results did not describe those dialysis facilities without data, the rate of dialysis facilities without performance scores was low and would most likely not result in a baseline data shift.[451] However, missing data from the In-Center Hemodialysis

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440 Kshirsagar et al., “Patient Satisfaction Is Associated with Dialysis Facility Quality and Star Ratings.”
441 Kutner and Zhang, “Ability to Work among Patients with ESKD.”
442 Ajmal et al., “Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores.”
443 Almachraki et al., “Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers.”
444 Brady et al., “Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System.”
445 Kshirsagar et al., “Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings.”
446 Kshirsagar et al., “Patient Satisfaction Is Associated with Dialysis Facility Quality and Star Ratings.”
447 Kutner and Zhang, “Ability to Work among Patients with ESKD.”
448 Zhang, “The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region.”
449 Downes et al., “Development of a Critical Appraisal Tool to Assess the Quality of Cross-Sectional Studies (AXIS).”
450 Qi, Butler, and Joynt Maddox, “The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program.”
451 Downes et al., “Development of a Critical Appraisal Tool to Assess the Quality of Cross-Sectional Studies (AXIS).”

Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS), an ESRD QIP clinical measure, demonstrates that specific groups of patients are more or less likely to complete the survey. Brady et al. found that patients with multiple comorbidities, immobility, private insurance and Medicaid eligibility were more likely to have missing ICH CAHPS scores.[452] Concerns of differences between dialysis facility patients who complete and do not complete the ICH CAHPS survey led Dad et al. to examine non-response bias and generalizability of the survey tool. Dad et al. found that men, non-white, younger, single, dual eligible for Medicare and Medicaid and less educated were more likely to be non-responders.[453]

One of the studies has a sample size that was not sufficiently large to estimate the prevalence of the conditions of interest with adequate precision. In this study, Kutner et al. explored depression scores and ESRD QIP clinical measures in relation to the ability work.[454] Two of the eleven studies used primary data analysis and secondary analysis,[455,456] and nine of the studies performed secondary analysis using previously collected data from USRDS and CMS. The facility level data which CMS publicly provides aims to be a total population sampling, which helps generate analytic findings that are more generalizable and less of a likelihood for sampling bias.[457] These nine studies also used neighborhood level data by zip code to elicit patient characteristics such as race or socioeconomic status. Using zip code area as a proxy for the dialysis facility patient population characteristics may not be an accurate reflection of the

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452 Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
453 Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
454 Kutner and Zhang, "Ability to Work among Patients with ESKD."
455 Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
456 Kutner and Zhang, "Ability to Work among Patients with ESKD."
457 Boo and Froelicher, "Secondary Analysis of National Survey Datasets."

dialysis facility patients. Zip codes can be economically and ethnically very diverse, and may lead to false assumptions about facility characteristics.[458,459]

The Kutner et al. study, which was the lowest scoring on the AXIS criteria tool, performed medical record reviews and patient interviews on 528 dialysis patients to elicit how ESRD QIP targeted measures are associated with ability to work. However, the study did not address non-responders or limitations.[460] The Dad et al. study examined medical records and patient surveys associated with non-response to the ICH CAHPS to elicit whether non-responders differ from responders. To account for missing data, the researchers performed sensitivity analyses using multiple imputation of missing covariates.[461] In addition, five of the studies reported a conflict of interest, which was disclosed as funding from or an employee of a large dialysis facility company. See Table 5 for each manuscripts' individual evaluations.

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458 Gottlieb, Francis, and Beck, "Uses and Misuses of Patient- and Neighborhood-Level Social Determinants of Health Data."
459 Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
460 Kutner and Zhang, "Ability to Work among Patients with ESKD."
461 Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."

Table 5. Appraisal Tool for Cross-Sectional Studies (AXIS)

	Intro				Methods						Results				Discussion				Other	
Author and Date	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13***	**14**	**15**	**16**	**17**	**18**	**19***	**20**
Ajmal et al. (2019)	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y
Almachraki et al. (2016)	Y	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y
Bao et al (2017)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y
Brady et al. (2018)	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Dad et al. (2018)	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y	Y
Kshirsager et al. (2017)	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y
Kshirsager et al. (2018)	N	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	N	N	N	Y	N	Y	Y	Y
Kutner et al. (2017)	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	Y
Qi et al (2019)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y
Saunders et al. (2017)	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y
Zhang et al. (2016)	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y

*These questions are reverse coded ('No' response to the question equates to the criteria being met)

Small variants in outcomes were reported by some of the studies. Ten publications had similar aims using the same data, but reported slightly different outcomes. Specifically, articles analyzing dialysis facility performance and facility and neighborhood characteristics found dissimilar results regarding the relationship between for the facility's profit status and performance outcome. Ajmal et al. and Almachraki et al. found no differences between for-profit versus nonprofit dialysis providers and total performance scores. However, Almachraki et al. reported that large dialysis organizations account for a significant proportion of providers of patients in high poverty areas, and these facilities tended to score lower. Kshirsager et al. found a minimal association between performance and facility profit status. While Brady et al. found patient experience, which is the highest weighted ESRD QIP measure, was worse at for-profit facilities.[462] Conversely, Saunders et al. and Zhang reported that for-profit facilities are more

[462] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."

likely to perform better than non-profit facilities.[463,464,465,466,467,468] Another inconsistency in reported outcomes was the association of Hispanics and ESRD QIP performance scores. Ajmal et al. found a higher proportion of Hispanics associated with higher scores, while Kshirsager et al. found no association among the proportion of Hispanics and facility scores. However, Kshirsager et al. used county level data and not patient level data.[469,470] While the majority of the studies used the same data sources, a discrepancy in outcomes occurred. This could undermine the validity of the studies and a meaningful synthesis of the findings.

However, the majority of the cross-sectional studies evaluated the ESRD QIP from different years and therefore the snapshot of one year may be different from the next year. This could have accounted for the variation in findings amongst the studies, and may also misrepresent the current status of the dialysis population. While changes over time in the dialysis facility costs and patient outcomes was the aim of this systematic review, the studies were not longitudinal and were limited to the ESRD QIP's infrastructure and design. This included examination of

[463] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[464] Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
[465] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
[466] Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
[467] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[468] Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."
[469] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[470] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."

individual measures and facility and neighborhood variables associated with overall facility performance.[471,472,473,474,475,476,477,478]

Eight of the studies reported race and poverty discrepancies in the ESRD QIP. The association of the ESRD QIP on facilities serving patients living in poorer areas and a higher African American patient population was negative. Three of the studies were neutral in regard to the ESRD QIP. Ajmal et al., Kshirsager et al., Saunders et al. and Zhang et al. reported facilities reporting lower performance scores were more likely to be serving a greater proportion of the African American patient population.[479,480,481,482] Almachraki et al. reported penalties were more likely given to patient in high poverty areas.[483] Exploring ICH CAHPS scores, Brady et al. found African American and Native Americans were less likely to report a positive experience with their care at a dialysis facility.[484] Dad et al. found non-responders of the ICH CAHPS were more likely to be non-white, less educated, non-English speaking and poor.[485] Qi et al. found dialysis facilities providing care to a higher proportion of African American or dually enrolled patients

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471 Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
472 Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
473 Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
474 Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
475 Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
476 Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
477 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
478 Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."
479 Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
480 Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
481 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
482 Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."
483 Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
484 Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
485 Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."

had lower ESRD QIP performance scores.[486] Two of the three studies exhibiting neutral associations with the ESRD QIP addressed dialysis facility practice patterns and its relation to targeted measure achievement.[487,488] The third study addressed the relationship of depression, inability to work and the ESRD QIP measures.[489]

Discussion

The objective of this systematic review was to better understand the impact of the ESRD QIP since its implementation by collecting and critically appraising research evaluating the program. The new knowledge generated about the ESRD QIP addressed characteristics of high and low performing dialysis facilities. However, it did not address whether the changes in patient outcomes were attributed to the ESRD QIP, nor did any of the studies address the impact of the program on overall costs. A common theme highlighted throughout the studies was the racial and socio-economic disparities that exist for lower performing facilities.[490,491,492,493,494,495] Dialysis facilities in predominantly African American communities and lower-income communities had a greater likelihood to have worse performance on individual measures and total performance

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[486] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[487] Kshirsagar et al., "Patient Satisfaction Is Associated with Dialysis Facility Quality and Star Ratings."
[488] Bao and Bardhan, "Antecedents of Patient Health Outcomes in Dialysis Clinics: A National Study."
[489] Kutner and Zhang, "Ability to Work among Patients with ESKD."
[490] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[491] Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
[492] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
[493] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[494] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[495] Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."

scores.[496,497,498,499,500,501,502,503] Worse performance translates into lower quality of care, which could exacerbate the racial and socioeconomic disparities present within the ESRD population. Furthermore, these poorly performing facilities which receive payment reductions may be in the greatest need for more funding and resources.[504,505] Disparities in delivery of care and health outcomes negatively impact minorities and poorer patients, and also constrain the comprehensive improvement in care for the entire dialysis population. Failure to address these disparities may exacerbate vulnerable patients' quality of care and health outcomes. Policy action to address the challenges confronting minority and high-poverty dialysis patients was a common recommendation from the authors.[506,507,508,509,510,511,512,513]

Prior research has revealed similar issues with health outcome disparities for dialysis patients. While the goal of the ESRD QIP is to motivate dialysis facility providers to improve

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[496] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[497] Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
[498] Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
[499] Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
[500] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
[501] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[502] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[503] Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."
[504] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[505] Saunders and Chin, "Variation in Dialysis Quality Measures by Facility, Neighborhood, and Region."
[506] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[507] Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
[508] Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
[509] Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
[510] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
[511] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[512] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[513] Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."

patient care for all patients,[514] the ability to achieve the quality outcomes designated by the ESRD QIP can be influenced by a variety of factors. Previous to the ESRD QIP implementation, studies have demonstrated that facility type and the neighborhood in which dialysis patients receive their dialysis treatment affects clinical outcomes and mortality risk. Higher mortality rates were associated with patients treated at for-profit facilities,[515] and in predominantly African American communities. In addition, these earlier studies reported that patients living in African American communities are less likely to attain hemoglobin and dialysis adequacy measures, which are currently ESRD QIP measures.[516,517,518] Failing to maintain targeted hemoglobin levels in addition to escalating blood transfusion rates, which became a targeted measure in 2018, are more common in African American patients treated at small dialysis organizations.[519] Failure to achieve quality measures have been associated with dialysis facility and neighborhood characteristics, and current studies demonstrate that it continues to be problematic for the ESRD QIP.

Improvement in anemia management occurred in 2012, which was concurrent with the ESRD QIP implementation. Compared to anemia management measured prior to the inception of the ESRD QIP, anemia management after the program's implementation significantly improved by evidence of a decrease in overtreatment with erythropoiesis-stimulating agents (ESAs).[520] Saunders et al. acknowledged the successful decrease in medication overtreatment for dialysis patients with anemia occurring in the first of year of the ESRD QIP, however the authors noted

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[514] Centers for Medicare & Medicaid Services, "ESRD QIP Payment Year 2018 Program Details."
[515] Devereaux et al., "Comparison of Mortality between Private For-Profit and Private Not-for-Profit Hemodialysis Centers."
[516] Saunders and Chin, "Variation in Dialysis Quality Measures by Facility, Neighborhood, and Region."
[517] Mehrotra et al., "Neighborhood Location, Rurality, Geography, and Outcomes of Peritoneal Dialysis Patients in the United States."
[518] Rodriguez et al., "Geography Matters."
[519] Slinin and Ishani, "Dialysis Bundling and Small Dialysis Organizations."
[520] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"

that preceding events may have catalyzed the improvement.[521,522] In January 2011 the ESRD bundled payment, which added ESAs, was implemented, and during the preceding years new clinical evidence about excessive ESA treatment and poor patient outcomes was publicized. Both events were more likely associated with generating the improved change in anemia management.[523] This was confirmed by a 2012 Government Accountability Office (GAO) study, which concluded that the bundled payment change implemented in 2011 reduced ESRD medications utilization by 23 percent, which was predominantly a result of a decline in ESA use. Removing the financial incentive to utilize more ESAs than appropriate was associated with a significant and abrupt stop to unnecessary ESA use and improved anemia management.[524,525] While the ESRD QIP's anemia management improved, mechanisms that may misrepresent an accurate association of the program's implementation and targeted clinical outcomes require careful reflection.

Currently, the ESRD QIP anemia management goal target is a hemoglobin level of <12g/dl, which was criticized for being a population-based metric that fails to foster individualized patient care.[526] However, Medicare reports that the current measures are selected as most important to quality care in conjunction with better patient outcomes. In addition, the increase and changes in measures has allowed the ESRD QIP to evolve.[527,528] While a wide-ranging set of quality measures can allow for a more comprehensive improvement in care, the

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521 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
522 Levinson, "Update: Medicare Payments for End Stage Renal Disease Drugs."
523 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
524 United States Government Accountability Office, "End Stage Renal Disease: Drug Utilization Suggests Bundled Payment Is Too High."
525 Swaminathan et al., "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs."
526 Kutner and Zhang, "Ability to Work among Patients with ESKD."
527 Centers for Medicare & Medicaid Services, "Meaningful Measures Hub."
528 Centers for Medicare & Medicaid Services, "ESRD QIP Payment Year 2018 Program Details."

increasing number of measures are believed to be more burdensome for dialysis providers.[529,530] An increase in administrative responsibilities can limit time with patients, and a preoccupation of the provider with attaining quality performance measures has been linked with discounting other essential issues such as providing individualized care.[531,532,5] An ever expanding number of quality measures that fail to address individualized care is believed by some researchers and physicians to be problematic and weaken the program's effectiveness.[533] The incentive program's one-size-fits-all approach to care may deter providers from delivering patient-centered care that has shown to improve patient outcomes and quality of life.[534,535,536] Incentivizing providers to focus on achieving established quality measures often prevents tailoring care to the individual patient and his or her wishes.[537]

ESRD patients are a diverse group with singular needs and different treatment goals. Variables such as age, comorbidities and frailty have a significant impact on individual preferences and decisions about treatment.[538] For example, the treatment goal of some ESRD patients is long-term maintenance. However, when nearing the end of life, those suffering from multiple comorbidities are best served by focusing on symptom management, pain control and enhancing quality of life. Focusing on established quality standards often precludes considering patient values and preferences.[539] Quality of care is difficult to define and measure especially for

529 Damberg, Sorbero, Lovejoy, Raaen, Mandel, "Measuring Success in Health Care Value-Based Purchasing Programs."
530 Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
531 Meyer et al., "More Quality Measures versus Measuring What Matters."
532 Conway, "The Core Quality Measures Collaborative."
533 Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
534 Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
535 Epstein et al., "Why The Nation Needs A Policy Push On Patient-Centered Health Care."
536 O'Hare et al., "Patient-Centered Care."
537 Hysong et al., "Reports of Unintended Consequences of Financial Incentives to Improve Management of Hypertension."
538 Kliger, "Quality Measures for Dialysis."
539 Moss and Davison, "How the ESRD Quality Incentive Program Could Potentially Improve Quality of Life for Patients on Dialysis."

the ESRD population, who are a diverse group of individuals. When delivery of care requires the provider to adapt to a patient's individual needs, maximizing quality of life for that individual transcends achieving pre-established quality measures. Often those creating quality measures are less interested about a patient's individual's needs, but are more interested in identifying correctable deficiencies.[540]

The aim of the ESRD QIP is to promote high quality care for all patients in outpatient dialysis facilities using a penalty scheme to incentivize providers. The risk of a penalty is aimed to incentivize providers to attain established standards determined by Medicare. However, the structure of the penalty design prevents any allowance of recovering facility administrative costs to implement the program, in addition to penalizing facilities that often need the most resources.[541] The small number of facilities incurring penalties are more likely to be treating poorer and more vulnerable patients. However, for those providers who are largely successful at achieving patient targeted measures, findings to suggest improved dialysis patient outcomes is lacking.[542,543] While penalties may be more effective in changing provider behavior because a person tends to be more sensitive to losing something than gaining something, unintended consequences associated with a negative psychological response to being penalized can occur.[544]

The design of an incentive program requires that a provider has substantial control in influencing the outcome for a targeted measure to be effective. This can be especially problematic for the ESRD population, who are a vulnerable group of diverse individuals. When delivery of care requires the provider to adapt to a patient's individual needs, maximizing quality of life for

540 Donabedian, "The Quality of Care."
541 Julia James et al., "Health Policy Brief: Pay-for-Performance."
542 Flodgren et al., "An Overview of Reviews Evaluating the Effectiveness of Financial Incentives in Changing Healthcare Professional Behaviours and Patient Outcomes."
543 Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
544 Mehrotra, Sorbero, and Damberg, "Using the Lessons of Behavioral Economics to Design More Effective Pay-for-Performance Programs."

that individual transcends achieving pre-established quality measures.[545] Aimed to improve dialysis care and reduce costs, the QIP was designed to monitor the quality of dialysis care and patient outcomes for a population of high-cost Medicare beneficiaries who experience significant physical and psychosocial burdens.[546] Whether achieving the clinical measure standards and high performance scores aligns with the overall goal of cost-effectively improving patient outcomes remains unclear.

Conclusions and Limitations

Since its implementation in 2012, a limited number of studies has examined the ESRD QIP. Additionally, no studies have evaluated whether the program has improved patient outcomes nor evaluated whether program costs have been reduced. Yet, the ESRD QIP continues to be recognized by the CMS as a valuable means to providing quality care. Even though most dialysis facilities have not received a penalty, whether patient outcomes have improved has yet to be determined.[547,548] Evaluating federally mandated pay-for-performance programs can be difficult because of the innate methodological weaknesses. Failing to have a no-treatment control group, inability to account for confounding variables and lack of patient-level data can present problems with internal and external validity.[549] Analysis of facility level data, which is largely used in evaluation of the ESRD QIP, can have different findings in size and direction compared to patient level data. These inconsistencies can occur because facility-level relationships fail to include associations between patient performance measures and outcomes within facilities. Furthermore, dialysis facilities may have dissimilar confounders than patient level data.[550]

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545 Donabedian, "The Quality of Care."
546 Centers for Medicare & Medicaid Services, "Dialysis Facility Compare."
547 Wanchoo, Hazzan, and Fishbane, "Update on the End-Stage Renal Disease Quality Incentive Program."
548 Hogan, "ESRD QIP: The Good, the Not So Good, and the Mysterious."
549 Damberg et al., "Measuring Success in Health Care Value-Based Purchasing Programs."
550 Finney et al., "Why Health Care Process Performance Measures Can Have Different Relationships to Outcomes for Patients and Hospitals."

The majority of the studies in this systematic review found generally negative results associated with the ESRD QIP, and three studies had a mix of positive and negative results. While the efficacy of the ESRD QIP remains elusive, the program continues to evolve and become more complex. Clinical measures annually change and technical specifications for the ESRD QIP have been proposed through 2024.[551] Before continuing to add new measures, further research about the long-term effects of the program is warranted. Consistent monitoring of patient outcomes would be helpful to confirm that the ESRD QIP is successfully achieving its objectives.[552] This is especially important for disadvantaged patients who receive dialysis at facilities incurring penalties.

Paying for quality healthcare services is an attractive idea, and has led to the proliferation of various incentive programs throughout federally sponsored entitlement programs. However, incentivizing providers has not substantiated better value or care for patients. Since a reward is not provided for attaining the ESRD QIP targeted measures, the payment reductions will potentially afford Medicare savings. However, most dialysis facilities have achieved the targeted measures and have incurred no penalty,[553] and very few dialysis facilities have received the full 2% penalty. This means most dialysis facilities are achieving the standards that Medicare matched with high-quality care.[554] Researchers question whether the ESRD QIP measures are indicative of quality dialysis care and improved patient outcomes. While the cross-sectional studies evaluating the ESRD QIP have been largely negative and propose changes to the clinical measures, none of them question the efficacy of the ESRD QIP. More research is needed to better

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[551] Centers for Medicare & Medicaid Services, "Centers for Medicare & Medicaid Services End-Stage Renal Disease Quality Incentive Program Payment Year 2024 Proposed Measure Technical Specifications."
[552] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[553] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[554] Weiner and Watnick.

understand whether the ESRD QIP is incentivizing quality care that is cost-effectively improving patient outcomes.

This systematic review is subject to limitations. First, the evaluation of the ESRD QIP was limited to cross-sectional studies. The lack of prior research studies evaluating the ESRD QIP was a disadvantage to the overall synthesis of the evidence. As an important program that aims to cost-effectively improve care for a vulnerable population of Medicare beneficiaries, the ESRD QIP would benefit from more peer-reviewed analysis to shape the foundation for a body of literature that conveys its weaknesses and strengths. Recognizing the paucity of studies performed on the ESRD QIP serves as a pressing opportunity to not only identify the gap in the literature but to communicate the need for further research. Understanding the policy impact of the ESRD QIP can be challenging. As a natural experiment, the ESRD QIP cannot be manipulated and therefore requires a deliberate understanding of alternative explanations to changes in patient health outcomes.[555] The cross-sectional design of the included studies fails to offer data that addresses the impact of time on the variables associated with the ESRD QIP. Therefore, addressing this study's aims and identifying a causal relationship of the ESRD QIP impact on patient outcomes is difficult. While no study claimed a causal relationship, the associations reported in the findings were tenuous or tangential to the assessment of the ESRD QIP.[556]

Another limitation of this systematic review and a possible rationale for the small number of studies is the negative publication bias. Nephrologists and dialysis facility providers may have been affected by negative publication bias because health care executives may be disincentivized to publish negative or ambiguous findings of the federally mandated pay-for-performance

[555] Craig et al., "Natural Experiments."
[556] Caruana et al., "Longitudinal Studies."

program.[557] Additionally the quality assessment score of each manuscript was divided into four intervals based on the 20-point AXIS tool. Each quartile contains 25% of the scores and are compared with the entire set of scores. This forced distribution is a rudimentary rating system that may not reflect the true quality assessment of each manuscript. In addition, one researcher used the appraisal tool, and the degree of inter-rater reliability could not be assessed.

[557] Joober et al., "Publication Bias."

CHAPTER FOUR

Introduction

Chapter four of this dissertation will address the following questions:

1. ***What facility and neighborhood level characteristics influence the likelihood of a payment reduction under the ESRD QIP since its implementation in 2012?***

   H_0: *No statistically significant factors exist between the variables that influence penalty status, and all of the regression coefficients in the model are equal to zero.*

   H_1: *At least one statistically significant factor exists between the variables that influence penalty status, and at least one regression coefficient in the model is not equal to zero.*

2. *How does the dialysis facility's star-rating compare to a facility's ESRD QIP penalty status?*

   H_0: *There is no monotonic association between the two variables.*

   H_1: *A monotonic association between the two variables exists.*

The ESRD QIP builds on previous attempts to cost-effectively improve dialysis care by incentivizing providers to achieve targeted clinical measures that lead to better quality care and improved patient outcomes.[558,559,560] The reporting of targeted measures began in 2012 with two easily achievable and retrievable clinical measures: hemoglobin levels and minimum urea reduction ratios. Each year new measures have been added and become more complex, such as

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558 Centers for Medicare & Medicaid Services, "ESRD QIP Payment Year 2018 Program Details."

559 Department of Health and Human Services, "Medicare Program; End-Stage Renal Disease Prospective Payment System."

560 Centers for Medicare & Medicaid Services, "CMS ESRD Measures Manual."

the type of vascular access a patient receives.[561,562] The design of the ESRD QIP aims to improve dialysis patient health outcomes, and for dialysis facilities that do not achieve the targeted measures, a payment reduction of up to 2% is incurred.[563] Similar Medicare pay-for-performance models have been implemented to curb costs and improve health outcomes, and analyses has demonstrated that performance on targeted outcomes is often associated with characteristics of the dialysis facility's neighborhood.[564,565,566]

Since its implementation in 2012, the impact of the ESRD QIP has been unclear. One area of debate is the factors that are outside of the dialysis facilities' control and may impact a facility incurring a penalty.[567] Social and physical determinants of health existing in the neighborhoods which patients live, such as social support, poverty levels, transportation options, public safety, and availability of resources to meet every day needs can influence health outcomes.[568] The conditions in the neighborhoods which people live, work, and spend their time impact a broad range of health and quality-of-life outcomes. Social determinants of health, such as employment and socioeconomic status, exist in the neighborhoods people live and are strong indicators of health outcomes.[569,570] Researchers have demonstrated that health disparities such as chronic diseases, post hospitalization mortality rates and mortality rates in general are related with geographic location.[571,572] Neighborhood characteristics have also been shown to influence

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561 Centers for Medicare & Medicaid Services, "ESRD QIP Summary: Payment Years 2012 - 2016."
562 Centers for Medicare & Medicaid Services, "ESRD QIP Summary: Payment Years 2016 - 2020," 20.
563 Centers for Medicare and Medicaid Services, "ESRD Quality Incentive Program Overview."
564 Steinwachs et al., "Accounting for Social Risk Factors in Medicare Payment : Health and Medicine Division."
565 Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
566 Diez Roux, "Investigating Neighborhood and Area Effects on Health."
567 Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
568 Department of Health and Human Services, "Healthy People: Social Determinants of Health."
569 Kim, Zhang, and Ancker, "Augmenting Community-Level Social Determinants of Health Data with Individual-Level Survey Data."
570 Goodman et al., "Disparities in TKA Outcomes."
571 Murray et al., "The Impact of Geography on Health Disparities in the United States: Different Perspectives."
572 Wen and Christakis, "Neighborhood Effects on Posthospitalization Mortality: A Population-Based Cohort Study of the Elderly in Chicago."

low birth weights rates, children's health outcomes and academic achievement above and beyond individual and family level aspects.[573,574]

A handful of studies have demonstrated an association between dialysis facilities' penalty status and neighborhood sociodemographic factors. Neighborhoods with poorer patients and a greater proportion of African Americans have been associated with lower dialysis facility performance scores.[575,576,577,578] While associations between dialysis facility neighborhood characteristics and penalty status have been established using cross-sectional data, no research has been performed using longitudinal analysis from inception of the program to the current year. Nor has any research used census tract data to examine neighborhood characteristics. All previous studies have employed zip code areas to elicit neighborhood characteristics, which can cross into neighboring states and have considerably less granularity than census tracts. With a richer set of related and more reliable demographic and economic data, census tracts are largely static geographical areas that are more suitable for analysis.[579]

Thus, the objective of this chapter is to examine over an extended period the extent to which neighborhood characteristics influence dialysis facility performance. By espousing a geographical perspective, this chapter contributes to the literature on dialysis facility penalty status highlighting health resource promotion and allocation across different neighborhoods. Characteristics of neighborhoods have shown to impact health conditions and status, and

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573 Murray et al., "The Impact of Geography on Health Disparities in the United States: Different Perspectives."
574 Kim et al., "School and Behavioral Outcomes Among Inner City Children: Five-Year Follow-Up."
575 Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
576 Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
577 Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
578 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
579 US Census Bureau, "2010 Geographic Terms and Concepts - Census Tract."

understanding how the neighborhood impacts health outcomes could have significant policy implications for decreasing disparities and promoting health of the dialysis patient.[580,581]
First, I will examine whether dialysis facility and neighborhood characteristics are associated with a facility receiving a penalty under the ESRD QIP. Then I will compare each facility's star rating and penalty status to determine whether a high star-rating is commensurate with a facility not receiving a penalty; and whether a low star-rating is commensurate with a facility receiving a penalty.

Methods

Research Design

Secondary analysis of panel data, which comprises time series observations of dialysis facilities, will be used to answer objective two of the dissertation. This longitudinal quantitative research design using dialysis facility and neighborhood examines the impact of the ESRD QIP from 2012 through 2020. With repeated observations on thousands of dialysis facilities, which comprise the vast majority of facilities throughout the country, panel data analysis allows an examination of the dynamics of change associated with the ESRD QIP. Joining time series with cross-sectional data, as opposed to employing one of these two components, augments the quality and quantity of data.[582,583] In addition, the analysis of large volumes of dialysis facility data adds a more comprehensive depiction of the policy's impact, which allows for better policy evaluation and can lead to crafting improved policies.[584]

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[580] Yen and Kaplan, "Poverty Area Residence and Changes in Depression and Perceived Health Status."
[581] Diez Roux, "Investigating Neighborhood and Area Effects on Health."
[582] Gujarati, D., *Basic Econometrics*.
[583] "Panel Data Analysis."
[584] Schintler and Kulkarni, "Big Data for Policy Analysis."

Data

Dialysis Facility Compare

Medicare's Dialysis Facility Compare (DFC) website is publicly available and provides national data on the vast majority of dialysis facilities across the United States and its territories. With information on over 7,000 dialysis facilities, the DFC website includes each facility's ESRD QIP penalty status and performance on individual measures. Penalty status data is available on the DFC website for the years 2012 through 2020. The ESRD QIP was implemented in 2012, therefore, recordings of penalty status data started in 2012. DFC also provides each facility's star-ratings, facility characteristics and performance on the individual measures which correspond to the star-ratings.[585] The aim of the star-ratings is to provide patients, caregivers and other consumers, accessible information that is easy to understand about each facilities performance on delivery care compared to other facilities. Also contained in the star-rating files are the facilities' structural characteristics such as profit status, whether the facility has a late shift and the number of dialysis machines at the facility.[586] The star-rating data is available from 2015 through 2020. The DFC star-rating program started in 2015, and therefore recording of the star rating data started in 2015.

United States Census Bureau

Within the United States Census Bureau, the Census Geocoder is a geography program I used to obtain the census tract of each dialysis facility address in the country and U.S. territories. The Census Geocoder is an address look-up tool that converts an address into an approximate coordinate (longitude and latitude) and returns information about the address range that includes the census geography the address is within.[587] Geocoding an address requires selecting a

[585] Centers for Medicare & Medicaid Services, "Dialysis Facility Compare."
[586] Centers for Medicare & Medicaid Services.
[587] US Census Bureau, "2010 Geographic Terms and Concepts - Census Tract."

benchmark (time period) and vintage of geography. The benchmark is the time period when a snapshot of the data was created and the vintage of geography is the census or survey that the data is related. Therefore, the vintage available depends on the benchmark selected. The Census Geocoder allows for batch geocoding, which submits multiple addresses at a time. This is done by uniformly formatting in a single line with comma delimiters each address, uploading the file of addresses into the geocoder then clicking “Find.” For each address, the geocoder ascertains the approximate location offset from the street centerline. The longitude and latitude coordinates are then returned in addition to the address range the Census Bureau has on that stretch of road. That coordinate is then used to determine the geography that the address is within. The web interface "Find Geographies Using..." option will return a csv file that includes the state, county, census tract, and block that the address is located within.[588]

American Community Survey

The American Community Survey (ACS) data was accessed from Social Explorer, which is an online demographic research tool that contains all historical US census data from 1790 to the present. This independent software company allows for creating census related reports and downloading data.[589] The ACS, which surveys a representative sample of a community’s population, provides a detailed picture of a community’s people and housing. Surveying about 3.5 million households in the country each year, the ACS generates period estimates of collected data. I selected 2012-2016 and 2014-2018, which are 5-year estimates of population and housing characteristics. These 5-year intervals, which include census tracts, provide smaller margins of error than the 1-year estimates and increased statistical reliability for the census tracts’ smaller geographic area and population groups.[590] Signifying dialysis facility neighborhood-level

588 U.S. Census Bureau, “Census Bureau Public Geocoder.”
589 Beveridge, *Social Explorer*.
590 United States Census Bureau, “American Community Survey Information Guide.”

resources and social factors, census tracts are ideal geographic areas because they are small, relatively static, reliable statistical county subdivisions. With an average size of 4,000 people, census tracts can range from 1,200 to 8,000 people, and are relatively homogeneous with regards to community characteristics, income and housing. Across the country over 74,000 census tracts exist, and will be used in this study as proxies for neighborhood areas.[591]

Outcomes

The primary outcome is the dialysis facility's penalty status, which is a five-category measure of payment reduction. Each payment year the performance of a facility is linked to a payment reduction. Either a facility achieves the patient targeted measures and receives full reimbursement (0% penalty) or a facility is penalized with a reduction of either 0.5%, 1%, 1.5% or 2%. These penalties are calculated on a 30 to 100-point scale (depending on the year) as a weighted average of the clinical and reporting measures for that year. The clinical measures comprise 90% of the overall score and reporting measures comprise 10% of the overall score.[592] See Table 1 in Chapter 1 for the ESRD QIP summary of each year's clinical and reporting measures. Every year the score of the clinical measures at a facility are compared to the facility's performance from the previous year, and with the average score of facilities across the country. The facility being evaluated will receive the higher of those two scores, and the penalty amount will be based on the higher score.[593]

Covariates

The covariates chosen are based on univariate analysis of the variable, previous studies demonstrating relationships between the covariate and the outcome variable, and data availability.

591 US Census Bureau, "2010 Geographic Terms and Concepts - Census Tract."
592 Centers for Medicare & Medicaid Services, "CMS ESRD Measures Manual."
593 Centers for Medicare & Medicaid Services, "ESRD QIP Payment Year 2018 Program Details."

I explored dialysis facility and neighborhood characteristics, which represents the environment which dialysis treatment is provided and the resources associated with provisions of dialysis care. Applying Donabedian's framework to the ESRD QIP helps explain how the environment and structures of a dialysis facility and its surrounding neighborhood, mediated by the ESRD QIP process measures, can impact dialysis patient health outcomes.[594] Structural aspects of the dialysis facility and characteristics of the organization are markers of the healthcare provider's capacity to deliver quality care. While structure does not directly measure the care received or whether it has improved patient health, it is associated with the environment which provides services essential to quality patient care.[595]

The facility level covariates selected include: profit status (profit or non-profit); chain status (chain owned or independent); late shift availability (yes or no); number of dialysis stations at the facility (facility size); offers in-center hemodialysis (yes or no); offers in-center peritoneal dialysis; offers home hemodialysis training (yes or no) and network number (1 through 18). Dialysis facilities are organized into eighteen network organizations, which are under contract with CMS and provide a link between the federal government and ESRD providers. Every network is geographically delineated by the number and concentration of ESRD beneficiaries in each area. For example, New York is network 2 while network 3 is comprised of New Jersey, Puerto Rico and the U.S. Virgin Islands. The role of each network is to provide oversight of ESRD patient care, collect data for the ESRD program and deliver technical support to ESRD patients and providers.[596,597]

The covariates representing dialysis facility neighborhood characteristics were elicited using census tract data, which is the most commonly acknowledged representation for a

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594 Donabedian, "Evaluating the Quality of Medical Care."
595 Donabedian, "The Quality of Care."
596 Wish and Meyer, "ESRD Networks: Past, Present, and Challenges for the Future."
597 Forum of ESRD Networks, "History — ESRD Network Forum."

neighborhood unit of analysis used within social science research.[598] The census tract-level variables selected for analysis included: population density, age, education level, race, federal poverty level, employment status and household income. *Population density* allows for a broad comparison of settlement intensity across geographic areas and reports the number of people living within one square mile if the U.S. population were evenly distributed across its land area. *Population density* values for different geographic areas, then, are most useful for small areas, such as neighborhood census tracts.[599] *Population density* is a potentially important variable because urban areas, as defined by higher population density, have been shown to impact the health outcomes of urban residents. Some studies suggest that residents living in highly populated areas experience higher rates of stress, smoking, smoking exposure and obesity.[600,601]

The variable *65 and older* is the percent of the population over the age of 65 to better understand the association of dialysis facility outcomes and the elderly. The *education level* variable was selected because Americans with lower education levels, especially those without a high school diploma, suffer from higher rates of illness and disability, and a shorter life expectancy.[602] Therefore, education level will measure the percentage of the population with an educational attainment less than a high school graduation. African Americans at all education levels suffer from worse health outcomes than their White counterparts. The percent of the dialysis facility neighborhood that is African American, White, Asian, American Indian and Native Hawaiian will be considered in the analysis. The federal poverty level (FPL) variable will consider the percent of the population below the FPL. Adults who live below the poverty level have a much greater risk of higher morbidity and mortality.[603] In addition, the variables

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598 Sperling, "The Tyranny of Census Geography: Small-Area Data and Neighborhood Statistics on JSTOR."
599 United States Census Bureau, "American Community Survey Information Guide."
600 Wang et al., "Exploring the Links between Population Density, Lifestyle, and Being Overweight."
601 Beenackers et al., "Urban Population Density and Mortality in a Compact Dutch City."
602 Flynn et al., *The Hidden Rules of Race*.
603 Khullar, D. and Chokshi, D., "Health, Income, & Poverty."

employment status and household income have associations with health outcomes and mortality.[604] For household income, dollar values of inflation were adjusted to the year 2018, which is the most current year of data.

The totality of these sociodemographic variables have been identified in the scientific literature as commonly influencing individual and group differences in the general population and dialysis patients' health status.[605,606,607] Studies of other life-changing chronic illnesses along with post-hospitalization mortality have demonstrated that neighborhood characteristics, such as socioeconomic status, influence the risk for adverse patient outcomes.[608,609,610,611]

Data Collection and Cleaning

The final dataset was built from multiple sources containing large volumes of data and requiring extensive data cleaning and manipulation. The Dialysis Facility Compare (DFC), Census Geocoder and United States Renal Data System files necessitated the most attention for inconsistencies, missing data and inaccuracies. The Social Explorer software tool providing the census tract neighborhood data information required the least amount of attention. The data cleaning process consisted of screening for errors or missing values then treating the problematic observations.[612] The DFC data consisted of nine files that included the penalty status outcome variable, and six files that included the star-rating outcome variable. The files also contained the dialysis facility provider number and various dialysis facility characteristics. Each file contained

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[604] Robards et al., "Marital Status, Health and Mortality."
[605] Jankowska-Polańska et al., "Factors Affecting the Quality of Life of Chronic Dialysis Patients."
[606] Balhara et al., "Social Determinants of Health Associated with Hemodialysis Non-Adherence and Emergency Department Utilization."
[607] Plantinga et al., "Association of U.S. Dialysis Facility Neighborhood Characteristics with Facility-Level Kidney Transplantation."
[608] Udell Jacob A. et al., "Neighborhood Socioeconomic Disadvantage and Care After Myocardial Infarction in the National Cardiovascular Data Registry."
[609] Wen and Christakis, "Neighborhood Effects on Posthospitalization Mortality: A Population-Based Cohort Study of the Elderly in Chicago."
[610] Diez Roux, "Investigating Neighborhood and Area Effects on Health."
[611] Gerber et al., "Neighborhood Socioeconomic Context and Long-Term Survival after Myocardial Infarction."
[612] Van den Broeck et al., "Data Cleaning."

5,572 to 7,421 dialysis facility provider numbers with corresponding data. The 2012 file consisted of 5,572 dialysis facilities and this number successively increases each year of the ESRD QIP. This is associated with some of the smaller nonprofit facilities' lag in adopting the technology required for reporting, and predominantly related to the annual growth in the number of dialysis facilities generated by the continually increasing number of ESRD patients requiring dialysis.[613]

Screening the DFC data files consisted of examining missing data or inconsistencies, and delineating expectations about normal ranges of observations. Screening each file systematically included noting the variable names and the values of the observations to determine whether the files were consistent with labeling the variables and each observation had an appropriate number or figure.[614] For example, most observations were listed as 0=no and 1=yes. However, several columns listed 1=yes and 2=no. Also, variable names were inconsistently labeled amongst the files, and missing observations occurred in columns such as profit status and number of dialysis stations. Some of the data was visibly incorrect. For example, some observations indicated that a Fresenius dialysis facility was a non-profit organization and a Catholic charity dialysis facility was a for-profit organization.

After identifying these errors and missing data, I began the treatment phase. First, I changed variable labels so they were consistent throughout all DFC files. The missing data was predominantly of observations that described the dialysis facility characteristics. For each missing observation, I ascertained the corresponding dialysis facility name and address. Then I searched for the facility's website online to obtain the missing information that I needed. For example, for a dialysis facility that did not list profit status, I searched online for the facility's website and obtained from the company's information page whether the facility was for-profit or non-profit.

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[613] Centers for Medicare & Medicaid Services, "Dialysis Facility Compare."
[614] Van den Broeck et al., "Data Cleaning."

For missing penalty status and star-rating data, I checked the corresponding column that lists the data availability rationale code as to why the data is missing, and to ensure a rationale for the missing data was provided. Very few facilities did not provide a rationale when they had missing data, and for those facilities that did not provide a rationale, I searched for the individual facility's webpage and on the DFC website to obtain the missing data. Also, I dropped variables not relevant to the research such as certification number and certification date.

Collecting and cleaning the census geocoder data to obtain each dialysis facility's census tract number was the most time-consuming process. First, I collected every dialysis facility's address for the years 2012 through 2020. This afforded nine files of approximately 58,000 addresses which I formatted into a single line with comma delimiters that included the unique id (provider number), street name, city, state and zip code. The formatting allowed for inputting the addresses into the census geocoder tool that finds geographies. Each year was a separate file submitted into the geocoder, therefore a total of nine files were submitted into the geocoder, and the geocoder returned nine files with the census tract data. To obtain the census tract number of the dialysis facility, the dialysis facility address was geocoded by inputting each dialysis facility address in the Census Geocoder and selecting a benchmark and vintage for the census tract data. The address range (AR) benchmark selected, which signifies the time period when the address range was captured, was "Public_AR_Current." This benchmark was chosen because it is the most recent snapshot of the census dataset. The vintage selected, which is the date when the geography information was captured, was "Census2010_Current." Vintage is the address ranges from the 2010 Census at the time of the current benchmark, and was selected based on the benchmark chosen.[615]

[615] U.S. Census Bureau, "Census Bureau Public Geocoder."

For each file that I submitted, the geocoder returns a csv file containing three columns: a two-digit state code, a three-digit county code and a six-digit census tract code. This ten-digit code from the three columns is linked to every dialysis facility address in the file and was used to collect from the census data the dialysis facilities' neighborhood data. Upon examining the nine csv files for each year that the geocoder provided, I observed approximately 1,000 missing values from one or all three columns. I also observed incorrect data in the columns. For example, some columns had all zeroes, which are incorrect codes for the state, county and census tract. I isolated the missing data and manually searched for each of the 1,000 addresses on google maps to find the longitude and latitude for each dialysis facility address (or location adjacent to the facility). Then I input the longitude and latitude data one at a time into the geocoder. Ascertaining the individual coordinates of each dialysis facility and submitting the coordinates one at a time into the geocoder provided the missing state, county and census tract data that the batch submission failed to provide.

The Social Explorer software, which provided the neighborhood characteristics for which the dialysis facility was located required the least amount of editing and manipulation. To collect the dialysis facility neighborhood data, I used the state, county and census tract codes provided by the geocoder. After converting the nine geocoded files into dta (STATA) files, I combined the three columns (state, county and census tract) into one to create a ten-digit geography code for each dialysis facility. This ten-digit format was required to merge the dialysis facility data with the neighborhood characteristics in the Social Explorer software. In Social Explorer, I selected "Tables," then the "American Community Survey (ACS) five-year estimates." I performed this process twice to obtain different five-year estimates for the different years of dialysis facility data. This provided two large datasets, which I later appended into one.

First, I extracted data on neighborhood characteristics from the 2012-2016 ACS for ESRD QIP years 2012 through 2016. For ESRD QIP years 2017-2020 I extracted data from the 2014-2018 ACS because that was the most current five-year estimate. This was appropriate because a lag time between the dialysis facility performance and the penalty received for that performance is about a year. I then selected "all census tracts" followed by the neighborhood characteristics for each census tract that I wanted displayed in the tables. The ACS files were matched to each geocoded dialysis facility address. After examining the two files I found ten rows with dialysis facility data but missing neighborhood data. Therefore, ten dialysis facilities were not matched with the ACS data. These ten dialysis facilities were located in American Samoa, Guam, the Northern Mariana Islands and the U.S. Virgin Islands. The American Community Survey (ACS) does not gather census tract data from these four major U.S. territories, therefore these facilities will be omitted. The American Community Survey collects information annually in the 50 U.S. states, the District of Columbia, and Puerto Rico, which will be used for this analysis.[616]

Appending and merging the data involved multiple steps. First, I merged each of the nine DFC files with the corresponding ACS file. The eleven-digit census tract identifier, called the Geographic Federal Information Processing Standard (GEO FIPS), exists in each DFC and ACS file and enables merging of files. For example, the 2012 DFC file was merged with the 2012-2016 ACS file by GEO FIPS and the 2013 DFC file was merged with 2012-2016 ACS file by GEO FIPS. Then the 2014 DFC file was merged with the 2014-2018 ACS file by GEO FIPS, the 2015 DFC file was merged with the 2014-2018 ACS file by GEO FIPS, etc. Each DFC file was merged with the most current date of the ACS file. Once all of the nine DFC files were merged with an ACS file, the new nine data files were appended into one large data set. The large DFC

[616] United States Census Bureau, "American Community Survey Information Guide."

and ACS joined data set was then uploaded into the GMU CUI Environment, where it was merged with the USRDS data by dialysis facility provider number.

Missing Data

The existing data contains missing values, and the patterns of missing data were examined prior to data analysis. Challenges of missing data are associated with a reduction in statistical power and biased estimates that can lead to invalid conclusions.[617] The aim of addressing missing data was to most accurately estimate the true value of the coefficient for each term in the model. This will be performed by deleting the observation with missing values or substituting the missing values. First, I determined the quantity and type of variables that have missing values, and the distribution of missing values across observations. Isolating missing values helped identify whether observations with missing data have systematically different data points to those observations with complete data.[618] Logistic regression can be used to estimate the extent to which variables from previous time points predict missing values from subsequent time points. Missing variables from previous time points that predict missing variables in subsequent time points are most likely to not have occurred completely at random.[619] However, the missing data demonstrated that missing variables from previous time points were not indicative of missing values at subsequent time points. For example, in 2018 the number of missing variables was 263, and the subsequent year had 80 missing variables.

Upon further examination of the facilities with missing data, the missing data did not depend on the data from the previous year and had nothing to do with the observed variables. That is, the missing data is not related to observed data as the most common missing data pattern is complete data. When one observation is missing then all of the observations for the dialysis

[617] Kang, "The Prevention and Handling of the Missing Data."
[618] Bhaskaran and Smeeth, "What Is the Difference between Missing Completely at Random and Missing at Random?"
[619] Young and Johnson, "Handling Missing Values in Longitudinal Panel Data with Multiple Imputation."

facility were missing. Therefore, missing data could not depend on observed data because no observed data for that dialysis facility existed. When data are missing completely at random then listwise deletion is be performed. Given that the sample size is large, and less than 5% of all the data is missing, this is a reasonable approach.[620] For panel data imputation, a linear regression that predicts missing values by creating a model can be used. If missing values appear to undermine the validity of the results, then methods for the analysis of longitudinal panel data in the presence of missing values will be applied.[621,622,623]

The most common missing observations were the dialysis facility's penalty status obtained from the DFC, and the variables obtained from the ACS. Approximately 4.5% of the penalty status observations were missing because not all dialysis facilities are eligible to receive a penalty status. A facility must have a minimum of 11 dialysis patients to receive a performance score, which generates a penalty status, on at least one clinical measure and one reporting measure. In addition, to be included in the ESRD QIP, a facility must obtain a Medicare Certification Number approximately 1.5 years prior to being eligible for a penalty. The facilities that are new or have not yet obtained a certification number are excluded from the ESRD QIP and therefore do not have a penalty status.[624] This data is missing by design of the ESRD QIP. No relationship between the missingness of the data and any values appears to exist. Therefore, the data is identified as missing completely at random.[625,626]

The second most common missing observations were from the ACS, which provides fourteen neighborhood characteristic variables for each dialysis facility, such as percent of the

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[620] Kang, "The Prevention and Handling of the Missing Data."
[621] Young and Johnson, "Handling Missing Values in Longitudinal Panel Data with Multiple Imputation."
[622] Perkins et al., "Principled Approaches to Missing Data in Epidemiologic Studies."
[623] Palmer and Royall, "Missing Data?"
[624] Centers for Medicare and Medicaid Services, "CMS ESRD Measures Manual for the 2019 Performance Period."
[625] Kang, "The Prevention and Handling of the Missing Data."
[626] Bhaskaran and Smeeth, "What Is the Difference between Missing Completely at Random and Missing at Random?"

population below the federal poverty level, race and employment status. About 4% of these observations were missing from the entire data set. When an observation from the ACS was missing, then the vast majority of the missing observations from the entire row were missing. That is, if one ACS variable for a dialysis facility is missing, then the entire row of the 14 ACS variables is generally missing. The reason for this is twofold. First, the ACS does not include census tract data in the following locations: Northern Marian Islands, American Samoa, the U.S. Marshall Islands, the U.S. Virgin Islands and Guam.[627] In these 5 U.S. territories, a total of 13 dialysis facilities are located. Fourteen variables for each of the 13 facilities over nine years equates to a total of 1,638 missing observations. This data is missing by design and no relationship between the missingness of the data and any values appears to exist. Therefore, the data is identified as missing completely at random.[628,629]

For the remaining missing observations from the ACS, an anomaly in retrieving the census tract identification number existed. Some of the dialysis facility addresses were not provided a census tract number. The Census Bureau's geocoder did not match a census tract number with the facility address, even though the facility was located in the continental U.S. Therefore, none of the ACS variables were obtained for that dialysis facility. In addition, some of the remaining missing observations had incorrect census tract numbers. For example, an extra zero was omitted in the census tract number obtained from the Census Bureau's geocoder, preventing a census tract number match to the census tract number in the ACS. This is a malfunction of the programming and appears to be a random subset of the data.[630,631] The type of missing data from the ACS and DFC allows for less biased analysis than if the data were not

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[627] US Census Bureau, "2010 Geographic Terms and Concepts - Census Tract."
[628] Kang, "The Prevention and Handling of the Missing Data."
[629] Bhaskaran and Smeeth, "What Is the Difference between Missing Completely at Random and Missing at Random?"
[630] Young and Johnson, "Handling Missing Values in Longitudinal Panel Data with Multiple Imputation."
[631] Palmer and Royall, "Missing Data?"

missing at random. Listwise deletion is an appropriate approach because of the type of missingness of the data and the large sample size. Since less than five percent of data points were missing, these cases were not included in the bivariate or regression analyses. While listwise deletion removes all data for a case (dialysis facility) that has one or more missing values, the majority of dialysis facilities in the country are included in this analysis so the estimated parameters should not be biased by the absence of the data.[632] See Table 6 for a tabulation of missing dialysis facility and neighborhood variables.

[632] Perkins et al., "Principled Approaches to Missing Data in Epidemiologic Studies."

Table 6. Missing Data: Dialysis Facility and Neighborhood Variables

Variable	Missing	Total	% Missing
Provider Number	0	57,806	0
Year	0	57,806	0
Network	183	57,806	0.32
Profit	644	57,806	1.11
Chain	644	57,806	1.11
Late Shift	644	57,806	1.11
Dialysis Station Number	644	57,806	1.11
Offers In-center HD	644	57,806	1.11
Offers In-center PD	644	57,806	1.11
Offers Home Training	644	57,806	1.11
Total Population	2,292	57,806	3.96
Population Density	2,292	57,806	3.96
Area	2,292	57,806	3.96
Age 65 and Over	2,338	57,806	4.04
White	2,338	57,806	4.04
Black	2,338	57,806	4.04
Asian	2,338	57,806	4.04
American Indian	2,338	57,806	4.04
Native Hawaiian	2,338	57,806	4.04
Education No High School Diploma	2,338	57,806	4.04
No Health Insurance	2,371	57,806	4.10
Income Below FPL	2,375	57,806	4.11
Unemployed	2,382	57,806	4.12
Median Household Income	2,444	57,806	4.23
Penalty	2,628	57,806	4.55

To examine the missing data pattern, I generated indicators for missingness. The new variables created begin with the prefix “miss” and correspond to the original variables in the data set. Logistic regression models are conducted to evaluate whether any of the variables predict missingness. See Tables 7, 8 and 9 for variables that predict missingness. Variables associated with missingness that are statistically significant are identified as missing at random instead of missing completely at random. For example, profit and chain are associated with the missingness of penalty and statistically significant. Thus, the cases missing profit and chain are also missing penalty. This suggests that the data are missing at random as opposed to missing completely at random, as I originally stated. While the reason for missing data cannot be confirmed through statistical analysis, the regression analyses supports that the propensity for a dialysis facility data point to be missing is not associated with the missing data, but it is related to some of the observed data such as profit and chain. See Appendix A for additional logistic regression models examining missing data.

Table 7. Logistic Regression Model for Missing Data: Penalty

Missing Penalty	Coef.	P>|z|	[95% Conf.	Interval]
Profit	-0.39	0.01	-0.65	-0.12
Chain	-0.34	0.01	-0.60	-0.08
Late Shift	-0.43	0.01	-0.74	-0.12
Dialysis Station	-0.17	0.001	-0.18	-0.15
Offers In-Center HD	2.25	0.001	1.68	2.82
Offers In-Center PD	0.35	0.001	0.16	0.54
Offers Home HD Training	0.03	0.74	-0.17	0.24
Age 65 and Over	-1.12	0.08	-2.36	0.11
African American	-0.36	0.09	-0.77	0.05
Education No HS	-2.46	0.001	-3.65	-1.26
Unemployed	6.21	0.001	4.28	8.14
Income Below FPL	-1.22	0.04	-2.38	-0.07
Median Household Income	-2.07E-06	0.42	-7.05E-06	2.91E-06
Uninsured	4.95	0.001	3.66	6.24

Table 8. Logistic Regression Model for Missing Data: Uninsured

Missing Uninsured	Coef.	P>|z|	[95% Conf.	Interval]
Penalty	0.31	0.24	-0.21	0.84
Profit	0.16	0.67	-0.58	0.89
Chain	-1.26	0.001	-1.97	-0.56
Late Shift	1.42	0.001	0.91	1.93
Dialysis Station	0.06	0.001	0.04	0.09
Offers In-Center HD	-1.05	0.32	-3.11	1.01
Offers In-Center PD	0.37	0.13	-0.11	0.85
Offers Home HD Training	-2.30	0.001	-3.35	-1.25

Table 9. Logistic Regression Model for Missing Data: Income Below FPL

Missing Income Below FPL	Coef.	P>|z|	[95% Conf.	Interval]
Offers In-Center PD	-0.10	0.80	-0.92	0.71
Year	-0.11	0.14	-0.26	0.04
Penalty	0.42	0.48	-0.74	1.58
Profit	-1.39	0.05	-2.81	0.02
Chain	1.63	0.01	0.41	2.85
Late Shift	-2.29	0.001	-3.09	-1.49
Dialysis Station	0.03	0.26	-0.02	0.08
Age 65 and Over	47.80	0.001	38.11	57.50
Education No HS	-8.04	0.001	-10.60	-5.47

Data Analysis

Question 1 Data Analysis

To answer question one, I will use DFC and the ACS data to conduct random effects ordinal logistic regression to assess the quality of dialysis facility care associated with facility structural measures, and neighborhood sociodemographic factors and resources. This will involve dialysis facility outcomes associated with structural aspects of care to afford a clearer understanding of the dialysis facility's capacity to provide high-quality care.[633] Random effects, as opposed to fixed effects is selected because the dialysis facility and neighborhood characteristics change very little across time. With little variability existing within subjects, the standard errors from a fixed effects model would be too large to tolerate. Random effects models can estimate the effects of time-invariant variables, such as profit and chain status, and has smaller standard errors.[634] A random effects approach is appropriate because confidence exists that the unobservable variables are uncorrelated with independent variables in the model. Ordinal logistic regression is employed because the dependent variable, penalty status, is a categorical data type with five natural ordered categories (0, 0.5, 1, 1.5 and 2). A nonlinear model is applied

[633] Donabedian, "Evaluating the Quality of Medical Care."
[634] Scott, Simonoff, and Marx, *The SAGE Handbook of Multilevel Modeling*.

to accommodate the dependent variable (penalty status), which takes on five ordinal values. The independent variables are continuous and categorical.[635]

Covariates of interest (neighborhood and dialysis facility level variables) will be evaluated against penalty status using a stepwise ordinal regression analysis. A stepwise method is used for examination and refinement of the large numbers of potential independent variables to achieve the best fitting regression model.[636,637] The backward selection, which builds a model by successively removing variables, will begin with fitting the full model on all predictor variables. With each consecutive model run, the last term which is insignificant will be removed, then the model will be re-estimated. Removal will be based on a combination of the regression coefficient, standard error, which is used to calculate the z test statistic, the z-value and the p-value. Specifically, this will include a p value of less than 0.05 and a z statistic of greater than 1.96, which corresponds to a 95% confidence interval.[638,639] In addition, the regression models will be compared using Akaike information criterion (AIC) and Bayesian Information Criterion (BIC), which measures goodness of fit and model simplicity. AIC compares models by estimating the likelihood of a model to predict and estimate future values while BIC evaluates the trade-off between model fit and complexity. A lower AIC or BIC value signifies a better fitting model that is more parsimonious.[640,641]

A total of 5,577 dialysis facilities throughout the country existed in 2012 and all are included in the analysis. That number has increased each year to its current number of 7,420 dialysis facilities in 2020. The large data set captures multiple dialysis facility and neighborhood

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[635] Ananth and Kleinbaum, "Regression Models for Ordinal Responses."
[636] Pulkstenis and Robinson, "Goodness-of-Fit Tests for Ordinal Response Regression Models."
[637] StataCorp, "Stepwise Estimation."
[638] Minium, Clarke, and Coladarci, *Elements of Statistical Reasoning*.
[639] StataCorp, "Stepwise Estimation."
[640] Mohammed, Naugler, and Far, "Chapter 32: Emerging Business Intelligence Framework for a Clinical Laboratory Through Big Data Analytics."
[641] Kingdom and Prins, "Chapter 9 - Model Comparisons∗∗This Chapter Was Primarily Written by Nicolaas Prins."

level phenomena for the same units (dialysis facilities) from 2012 through 2020.[642] All analyses are based on non-missing data as the publicly available DFC data have been previously adjusted for case-mix and other factors, therefore imputations were not employed.[643] Age disparities were assessed by comparing the proportion of those $\geq$65 years old; and racial disparities were evaluated by comparing the proportion of African Americans in the dialysis facility neighborhood. Excluded from the analysis were 'other race,' 'Pacific Islanders' and 'two or more races,' which comprised a very small part of the sample size, which reduced the power to identify differences between them and other racial groups.[644] See Equation 1 for the model specification.

Equation 1. Ordinal Logistic Regression Model Specification

$$Log\left(\frac{g_{cit}}{1-g_{cit}}\right) = \alpha_c - [\beta_0 + \beta_1 \textit{Chain}_{i\,cit} + \beta_2 \textit{DialysisStations}_{cit} + \beta_3 \textit{OffersHD}_{cit} + \beta_4 \textit{OffersPD}_{cit} + \beta_5 \textit{Uninsured}_{cit} + \beta_6 \textit{PopulationDensity}_{cit} + \beta_7 \textit{NativeHawaiian}_{cit} + \beta_8 \textit{NoHighSchoolDiploma}_{cit} + \beta_9 \textit{Network1}_{cit} + \beta_{10} \textit{Network2}_{cit} + \ldots + \beta_{27} \textit{Network18}_{cit} + \beta_{28} \textit{Profit}_{cit} + \beta_{29} \textit{Lateshift}_{cit} + \beta_{30}(\textit{AfricanAmerican*IncomeBelowFPL})_{cit} + \beta_{31} \textit{OffersHomeHDTraining}_{cit} + \beta_{32} \textit{TotalPopulation}_{cit} + \beta_{33} \textit{Area}_{cit} + \beta_{34} \textit{Age65over}_{cit} + \beta_{35} \textit{White}_{cit} + \beta_{36} \textit{Asian}_{cit} + \beta_{37} \textit{AmericanIndian}_{cit} + +\beta_{38} \textit{Unemployed}_{cit} + \beta_{39} \textit{MedianHouseholdIncome}_{cit} + u_{cit}]$$

Where $Log\left(\frac{g_{cit}}{1-g_{cit}}\right)$ is the penalty status amount *c* for dialysis facility *i* at year *t.* The categories of *c* consist of five levels (0%, 0.5%, 1.0%, 1.5% and 2%), and $g_{cit} = \Pr(Y_{cit} \geq y_c | x_{it})$. X_{cit} are the facility and neighborhood level independent variables and β_0 is the estimated intercept coefficient. u_{cit} is the random effects for penalty status amount *c* for dialysis facility *i* at year *t*. αc is the cut points such that ($\alpha 1 < \alpha 2 < \ldots < \alpha C\text{-}1$). *AfricanAmerican*IncomeBelowFPL* is the interaction

[642] "Panel Data Analysis."
[643] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
[644] Sullivan and Feinn, "Using Effect Size—or Why the P Value Is Not Enough."

term between the proportion of African Americans in dialysis facility neighborhoods and income below the federal poverty level in dialysis facility neighborhoods. The cut points for the adjacent levels of the ordinal dependent variable penalty are used to differentiate the adjacent levels of penalty. The cut point is defined to be points on the latent variable that result in the different observed values on the proxy variable, which are categories of penalty status used to measure the latent variable. Specifically, cut points on the latent variable are used to differentiate 0% from 0.5%, 1%, 1.5% and 2% penalty status when values of the independent variables are evaluated at zero.

The analysis will begin with a summary of the data using standard descriptive statistics, such as mean and standard deviation for continuous variables, and frequency and percentage for categorical variables. Multicollinearity will be tested for continuous variables using the Variance Inflation Factor (VIF), and Spearman's Rank Correlation Coefficient test will be used for the categorical variables.[645] For the Spearman's test, correlation coefficients that are statistically significant at the $p < 0.05$ level; and greater than 0.4 or less than -0.4, indicating a moderate to strong relationship with other predictor variables, will be further investigated as to whether the collinear variable makes a unique contribution to the prediction.[646,647]

VIF will be employed for continuous variables and identifies the impact of multicollinearity on the variance of the i^{th} regression coefficient. When the VIF value exceeds 4, multicollinearity will be suspected and further investigation will ensue. Based on a literature, a VIF of 4 is a broad guide that indicates the variance of the i^{th} regression coefficient is 4 times greater than if the i^{th} predictor variable was independent of the other continuous predictor

[645] Ananth and Kleinbaum, "Regression Models for Ordinal Responses."
[646] Akoglu, "User's Guide to Correlation Coefficients."
[647] Schober, Boer, and Schwarte, "Correlation Coefficients."

variables. The VIF values > 4 will be interpreted in the context of other factors that may impact the variance of the i^{th} regression coefficient.[648,649]

Each covariate of interest (neighborhood and dialysis facility level variables) will be evaluated separately in bivariate analyses. Then the variables will be evaluated simultaneously in multivariable stepwise ordinal regression analysis. The regression model will also allow for an estimate of the independent relationship of age and penalty status while controlling the effects of each of the predictor variables. An interaction term is considered for neighborhood poverty level and proportion of African Americans as prior research has demonstrated that penalty status is associated with poorer neighborhoods and a greater proportion of African Americans.[650]

Question 2 Data Analysis

To answer question two, I will use Spearman's Rank Correlation Coefficient to measures the strength of association between penalty status and star-rating, along with the direction of the relationship. The null hypothesis for a Spearman correlation is that no monotonic association between penalty status and star-rating exists in the population. A monotonic relationship occurs when the value of one variable increases so does the other variable, or as the value of one variable increases, the other variable value decreases.[651] The strength of this bivariate relationship is indicated by the value of the correlation coefficient, Spearman's rho, which ranges from +1 and -1. A coefficient of ± 1 indicates a perfect degree of association between the two variables. A coefficient value closer to 0 is weaker.[652] Spearman's rho is used for non-parametric statistics as the two ranked variables penalty and star-rating do not fit a normal distribution.[653] To determine

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648 Liu and Zhang, "Residuals and Diagnostics for Ordinal Regression Models."
649 O'brien, "A Caution Regarding Rules of Thumb for Variance Inflation Factors."
650 Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
651 Griffiths, "A Pragmatic Approach to Spearman's Rank Correlation Coefficient."
652 Griffiths.
653 Astivia and Zumbo, "Population Models and Simulation Methods."

whether the correlation between variables is significant, I will compare the p-value to a 0.05 significance level.

<u>Results</u>

Question 1 Results

Descriptive statistics of dialysis facility and neighborhood characteristics describes and summarizes the data with notable patterns generated. Frequency tables for categorical data and summary statistics for continuous data are shown in Tables 10, 11 and 12. The categorical data displayed in Table 10 indicates that since the inception of the ESRD QIP, approximately 82% of facilities have not received a penalty. The majority of dialysis facilities are for-profit, part of a chain organization, and provide in-center hemodialysis. About half of the facilities offer in-center peritoneal dialysis and about 30% of the facilities offer home dialysis training. Network 6, which includes North Carolina, South Carolina and Georgia, totals the most dialysis facilities in the country. Network 1 or the 'New England Network,' which includes Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont, has the least number of dialysis facilities.

Table 10. Frequency of Facility Level Categorical Data

Variable	Observation	Frequency	Percent
Penalty	0	45,237	81.98
	0.5	5,891	10.68
	1	2,290	4.15
	1.5	1,202	2.18
	2	558	1.01
	Total	55,178	100
Network	1	1,662	2.88
	2	2,519	4.37
	3	1,832	3.18
	4	2,585	4.49
	5	3,213	5.58
	6	5,896	10.23
	7	3,683	6.39
	8	3,607	6.26
	9	5,141	8.92
	10	2,548	4.42
	11	4,188	7.27
	12	2,848	4.94
	13	2,813	4.88
	14	4,871	8.45
	15	2,958	5.13
	16	1,716	2.98
	17	2,340	4.06
	18	3,203	5.56
	Total	57,623	100
Offers Home HD Training	0	41,132	71.96
	1	16,030	28.04
	Total	57,162	100
Offers In-center PD	0	27,551	48.20
	1	29,611	51.80
	Total	57,162	100
Offers In-center HD	0	1,425	2.49
	1	55,737	97.51
	Total	57,162	100
Late shift	0	46,985	82.20
	1	10,177	17.80
	Total	57,162	100
Chain	0	7,833	13.70
	1	49,329	86.30
	Total	57,162	100
Profit	0	7,814	13.67
	1	49,348	86.33
	Total	57,162	100

The outcome variable, penalty status, is graphically represented in Figures 4 and 5. Figure 4 demonstrates that the distribution of penalty status is right-skewed. While a normal distribution is inappropriate for ordinal data, the histogram provides a visualization of inferring the mode. The most common type of penalty status variable, is "0" or no penalty. Over 80% of all dialysis facilities from the combined years of 2012 through 2020 received no penalty, and about 10% of dialysis facilities have received a 0.5% penalty. Less than 5% of all dialysis facilities received a penalty of 1%, 1.5% and 2%. The graph noticeably displays the distribution of penalty status categories, from 0 to 2%, tapering off to the right and a 0% penalty is the most frequent type of penalty.

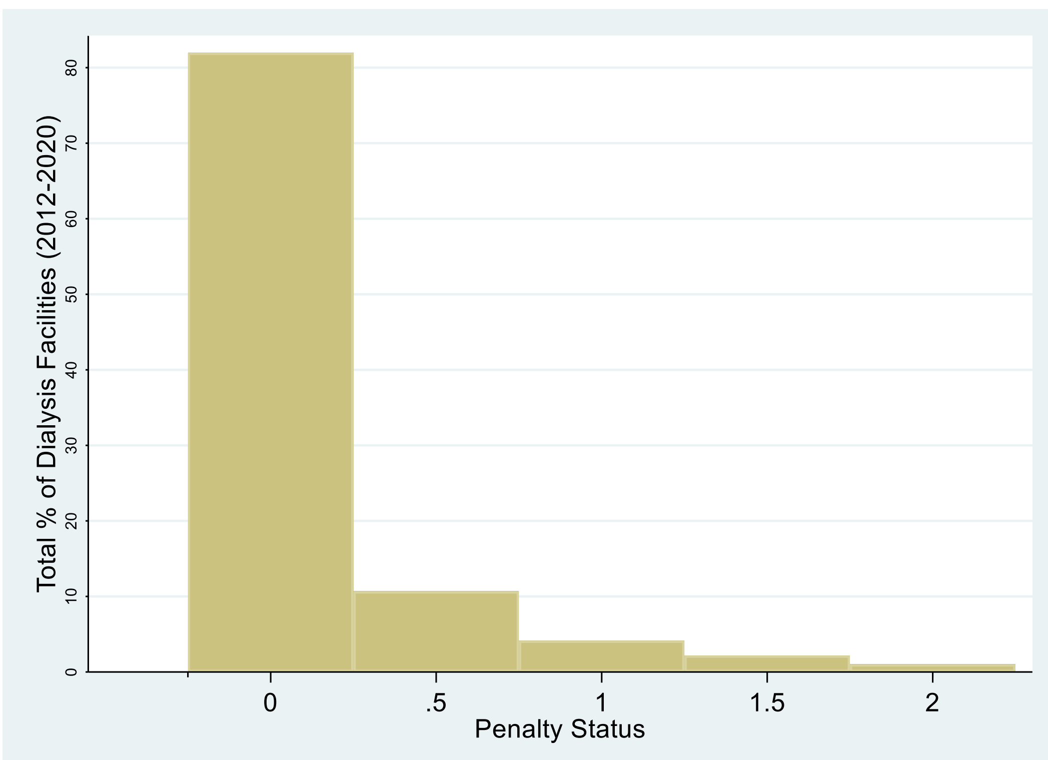

Figure 5. Dialysis Facility Penalty Status 2012-2020

Figure 5 provides a visual display of penalty status trends from 2012 through 2020. While the vast majority of facilities did not incur a penalty in initial years of the ESRD QIP, the graph demonstrates that the number of dialysis facilities receiving a penalty has considerably increased and continues to climb through 2020.

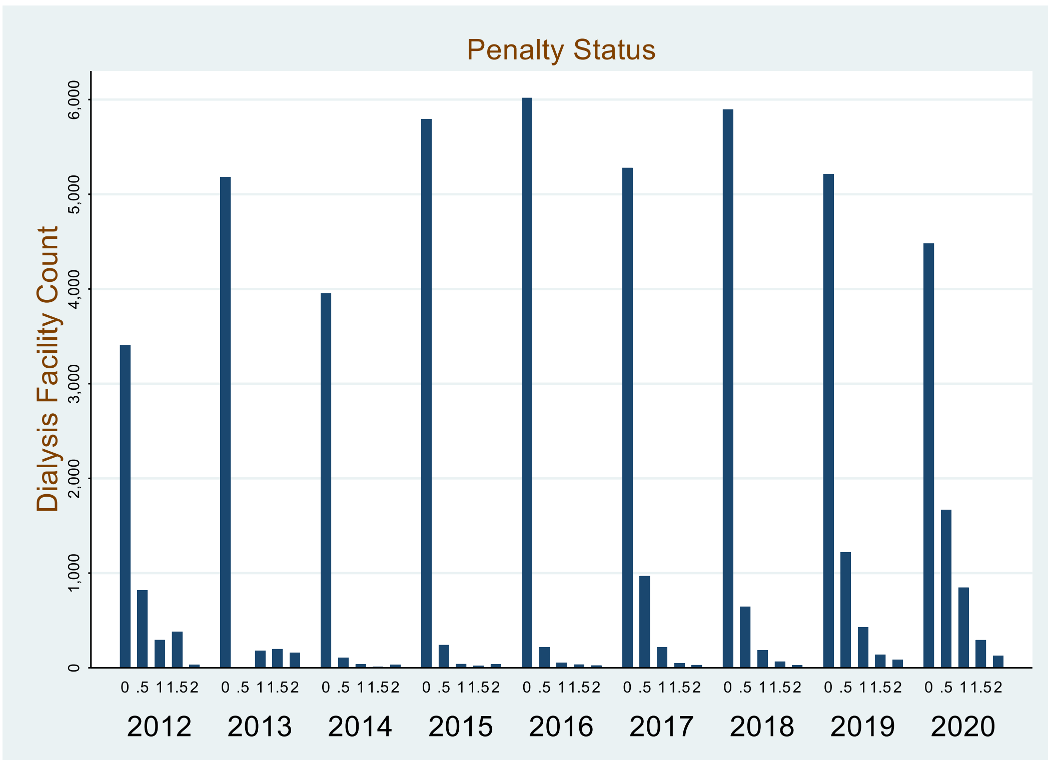

Figure 6. Dialysis Facility Penalty Status by Year

Table 12 displays the summary of categorical variables by year. In 2012 about 69% of the facilities did not receive a penalty, 17% received 0.5% penalty, 6% received a 1% penalty, 8% received a 1.5% penalty and <1% received the full 2% penalty. The percentage of facilities not receiving a penalty increased and peaked to 95% in 2014 and decreased slightly over the next two years. Facility performance began an overall downward trend in 2017 with 80% of facilities not receiving a penalty to 60% of facilities not receiving a penalty in 2020. The percentage of facilities offering: home dialysis training; in-center peritoneal dialysis; and a late shift have remained largely constant with marginal fluctuations resulting in a slight overall increase. The percentage of facilities offering in-center peritoneal dialysis training increased 4% from 2012 through 2020, and the percentage of facilities offering home dialysis training increased 2% from 2012 through 2020. The variables chain and profit status have consistently, albeit marginally, increased from 2012 through 2020. In 2012, 83% of dialysis facilities were for-profit and 83% belonged to a chain organization. By 2020, profit status increased to 88% and chain status increase to 89%. Network is excluded as this variable did not change from 2012 through 2020.

In 2014 approximately 1,500 fewer dialysis facilities reported a penalty status compared to the prior year. A possible rationale is that in 2014, the number of reporting and clinical measures increased. The targeted measures used in the first two years of the ESRD QIP were measures that dialysis facilities had been collecting for decades. Therefore, reporting on additional measures that facilities had not previously collected may have created a reporting burden for providers. Following 2014 the number of dialysis facilities participating in the ESRD QIP resumed its upward trend. A rationale for this may be that the dialysis facility's reporting system which providers use to participate in the ESRD QIP had expanded capabilities for the increasing number of reportable measures. While speculation about the rationale for a decrease in the total number of dialysis facilities reporting targeted measures in 2014, certainty exists that year 2014 was an anomaly for reporting targeted measures. Excluding that year as an observation, the overall trajectory of the total number of facilities reporting targeted measures significantly increases on an annual basis.

Table 11. Frequency of Facility Level Categorical Data by Year

	2012			2013			2014		
Variable	**Obs**	**Frequency**	**Percent**	**Obs**	**Frequency**	**Percent**	**Obs**	**Frequency**	**Percent**
Penalty	0	3,411	69.08	0	5,183	90.55	0	3,957	95.44
	0.5	818	16.57	0.5	0	0	0.5	107	2.58
	1	295	5.97	1	182	3.18	1	38	0.92
	1.5	382	7.74	1.5	199	3.48	1.5	11	0.27
	2	32	0.65	2	160	2.8	2	33	0.88
	Total	4,938	100	Total	5,724	100	Total	4,146	100
Offers Home HD Training	0	4,116	73.9	0	4,208	73.52	0	3,032	73.13
	1	1,454	26.1	1	1,516	26.48	1	1,114	26.87
	Total	5,570	100	Total	5,724	100	Total	4,146	100
Offers In-Center PD	0	2,854	51.24	0	2,909	50.82	0	1,812	43.7
	1	2,716	48.76	1	2,815	49.18	1	2,334	56.3
	Total	5,570	100	Total	5,724	100	Total	4,146	100
Offers In-Center HD	0	17	0.31	0	13	0.23	0	4	0.1
	1	5,553	99.69	1	5,711	99.77	1	4,142	99.9
	Total	5,570	100	Total	5,724	100	Total	4,146	100
Late Shift	0	4,459	80.05	0	4,610	80.54	0	3,322	80.13
	1	1,111	19.95	1	1,114	19.46	1	824	19.87
	Total	5,570	100	Total	5,724	100	Total	4,146	100
Profit	0	933	16.75	0	925	16.16	0	648	15.63
	1	4,637	83.25	1	4,799	83.84	1	3,498	84.37
	Total	5,570	100	Total	5,724	100	Total	4,146	100
Chain	0	966	17.34	0	950	16.16	0	661	15.94
	1	4,604	82.66	1	4,774	83.84	1	3,485	84.06
	Total	5,570	100	Total	5,724	100	Total	4,146	100

	2015			2016			2017		
Variable	**Obs**	**Frequency**	**Percent**	**Obs**	**Frequency**	**Percent**	**Obs**	**Frequency**	**Percent**
Penalty	0	5,795	94.41	0	6,019	94.74	0	5,280	80.64
	0.5	242	3.94	0.5	219	3.45	0.5	970	14.81
	1	41	0.67	1	53	0.83	1	218	3.33
	1.5	23	0.37	1.5	36	0.57	1.5	50	0.76
	2	37	0.6	2	26	0.41	2	30	0.46
	Total	6,138	100	Total	6,353	100	Total	6,548	100
Offers Home HD Training	0	4,596	72.43	0	4,662	71.48	0	4,875	71.29
	1	1,749	27.57	1	1,860	28.52	1	1,963	28.71
	Total	6,345	100	Total	6,522	100	Total	6,838	100
Offers In-Center PD	0	3,154	49.71	0	3,170	48.6	0	3,281	47.98
	1	3,191	50.29	1	3,352	51.4	1	3,557	52.02
	Total	6,345	100	Total	6,522	100	Total	6,838	100
Offers In-Center HD	0	1	0.02	0	0	0	0	381	5.57
	1	6,344	99.98	1	6,522	100	1	6,457	94.43
	Total	6,345	100	Total	6,522	100	Total	6,838	100
Late Shift	0	5,211	82.13	0	5,375	82.41	0	5,650	82.63
	1	1,134	17.87	1	1,147	17.59	1	1,188	17.37
	Total	6,345	100	Total	6,522	100	Total	6,838	100
Profit	0	929	14.64	0	891	13.66	0	961	14.05
	1	5,416	85.36	1	5,631	86.34	1	5,877	85.95
	Total	6,345	100	Total	6,522	100	Total	6,838	100
Chain	0	929	14.64	0	889	13.41	0	917	14.05
	1	5,416	85.36	1	5,633	86.59	1	5,921	85.95
	Total	6,345	100	Total	6,522	100	Total	6,838	100

Variable	2018 Obs	2018 Frequency	2018 Percent	2019 Obs	2019 Frequency	2019 Percent	2020 Obs	2020 Frequency	2020 Percent
Penalty	0	5,897	86.4	0	5,214	73.58	0	4,481	60.39
	0.5	647	9.48	0.5	1,219	17.2	0.5	1,669	22.49
	1	186	2.73	1	428	6.04	1	849	11.44
	1.5	67	0.98	1.5	140	1.98	1.5	294	3.96
	2	28	0.41	2	85	1.2	2	127	1.71
	Total	6,825	100	Total	7,086	100	Total	7,420	100
Offers Home HD Training	0	5,046	71.46	0	5,206	70.68	0	5,391	71.03
	1	2,015	28.54	1	2,160	29.32	1	2,199	28.97
	Total	7,061	100	Total	7,366	100	Total	7,590	100
Offers In-Center PD	0	3,401	48.17	0	3,389	46.01	0	3,581	47.18
	1	3,660	51.83	1	3,977	53.99	1	4,009	52.82
	Total	7,061	100	Total	7,366	100	Total	7,590	100
Offers In-Center HD	0	407	5.76	0	148	2.01	0	454	5.98
	1	6,654	94.24	1	7,218	97.99	1	7,136	94.02
	Total	7,061	100	Total	7,366	100	Total	7,590	100
Late Shift	0	5,884	83.33	0	6,149	83.48	0	6,325	83.33
	1	1,177	16.67	1	1,217	16.52	1	1,265	16.67
	Total	7,061	100	Total	7,366	100	Total	7,590	100
Profit	0	778	11.02	0	881	11.96	0	868	11.44
	1	6,283	88.98	1	6,485	88.04	1	6,722	88.56
	Total	7,061	100	Total	7,366	100	Total	7,590	100
Chain	0	868	12.29	0	823	11.17	0	830	10.94
	1	6,193	87.71	1	6,543	88.83	1	6,760	89.06
	Total	7,061	100	Total	7,366	100	Total	7,590	100

Table 13 displays summary statistics of the continuous variables from 2012 through 2020 (number of dialysis stations and neighborhood characteristics). Since 2012 small incremental organizational and structural changes have occurred. From 2012 to 2020, dialysis facilities offering home HD increased from 26% to 29%; dialysis facilities offering in-center PD increased from 49% to 53%; and dialysis facilities offering in-center HD decreased from 99% to 94%. In addition, the number of chain-owned and for-profit dialysis facilities increased from 83% to 89%. This illustrates the change in the dialysis industry’s market structure over the eight years. For-profit dialysis facility providers and dialysis chain organizations have been a principal source of growth since 1980 with a proliferation in the numbers of facilities and patients receiving treatment. While the number of dialysis facilities across the country have increased over time, independent dialysis facilities have decreased and overall market concentration has increased.[654,655]

During this time, the number of facilities offering home HD training increased from 26% to 29%; the number of facilities offering in-center PD increased from 49% to 53%; and the number of facilities offering in-center HD decreased from 99% to 95%. Overall, the data demonstrates a relatively stable trend in number of dialysis machines per facility and neighborhood characteristics. In 2013, the maximum value for number of dialysis stations is 117, which is considerably higher than previous years. This peculiarity was further investigated by examining the original data set and the dialysis facility's website, which confirmed that number of dialysis stations was 117. Therefore, a data entry issue did not exist and the number was maintained in the data set.

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654 Erickson et al., "Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition."
655 Program, Rettig, and Levinsky, "Structure of the Provider Community."

Table 12. Summary Statistics of Continuous Data (Facility/Neighborhood Characteristics)

Year	Variable	# of Obs	Mean	Std. Dev.	Min	Max
	Dialysis Station Number	5,570	18.09	8.26	0	60
	Total Population	5,535	4860	2284	0	39003
	Population Density	5,535	4300	9512	0	195501
	Area	5,535	19.03	111.77	0.03	3679
	Age 65 and Over	5,529	0.16	0.08	0	0.82
	White	5,529	0.68	0.26	0	1
	African American	5,529	0.18	0.24	0	0.996
2012	Asian	5,529	0.05	0.09	0	0.91
	American Indian	5,529	0.01	0.07	0	0.97
	Native Hawaiian	5,529	0.00	0.01	0	0.33
	Less than a High School Diploma	5,529	0.15	0.10	0	0.75
	Unemployed	5,527	0.08	0.05	0	0.60
	Median Household Income	5,521	50842	23856	3378	205865
	Income below the FPL	5,527	0.19	0.13	0	0.89
	No Health Insurance	5,527	0.13	0.08	0	0.58
	Dialysis Station Number	5,724	18.09	8.52	0	117
	Total Population	5,678	4870	2287	0	39003
	Population Density	5,678	4300	9427	0	195501
	Area	5,678	18.75	110.42	0.03	3679
	Age 65 and Over	5,671	0.16	0.08	0	0.82
	White	5,671	0.68	0.26	0	1
	African American	5,671	0.19	0.24	0	1
2013	Asian	5,671	0.05	0.09	0	0.91
	American Indian	5,671	0.01	0.07	0	0.97
	Native Hawaiian	5,671	0.00	0.01	0	0.33
	Less than a High School Diploma	5,671	0.15	0.10	0	0.75
	Unemployed	5,668	0.08	0.05	0	0.60
	Median Household Income	5,662	50958	23849	3378	205865
	Income below the FPL	5,668	0.19	0.13	0	0.89
	No Health Insurance	5,668	0.13	0.08	0	0.58
	Dialysis Station Number	4,146	17.80	8.45	0	80
	Total Population	4,045	4885	2442	0	39919
	Population Density	4,045	4662	10725	0	187438
	Area	4,045	14.71	54.96	0.03	829
	Age 65 and Over	4,042	0.17	0.08	0	0.84
	White	4,042	0.66	0.27	0	1
	African American	4,042	0.20	0.25	0	1
2014	Asian	4,042	0.05	0.09	0	0.93
	American Indian	4,042	0.01	0.06	0	0.97
	Native Hawaiian	4,042	0.00	0.01	0	0.35
	Less than a High School Diploma	4,042	0.13	0.09	0	0.73
	Unemployed	4,037	0.07	0.05	0	1
	Median Household Income	4,032	55630	26330	3583	229139
	Income below the FPL	4,038	0.18	0.12	0	1
	No Health Insurance	4,038	0.10	0.06	0	0.55

Year	Variable	# of Obs	Mean	Std. Dev.	Min	Max
2015	Dialysis Station Number	6,345	17.60	8.49	0	80
	Total Population	6,118	4998	2485	0	39919
	Population Density	6,118	4245	8993	0	187438
	Area	6,118	15.84	63.39	0.03	829
	Age 65 and Over	6,114	0.17	0.08	0	0.85
	White	6,114	0.68	0.26	0	1
	African American	6,114	0.18	0.24	0	1
	Asian	6,114	0.05	0.09	0	0.93
	American Indian	6,114	0.01	0.07	0	1
	Native Hawaiian	6,114	0.00	0.01	0	0.39
	Less than a High School Diploma	6,114	0.14	0.10	0	0.73
	Unemployed	6,109	0.07	0.05	0	1
	Median Household Income	6,102	55654	25948	2499	229139
	Income below the FPL	6,110	0.18	0.12	0	1
	No Health Insurance	6,110	0.10	0.07	0	0.55
2016	Dialysis Station Number	6,522	17.56	8.47	0	80
	Total Population	6,333	5039	2683	0	70271
	Population Density	6,333	4226	8755	0	151734
	Area	6,333	15.64	62.89	0.03	829
	Age 65 and Over	6,329	0.17	0.08	0	0.85
	White	6,329	0.68	0.26	0	1
	African American	6,329	0.18	0.24	0	1
	Asian	6,329	0.05	0.09	0	0.93
	American Indian	6,329	0.01	0.06	0	1
	Native Hawaiian	6,329	0.00	0.01	0	0.39
	Less than a High School Diploma	6,329	0.14	0.10	0	0.73
	Unemployed	6,324	0.07	0.05	0	1
	Median Household Income	6,316	56025	26147	2499	219167
	Income below the FPL	6,325	0.18	0.12	0	1
	No Health Insurance	6,325	0.10	0.07	0	0.55
2017	Dialysis Station Number	6,838	17.32	8.53	0	80
	Total Population	6,533	5049	2680	0	70271
	Population Density	6,533	4183	8678	0	151734
	Area	6,533	15.66	62.41	0.03	829
	Age 65 and Over	6,529	0.17	0.08	0	0.85
	White	6,529	0.68	0.26	0	1
	African American	6,529	0.18	0.24	0	1
	Asian	6,529	0.05	0.09	0	0.93
	American Indian	6,529	0.01	0.06	0	1
	Native Hawaiian	6,529	0.00	0.01	0	0.39
	Less than a High School Diploma	6,529	0.14	0.10	0	0.73
	Unemployed	6,523	0.07	0.05	0	1
	Median Household Income	6,516	56070	26045	3583	219167
	Income below the FPL	6,524	0.18	0.12	0	1
	No Health Insurance	6,525	0.10	0.07	0	0.55

Year	Variable	# of Obs	Mean	Std. Dev.	Min	Max
	Dialysis Station Number	7,061	17.38	8.56	0	80
	Total Population	6,808	5062	2710	0	70271
	Population Density	6,808	4172	8598	0	151734
	Area	6,808	15.37	61.26	0.03	829
	Age 65 and Over	6,803	0.16	0.08	0	0.85
	White	6,803	0.68	0.26	0	1
	African American	6,803	0.19	0.24	0	1
2018	Asian	6,803	0.05	0.09	0	0.93
	American Indian	6,803	0.01	0.06	0	1
	Native Hawaiian	6,803	0.00	0.01	0	0.39
	Less than a High School Diploma	6,803	0.14	0.10	0	0.73
	Unemployed	6,797	0.07	0.05	0	1
	Median Household Income	6,790	56347	26127	3583	219167
	Income below the FPL	6,798	0.18	0.12	0	1
	No Health Insurance	6,799	0.10	0.07	0	0.55
	Dialysis Station Number	7,366	17.38	8.49	0	80
	Total Population	7,066	5106	2737	0	42978
	Population Density	7,066	4202	8790	0	151734
	Area	7,066	15.25	61.16	0.03	829
	Age 65 and Over	7,061	0.16	0.08	0	0.85
	White	7,061	0.67	0.25	0	1
	African American	7,061	0.19	0.24	0	1
2019	Asian	7,061	0.05	0.09	0	0.93
	American Indian	7,061	0.01	0.06	0	1
	Native Hawaiian	7,061	0.00	0.01	0	0.39
	Less than a High School Diploma	7,061	0.14	0.10	0	0.73
	Unemployed	7,055	0.07	0.05	0	1
	Median Household Income	7,047	56673	26319	3583	219167
	Income below the FPL	7,056	0.17	0.12	0	1
	No Health Insurance	7,057	0.10	0.07	0	0.55
	Dialysis Station Number	7,590	17.43	8.51	0	80
	Total Population	7,398	5121	2701	0	42978
	Population Density	7,398	4166	8615	0	151734
	Area	7,398	14.93	59.85	0.03	829
	Age 65 and Over	7,390	0.16	0.08	0	0.85
	White	7,390	0.67	0.25	0	1
	African American	7,390	0.19	0.24	0	1
2020	Asian	7,390	0.05	0.09	0	0.93
	American Indian	7,390	0.01	0.06	0	1
	Native Hawaiian	7,390	0.00	0.01	0	0.39
	Less than a High School Diploma	7,390	0.14	0.10	0	0.73
	Unemployed	7,384	0.07	0.05	0	1
	Median Household Income	7,376	56945	26587	3583	236797
	Income below the FPL	7,385	0.17	0.12	0	1
	No Health Insurance	7,386	0.10	0.07	0	0.55

Prior to conducting bivariate and regression analysis, multicollinearity of categorical variables is tested using Spearman’s rank correlation coefficient and continuous variables are tested using the Variance Inflation Factor. After conducting multicollinearity testing, I conducted ordinal regression analysis with all predictor variables included in the model. This confirmed that variables with multicollinearity inflated the variances of the parameter estimates, and generated parameter estimates with an incorrect positive or negative sign, which was of an unlikely magnitude.[656,657]

The Spearman's rho, a non-parametric test, was first performed to measure the strength of association between the predictor variables that are categorical. See Table 14. The p-value of less than 0.001 indicates that the correlation coefficient is significantly different from 0, and a linear relationship exists. With a low p value, I conclude that the ranks are correlated. The output identifies two sets of correlated variables. The association between chain and profit status is 0.64. Therefore, the null hypothesis that profit and chain are independent is rejected. Since profit and chain are related, each were regressed with the other variables in separate models. The Spearman's rho for home training and in-center PD is 0.52. Therefore, the null hypothesis that home training and in-center PD are independent is rejected. Since home training and in-center PD are related, each were regressed with the other variables in separate models.

[656] Midi, Sarkar, and Rana, “Collinearity Diagnostics of Binary Logistic Regression Model.”
[657] O’brien, “A Caution Regarding Rules of Thumb for Variance Inflation Factors.”

Table 13. Spearman's Rank Order Correlation of Categorical Facility Level Characteristics

	In-Center HD	In-Center PD	Home Training	Late Shift	Profit	Chain
In-Center HD	1					
In-Center PD	-0.1408	1				
Home Training	-0.1035	0.5216	1			
Late Shift	0.07	0.06	0.087	1		
Profit	-0.0172	0.0265	0.0637	-0.0518	1	
Chain	0.0273	0.0148	0.0514	-0.0321	0.6353	1
Number of obs =	57162					
Spearman's rho =	0.6353					
Test of Ho:	Profit and Chain are Independent					
Prob > t =	0.0000					

To quantify the extent of correlation amongst continuous predictor variables, VIF was conducted. Predictor variables with multicollinearity included white (14.02) and African American (11.8). These higher values are problematic when examining the contribution of the predictors to the regression model. See Table 15.

Table 14. VIF of Facility and Neighborhood Characteristics

Variable	VIF	1/VIF
White	14.02	0.071
Black	11.8	0.085
Asian	3.13	0.319
Income below the Poverty Level	3.12	0.321
Median Household Income	2.71	0.369
Less than a High School Diploma	2.45	0.409
American Indian	2.04	0.490
No Health Insurance	1.82	0.549
Unemployed	1.75	0.573
Age 65 and Over	1.35	0.740
Population Density	1.18	0.850
Area	1.17	0.855
Native Hawaiian	1.16	0.861
Total Population	1.11	0.897
Dialysis Station Number	1.08	0.930
Mean VIF	3.33	

Bivariate analysis between penalty status, and facility and neighborhood characteristics demonstrated statistical significance at the 0.05 level. See Appendix A for all bivariate analyses output of dialysis and neighborhood characteristics. All bivariate analyses have a p-value less than the significance level, therefore the null hypothesis, which states that the regression coefficient in the model is equal to zero, is rejected. Dialysis facility characteristics with the strongest association to penalty status include: age 65 and over; belonging to a chain organization; offering in-center hemodialysis; belonging to ESRD Network 2 (New York); belonging to ESRD Network 7 (Florida); and belonging to ESRD Network 16 (Alaska, Idaho, Montana, Oregon, and Washington).

The ordered logit for chain affiliated facilities being in a higher penalty status category is 0.70 less than non-chain affiliated facilities, when the other variables in the model are held constant. The ordered logit for offers in-center hemodialysis being in a higher penalty status category is 0.75 less than not offering in-center hemodialysis, when the other variables in the model are held constant. The ordered logit for Network 2 being in a higher penalty status category is 0.96 greater than all other networks, when the other variables in the model are held constant. The ordered logit for Network 7 being in a higher penalty status category is 0.85 greater than all other networks, when the other variables in the model are held constant. The ordered logit for Network 16 being in a higher penalty status category is 0.54 less than all other networks, when the other variables in the model are held constant.

Dialysis facility neighborhood characteristics with the strongest association to penalty status include: the proportion of individual 65 years old and over; White; African American; American Indian; Native Hawaiian; being unemployed; having an income below the FPL; and having no health insurance. The ordered log-odds estimate for a one-unit increase in age 65 and over results in a 0.81 decrease in the ordered log-odds of being in a higher penalty status category, while the other variables in the model are held constant. The ordered log-odds estimate for a one-unit increase in White results in a 0.84 decrease in the ordered log-odds of being in a higher penalty status category, while the other variables in the model are held constant. The ordered log-odds estimate for a one-unit increase in African American results in a 1.10 increase in the ordered log-odds of being in a higher penalty status category, while the other variables in the model are held constant. The ordered log-odds estimate for a one-unit increase in American Indian results in a 1.15 decrease in the ordered log-odds of being in a higher penalty status category, while the other variables in the model are held constant.

The ordered log-odds estimate for a one-unit increase in unemployed results in a 2.24 increase in the ordered log-odds of being in a higher penalty status category, while the other variables in the model are held constant. The ordered log-odds estimate for a one-unit increase in income below the FPL results in a 1.23 increase in the ordered log-odds of being in a higher penalty status category, while the other variables in the model are held constant. The ordered log-odds estimate for a one-unit increase in no health insurance results in an 0.90 increase in the ordered log-odds of being in a higher penalty status category, while the other variables in the model are held constant. See Table 16 for the summary of bivariate analysis between penalty status and dialysis facility/neighborhood characteristics with statistically significant strong associations.

Table 15. Bivariate Analysis: Penalty and Dialysis Facility/Neighborhood Characteristics

Penalty	Coef.	P>|z|	[95% Conf. Interval]	
Chain	-0.70	0.001	-0.78	-0.62
Offers In-Center HD	-0.75	0.001	-0.90	-0.47
Network 2 (New York)	0.96	0.001	0.71	1.21
Network 7 (Florida)	0.85	0.001	0.61	1.08
Age 65 and Over	-0.81	0.001	-1.22	-0.39
White	-0.84	0.001	-1.0	-0.71
African American	1.10	0.001	0.97	1.23
American Indian	-1.15	0.001	-1.76	-0.55
Unemployed	2.24	0.001	1.63	2.86
Income Below the FPL	1.23	0.001	0.97	1.48
No Health Insurance	0.90	0.001	0.45	1.34

I then conducted bivariate analysis between age and penalty status using facility level data. See Table 18. With 54,841 observations, the Wald Chi-Square of 14.07 and a p-value of $\leq$0.001 shows that the model is statistically significant, as compared to the null model with no predictors. The ordered logit estimate comparing the proportion of individuals in the dialysis facility neighborhood age 65 and over for level of penalty status, given the other variables in the model are held constant, is -0.81 (95% CI -1.23, -0.39) and statistically significant at $p<0.001$. For a one-unit increase in age 65 and over, a 0.81 decrease in the log odds of having a higher penalty status is expected, given all of the other variables in the model are held constant. Entering race into the model as a control variable caused the age variable coefficient to become weaker (-0.22) and not statistically significant. See Appendix A for analysis including race.

Table 16. Bivariate Analysis between Age and Penalty (Facility Level Data)

penalty	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
age_65_and_over	-.8069756	.2151129	-3.75	0.000	-1.228589	-.3853622
/cut1	1.620055	.0394092			1.542815	1.697296
/cut2	2.754059	.041829			2.672075	2.836042
/cut3	3.690759	.0460133			3.600575	3.780943
/cut4	4.901524	.0583126			4.787233	5.015814
/sigma2_u	1.035636	.0440195			.9528555	1.125608

After performing bivariate analyses to explore the data and elicit the association between age and penalty status, I conducted regression analyses. Each covariate of interest (neighborhood and dialysis facility level variables) is evaluated using stepwise random effects ordinal regression.[658] Employing backward and forward selection techniques, I first entered all of the variables in the block in a single step and then removed them one at a time based on removal criteria. Stepwise variable entry and removal examines the dialysis facility and neighborhood variables in the block at each step for entry or removal.[659]

First, I added the interaction term of *African American* and *Income below the FPL*. A statistical interaction effect occurs between the two independent variables *African American* and *Income below the FPL*, and the dependent variable *penalty status*. *African Americans* with *Income below the FPL* have a greater likelihood to have a higher dialysis facility *penalty status*. Then I remove variables, starting with profit status, and then late shift. Neither was statistically significant in the full model and in bivariate analyses the statistically significant relationship was weak. In addition, profit and chain status were highly related. Research has demonstrated that

[658] Scott, Simonoff, and Marx, *The SAGE Handbook of Multilevel Modeling*.
[659] Alexopoulos, "Introduction to Multivariate Regression Analysis."

dialysis facility chains are associated with a greater risk for poor outcomes.[660,661] Therefore, profit status was removed as the chain concept more relevant to evaluate.

In the next model, *offers home HD training* was removed as it was highly correlated with *offers in-center PD*. Since *offers in-center PD* has a stronger coefficient, smaller standard error, larger z statistic and a smaller confidence interval, the variable remained. BIC is reduced compared to the previous model. While AIC increased slightly, *offers home HD training* remained in the model because of its correlation to *offers in-center PD*. In the subsequent models, population and area are removed, followed by *population density*. This caused the AIC and BIC to increase, therefore *population density* was placed back in the model, which produced lower AIC and BIC values. In the next model, race variables are removed except for *African American* and *Native Hawaiian*, which are the only two statistically significant race variables in the model, and this generated lower AIC and BIC values.

The next variable removed from the model is *median household income* because it has a moderately high VIF, and was correlated to the variable *income below the FPL*, which is more relevant to the analyses. While health disparities exist between lower and higher socioeconomic status individuals, beyond a certain point, additional wealth produces smaller and smaller increased health benefits. Therefore, removing *median household income* is more appropriate since it does not as specifically capture the impact poverty exerts on health.[662] The next variable removed from the model is *unemployed* because it is not statistically significant and is highly correlated with *income below the FPL*. The AIC and BIC values decreased, which helps confirm the variable should be removed. The *no health insurance* variable was next removed as it was not statistically significant. The *age 65 and over* variable, which was not statistically significant, was

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[660] Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."
[661] Zhang, Cotter, and Thamer, "The Effect of Dialysis Chains on Mortality among Patients Receiving Hemodialysis."
[662] Galama and van Kippersluis, "A Theory of Socio-Economic Disparities in Health over the Life Cycle."

then removed. The estimated coefficients for the age variable and facility penalty status are not statistically significant in the majority of the models. As the models become more refined, the age coefficients became weaker and the p-value is no longer statistically significant. In addition, the goodness of fit criteria indicates that age variable results in a poorer model fit when left in the model.

In the next iteration of model fitting, I replaced the *no health insurance* variable back in the model. With the *age 65 and over* removed and the *no health insurance* variable place back in the model, all the variables are statistically significant, and the AIC and BIC are reduced. For the variable *network*, a dummy variable coding system is used and the reference group is Network 1. To test the hypothesis that networks 2 through 18 are jointly zero, I used STATA's 'Test Parameters' which performs Wald tests of simple and composite nonlinear hypotheses about the parameters of a model.[663] See Table 19. The overall test for the variable *network* is statistically significant. In addition, the AIC and BIC are reduced with the variable in the model. Therefore, the variable *network* is maintained in the model.

[663] StataCorp, "Test Hypotheses after Estimation."

Table 17. Test Parameter for Network

Test Paramenter			
(1)	[Penalty]	2.	Network = 0
(2)	[Penalty]	3.	Network = 0
(3)	[Penalty]	4.	Network = 0
(4)	[Penalty]	5.	Network = 0
(5)	[Penalty]	6.	Network = 0
(6)	[Penalty]	7.	Network = 0
(7)	[Penalty]	8.	Network = 0
(8)	[Penalty]	9.	Network = 0
(9)	[Penalty]	10.	Network = 0
(10)	[Penalty]	11.	Network = 0
(11)	[Penalty]	12.	Network = 0
(12)	[Penalty]	13.	Network = 0
(13)	[Penalty]	14.	Network = 0
(14)	[Penalty]	15.	Network = 0
(15)	[Penalty]	16.	Network = 0
(16)	[Penalty]	17.	Network = 0
(17)	[Penalty]	18.	Network = 0
chi2(17) = 277.09			
Prob > chi2 = 0.0000			

While the *unemployed* variable failed to demonstrate statistical significance in earlier models, it is placed back in the model because *unemployed* has a relatively low VIF and studies have shown that unemployment can be associated with poorer health outcomes.[664,665,666] Therefore, I conducted a subsequent regression analysis. However, the variable shows to be statistically insignificant and the BIC is reduced. Consequently, *unemployed* is removed again generating the final model, which emerges as the most parsimonious and best fitting model.

[664] Udell Jacob A. et al., "Neighborhood Socioeconomic Disadvantage and Care After Myocardial Infarction in the National Cardiovascular Data Registry."
[665] Gerber et al., "Neighborhood Socioeconomic Context and Long-Term Survival after Myocardial Infarction."
[666] Norström et al., "Does Unemployment Contribute to Poorer Health-Related Quality of Life among Swedish Adults?"

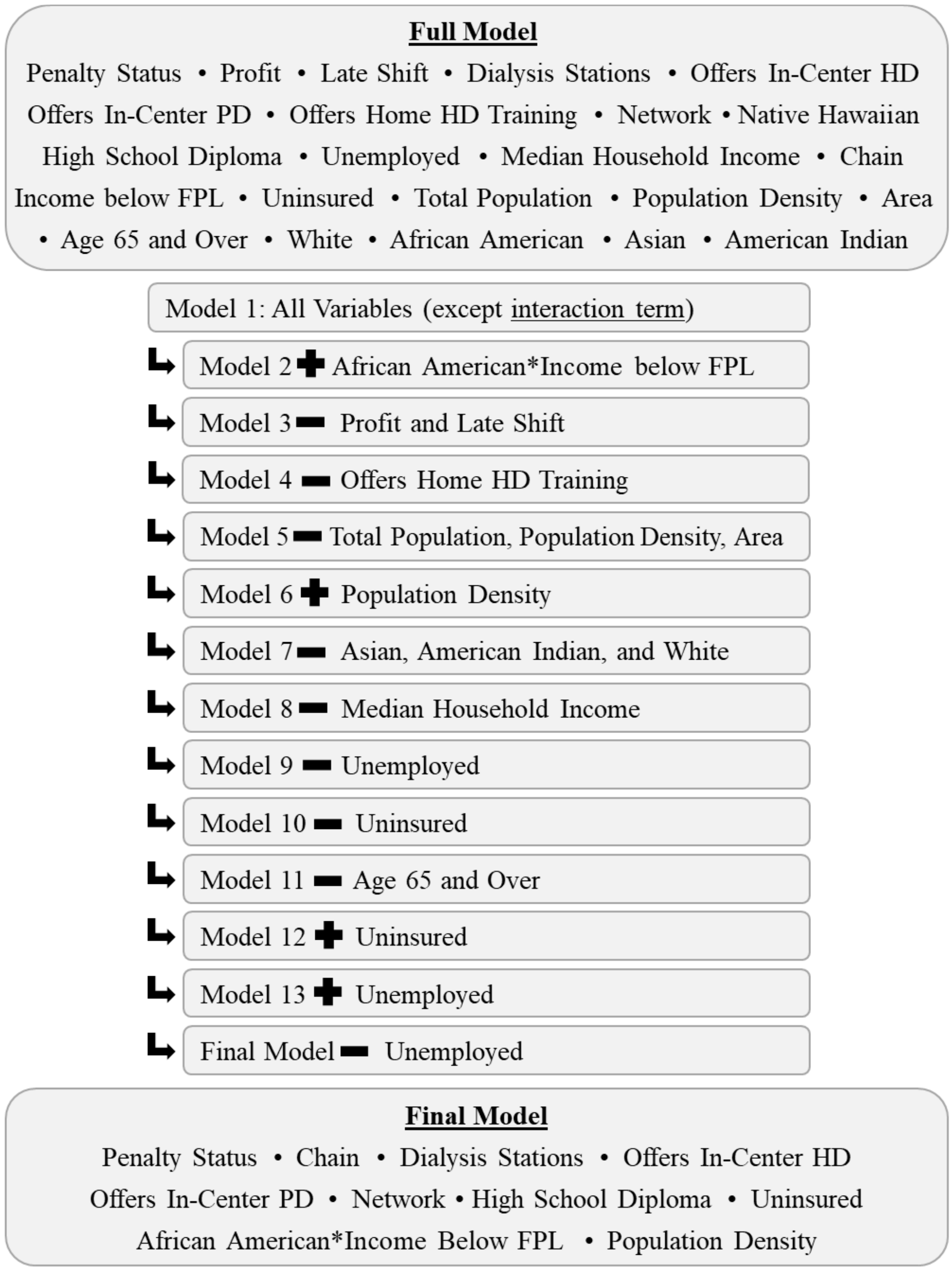

Figure 7. Model Fitting Process

After re-examining the sequence of variables entered and removed, the final model is constructed and displayed in Table 20. With 54,164 observations, random effects ordered logistic regression is conducted. The Wald Chi-Square statistic (1118.85), which tests the hypothesis that at least one of the predictors' regression coefficient is not equal to zero, has 25 degrees of freedom of the Chi-Square distribution, is statistically significant at $p < 0.0001$. The small p-value of <0.0001 suggests that at least one of the regression coefficients in the model is not equal to zero. Based on model fitting (see above), the age variable was not included in the final model. The expected penalty amount for a dialysis facility affiliated with a *chain* organization, which is statistically significant at the $p<0.001$, is -0.72 (95%CI: -0.80, -0.64), while holding all other variables in the model constant. Therefore, dialysis facilities that are part of a *chain* organization, compared to facilities that are non-chain affiliated, are 0.72 less likely to receive a penalty. The expected penalty amount for the number of *dialysis stations*, which is statistically significant at the $p<0.001$, is 0.02 (95%CI: 0.01, 0.02), while holding all other variables in the model constant. For a one-unit increase in the number of *dialysis stations*, given the other variables are held constant in the model, the predicted penalty amount would increase by 0.02 units. Dialysis facilities with more dialysis stations are marginally more likely to receive a penalty.

The expected penalty amount for a dialysis facility that *offers in-center HD*, which is statistically significant at the $p<0.001$, is -0.81 (95%CI: -0.97, -0.64), while holding all other variables in the model constant. For a one-unit increase in the number of facilities that *offers in-center HD*, the predicted penalty amount would decrease by 0.81 units. Therefore, dialysis facilities offering in-center HD, compared to those facilities that do not, are less likely to receive a penalty. The expected penalty amount for a dialysis facility that *offers in-center PD*, which is statistically significant at the $p < 0.001$, is 0.26 (95%CI: 0.20, 0.32), while holding all other variables in the model constant. For a one-unit increase in the number of facilities that *offers in-*

center PD, the predicted penalty amount would increase by 0.26 units. Therefore, dialysis facilities that offer in-center PD, compared to facilities that do not offer in-center PD, are somewhat more likely to receive a penalty.

The expected penalty amount for the proportion of the neighborhood population (where the dialysis facility is located) who is *uninsured*, is 0.68 (95%CI: 0.09, 1.27) and statistically significant at the $p < 0.05$, while holding all other variables in the model constant. For a one-unit increase in *uninsured*, the predicted penalty amount would increase by 0.68 units. Therefore, dialysis facilities located in neighborhoods with a greater proportion of uninsured individuals are more likely to receive a penalty. A statistically significant interaction effects exists when the effect of African American on the dialysis facility penalty amount varies based on the value of income below the FPL. African Americans living below the FPL have more of negative impact on the dialysis facility penalty amount than non-African Americans living below the FPL. For a one-unit increase in the percent African American with income below the FPL, given all variables in the model are held constant, the predicted penalty amount increases by 2.20 units (95% CI: 1.80, 2.60).

The expected penalty amount for the proportion of no high school diploma (*No HS Diploma)* in a dialysis facility neighborhood is -0.67 (95% CI: -1.10, -0.24) and statistically significant at the $p < 0.01$, while holding all other variables in the model constant. For a one-unit increase in the proportion of the dialysis facility neighborhood with no high school diploma, the predicted penalty amount would decrease by 0.68 units. Therefore, dialysis facilities in neighborhoods with *No HS Diploma* are less likely to receive a penalty. For the variable *network*, the coefficients for Networks 2, 4, 5, 6, 7, 8, 9, 10, 13, 14, 16 and 18 are statistically significant at the .05 alpha level. This indicates that the aforementioned networks are significantly different from Network 1. The networks with the strongest statistically significant association with a higher penalty amount are Networks 2 (New York), 4 (Delaware and Pennsylvania), 5 (Virginia, West Virginia, Maryland and District of Columbia), 7 (Florida) and 9 (Indiana, Kentucky and Ohio). Network 7, which consists of dialysis facilities in the state of Florida, has the strongest association with a higher penalty amount. The expected penalty amount for Network 7 is 0.81 (95% CI: 0.58, 1.04) and statistically significant at the $p < 0.001$, while holding all other variables in the model constant. For a one-unit increase in Network 7, the predicted penalty amount would increase by 0.81 units.

Table 18. Regression Analysis: Penalty and Facility/Neighborhood Characteristics

Random-Effects Ordered Logistic Regression		Number of obs	=	54,164
Group Variable: providernumber		Number of groups	=	8,090
		Wald chi2(25)	=	1118.85
Log Likelihood = -34388.66		Prob > chi2	=	0
Penalty	**Coef.**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.001	-0.80	-0.64
Dialysis Station	0.02	0.001	0.01	0.02
Offers In-Center HD	-0.81	0.001	-0.97	-0.64
Offers In-Center PD	0.26	0.001	0.20	0.32
Uninsured	0.68	0.02	0.09	1.27
African American*Income Below FPL	2.20	0.001	1.80	2.60
Population Density	9.12E-06	0.001	5.62E-06	1.26E-05
No High School	-0.67	0.002	-1.10	-0.24
Network				
2	0.58	0.001	0.34	0.83
7	0.81	0.001	0.58	1.04
LR test vs. ologit model: chibar2(01) = 933.13		Prob >= chibar2 = 0.0000		

Question 2 Results

The relationship between a dialysis facility's penalty status and star-rating was examined. Ranging from one to five stars, the star-rating is an ordinal summary measure. A 5-star rating signifies a facility has delivered quality care above the national average and a facility with a one-star rating indicates that quality of care was much below the national average. Some of the star-rating measures overlap with the ESRD QIP measures, but the star-ratings also incorporate additional measures not used on the ESRD QIP.[667]

I first conducted a frequency table to generate a visual impression and clearer understanding of the penalty and star-rating data. See Table 21. The frequency table provides a cumulative count of each facility's penalty status and star-rating. It demonstrates that the majority of facilities which do not incur a penalty, do not necessarily share a high star-rating. The expectation that these facilities would have a high star-rating (of 4 or 5) was not supported. Over 4,000 facilities did not receive a penalty, however these facilities had a low star-rating, indicating that measured patient outcomes were below average compared to those for other facilities. This is surprising considering facilities that do not receive a penalty are deemed to be receiving quality care. Alternatively, none of the facilities receiving a 1.5% or 2% penalty were awarded a five-star rating.

Table 19. Frequency of Penalty Status and Star Rating

	Star Rating					
Penalty	**1**	**2**	**3**	**4**	**5**	**Total**
0	1,065	3,300	10,354	7,872	6,426	29,020
0.5	423	878	2,276	829	151	4,557
1	216	467	775	82	13	1,553
1.5	177	160	140	9	0	486
2	131	57	10	1	0	199

I conducted Spearman's Rank Correlation Coefficient to measure the overall strength of association between penalty status and star-rating, along with the direction of the relationship. First, I ran the test repeating the command by year to obtain the Spearman's rho for individual

[667] Kidney Epidemiology and Cost Center, "Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release."

years. The p-value of less than 0.001 indicates that the correlation coefficient is significantly different from 0, and a linear relationship exists. With a low p value, I conclude that the ranks are correlated. See Table 22. The dialysis facility star-rating program began in 2015, therefore the analysis includes the years 2015 through 2020. Throughout each year, the Spearman's rho demonstrates a statistically significant negative correlation. That is, the star-rating increases when the penalty status decreases. While the direction of the relationship is negative, the strength of the relationship is weak for the years 2015 through 2018. In 2019 and 2020 the strength of the statistically significant negative correlation becomes stronger.

Table 20. Spearman's Rank Correlation Coefficient of Penalty and Star Rating

Year	Number of Obs	Spearman's rho	Test of Ho	Prob > |t|
2015	5577	-0.2823	Fivestar and Penalty are independent	0.0000
2016	5814	-0.2670	Fivestar and Penalty are independent	0.0000
2017	5851	-0.4424	Fivestar and Penalty are independent	0.0000
2018	5741	-0.2927	Fivestar and Penalty are independent	0.0000
2019	6089	-0.5549	Fivestar and Penalty are independent	0.0000
2020	6743	-0.6086	Fivestar and Penalty are independent	0.0000

Second, I ran the Spearman's Rank Correlation combining all of the years. See Table 23. The p-value of less than 0.001 indicates that the correlation coefficient is significantly different from 0, and a linear relationship exists. With a low p value, I conclude that the ranks are correlated. Rejecting the null hypothesis that the two variables are independent, the relationship between penalty and star-rating is statistically significant. The Spearman's rho was -0.31, indicating a statistically significant, albeit weak negative relationship. Therefore, as star-rating increases, penalty status decreases. Both tests provide evidence to reject the null hypothesis and accept the claims that five-star rating and penalty status are independent. The data achieves a statistically significant Spearman rank-order correlation demonstrating that a 0% chance exists that the strength of the relationship found occurred by chance if the null hypothesis were true. While the p value is statistically significant, the relationship is weak to moderate.

Table 21. Spearman's Rank Correlation All Years Combined

Number of Obs = 35815
Spearman's rho = -0.3100
Test of Ho: Fivestar and Penalty are Independent
Prob > t = 0.0000

CHAPTER FIVE

Introduction

Chapter five examines question three of the dissertation and addresses the following questions:

> **1.** *Do dialysis patient targeted clinical outcomes vary by age since the 2012 ESRD QIP implementation?*
>
> ***H*$_0$*:*** *Patient clinical outcomes do not vary by age group since the 2012 ESRD QIP inception.*
>
> ***H*$_1$*:*** *Patient clinical outcomes do vary by age group since the 2012 ESRD QIP inception*
>
> **2.** *Do dialysis patient non-targeted clinical outcomes vary by age group since the 2012 ESRD QIP implementation*?
>
> ***H*$_0$*:*** *Non-target outcomes do not vary by age group since the 2012 ESRD QIP inception.*
>
> ***H*$_1$*:*** *Non-target outcomes do vary by age group since the 2012 ESRD QIP inception.*

Methods

Research Design

To answer this chapter's questions, secondary analysis of existing data for quantitative research will be used with a time series of cross sections. Containing data from 2012 through 2019, the pooled cross-sectional data are random samples from the entire dialysis population independent of each other at different points in time. The pooled data of dialysis patients is used to examine patterns of change over time for the primary explanatory variable dialysis patient age category and the dependent variables: hospice, renal replacement therapy discontinued prior to death, place of death, modality type, access type, ICU days and hemoglobin levels. USRDS does not provide data on the same patients each year, however the data is randomly sampled, and thus pooling cross-sectional patient level data across time to approximate panel data is feasible and the most statistically powerful for the type of data available.[668,669]

Data

United States Renal Data System

Data was collected from the United States Renal Data System (USRDS), which is a national data system that gathers, analyzes, and distributes information about chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States. Funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), USRDS contains de-identified patient level and dialysis facility level data.[670] Requesting data from USRDS required an institutional IRB approval memo, a Data Use Agreement and a dissertation proposal outline. The Standard Analysis Files (SAFs) requested from USRDS are data files that provide patient and facility specific information. Patient identifiers are removed or encrypted. Each patient is given an encrypted ID number to enable the merging of multiple Standard Analysis Files (SAFs).

I filed a USRDS Agreement for Release of Data in addition to USRDS formatted dissertation proposal outline.[671] The following are the SAFs and their descriptions: the core dataset, which contains numerous files consisting of basic patient data such as employment status, lab values, modality type and death notifications, and is required to use all the other SAFs; the Transplant datasets which contain detailed transplant and transplant follow-up data; the hospitalization dataset which comprises of diagnosis and surgical procedure codes for each patient's stay including the number of days in the hospital; and the CROWNWeb Clinical

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668 Hsiao, "Panel Data Analysis—Advantages and Challenges."
669 van der Steen et al., "Benefits and Pitfalls of Pooling Datasets from Comparable Observational Studies."
670 United States Renal Data System, "2017 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
671 United States Renal Data System, "2017 Researcher's Guide to the USRDS Database Appendix A: USRDS Products and Services."

Dataset, which is clinical data for hemodialysis adequacy, peritoneal dialysis adequacy, anemia management and vascular access type.

Outcomes

I examined two ESRD QIP targeted measures and five outcome measures, which impact the health and well-being of patients, that are not associated with the ESRD QIP. Hemoglobin level and AV fistula, which is a category of the *access type* outcome variable, are the two targeted ESRD QIP measures used in the analyses. These targeted outcomes capture quality measures of care that may not be appropriate for the elderly dialysis population. Research demonstrates that a single hemoglobin level target for all dialysis patients and an AV fistula target for all dialysis patients is problematic. For these measures, individualized targets may be more beneficial for a patient-centered approach to care.[672,673,674,675,676]

Hemoglobin levels are one of the most common complications for dialysis patients because their kidneys are unable to make the hormone that triggers the production of hemoglobin.[677] Dialysis patients tend to have low levels of hemoglobin, which can cause severe fatigue, weakness and cardiovascular problems. In response to low hemoglobin levels, dialysis patients are given medication to increase their levels. While increasing hemoglobin levels with medication is necessary, excessive use of medication to artificially raise hemoglobin levels has been associated with an increased risk for cardiovascular events and mortality.[678,679]

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672 Muirhead, "A Rationale for an Individualized Haemoglobin Target."
673 Pollak, Lorch, and Pollak, "Perpetuating Sub-Optimal Care: CMS, QIPs, and the Hemoglobin Myth."
674 Fuertinger et al., "Prediction of Hemoglobin Levels in Individual Hemodialysis Patients by Means of a Mathematical Model of Erythropoiesis."
675 Kalloo, Blake, and Wish, "A Patient-Centered Approach to Hemodialysis Vascular Access in the Era of Fistula First."
676 DeSilva et al., "Fistula First Is Not Always the Best Strategy for the Elderly."
677 Pollak, Lorch, and Pollak, "Perpetuating Sub-Optimal Care: CMS, QIPs, and the Hemoglobin Myth."
678 Pascual et al., "Regression of Left Ventricular Hypertrophy after Partial Correction of Anemia with Erythropoietin in Patients on Hemodialysis."
679 Foley et al., "The Impact of Anemia on Cardiomyopathy, Morbidity, and Mortality in End-Stage Renal Disease."

Studies have demonstrated that increasing dialysis patient hemoglobin levels to achieve the national guideline does not necessarily improve all dialysis patient health outcomes. The recommended level of hemoglobin correction can benefit relatively healthy dialysis patients but for those with cardiovascular disease, a common occurrence in elderly ESRD patients, an increased hemoglobin level is not associated with a better outcome.[680,681] Low hemoglobin levels are a common problem in the ESRD population and disproportionately impact elderly patients.[682,683] Optimal hemoglobin levels for different age groups may vary, and therefore incentivizing providers to achieve the QIP's targeted hemoglobin level for all dialysis patients may increase health disparities in older adults.

Fistula is a complex targeted QIP measure not easily attributable to the provider and does not necessarily translate into better health outcomes for all ESRD patients. Patient and system level factors, such as older age, are associated with whether a patient receives a fistula.[684] Fistula placement is the surgical connection of an artery to a vein. The vessels, which form the fistula, are connected by a tube to the dialysis machine to allow high volumes of blood to flow out and cleaned blood to return to the body. For a fistula to endure the high volume of blood flow, a patient generally requires vessels with internal diameters of greater than two millimeters.[685] As a person ages, their blood vessels become less flexible and the diameters of their blood vessels

[680] Maekawa et al., "Influence of Atherosclerosis on the Relationship between Anaemia and Mortality Risk in Haemodialysis Patients."
[681] Foley, Curtis, and Parfrey, "Erythropoietin Therapy, Hemoglobin Targets, and Quality of Life in Healthy Hemodialysis Patients."
[682] Juárez-Cedillo et al., "Prevalence of Anemia and Its Impact on the State of Frailty in Elderly People Living in the Community."
[683] Winkelmayer et al., "Trends in Anemia Care in Older Patients Approaching End-Stage Renal Disease in the United States (1995-2010)."
[684] Gupta and Wish, "Do Current Quality Measures Truly Reflect the Quality of Dialysis?"
[685] U.S. Department of Health and Human Services, "Hemodialysis."

decrease, which creates a challenge for high velocity blood flow required by dialysis.[686] For the elderly, a fistula may create more adverse outcomes than their younger dialysis cohorts.

The five outcome measures not associated with the ESRD QIP and included in this analysis are: hospice; renal replacement therapy discontinued prior to death; place of death; number of days spent in the ICU during one hospital episode; and modality type. The outcome variables associated with end-of-life care (hospice, renal replacement therapy discontinued prior to death and place of death) are important aspects of care for elderly patients and reflective of quality care dimensions specific to older adults nearing death. For elderly patients, hemodialysis is universally offered, and has been associated with a considerable number of frail elderly ESRD patients receiving aggressive treatment as they near the end of life.[687] Even though the benefit of dialysis treatment decreases with age, a growing number of elderly patients are initiating dialysis.[688,689] Most dialysis patient deaths occur in older adults, however only about half of Medicare beneficiaries have been shown to have any end-of-life discussions about treatment preferences.[690] In addition, dialysis patients frequently die in the hospital and utilize hospice half as less compared to patients experiencing other terminal illnesses.[691]

Initially, the variables modality type and transplant were selected to examine ongoing policy efforts within the nephrology community to increase the number of ESRD patients who receive a transplant or select peritoneal dialysis instead of hemodialysis. However, the transplant data set, especially for the year 2018, contained far fewer data points compared to the data sets which it was merged. The transplant data available is most likely not representative of the overall

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686 Tucker and Mahajan, "Anatomy, Blood Vessels."
687 Thorsteinsdottir, Swetz, and Tilburt, "Dialysis in the Frail Elderly — A Current Ethical Problem, an Impending Ethical Crisis."
688 Johansen et al., "Significance of Frailty among Dialysis Patients."
689 O'Hare et al., "Regional Variation in Health Care Intensity and Treatment Practices for End-Stage Renal Disease in Older Adults."
690 Kale et al., "End-of-Life Discussions with Older Adults."
691 Schmidt and Moss, "Dying on Dialysis."

ESRD population and more likely an unreliable sample. Therefore, the variable modality type, which includes transplantation, is used to examine whether change over time for renal replacement therapies exist. The four categories of modality type are: kidney transplant, in-center hemodialysis (HD), home HD and peritoneal dialysis (PD).

Transplantation affords the best health outcomes and is the least costly treatment alternative for ESRD patients.[692] Second to transplantation, PD and home HD, is the least costly of renal replacement therapies, and has been shown to offer better health outcomes than in-center hemodialysis. Even though transplantation, PD and home HD are generally preferred over in-center hemodialysis because of cost, health outcomes and autonomy for patients; about 90% of ESRD patients initiate in-center HD.[693] Since the inception of the ESRD program, budgetary analyses and policy makers believed costs would be curbed by the number of ESRD patients receiving transplants and the number of patients using PD instead of in-center HD.[694,695] However, HD continues to be use by the majority of ESRD patients. Since the ESRD QIP aims to cost-effectively improve dialysis patient outcomes, examining the trend of renal replacement therapy use since the program's inception is important. These outcome variables will also be added as control variables to the statistical models when the variable is not the outcome. The control variables are incorporated in the regression analysis as input to separate their effects from the predictor variables.[696]

Predictors and Covariates

The primary predictor variable for answering question three is dialysis patient age, which will be used to understand the relationship between ESRD QIP targeted and non-targeted

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[692] Ronco et al., "Renal Replacement Therapy in Acute Kidney Injury."
[693] Tonelli et al., "Systematic Review."
[694] Hirth et al., "Chronic Illness, Treatment Choice and Workforce Participation."
[695] LeSourd, Fogel, and Johnston, *Benefit-Cost Analysis of Kidney Disease Programs*.
[696] Mertler and Reinhart, *Advanced and Multivariate Statistical Methods*.

outcomes. Each patient's age is grouped into four categories (0-44 =1, 45-64 = 2, 65-74 = 3, 75+ = 4). These age categories are chosen based on the categories which USRDS uses to divide patient ages, general similarities in risk for the disease and patient health outcomes, as well as highlighting the importance of the aging dialysis population. Dialysis patients $\geq$75 years old are the largest subset of ESRD patients initiating dialysis. In addition, those 65-74 years old have the highest prevalence rate and are the second fastest growing population. Aggregating individual observations of age into categories enables age group comparisons between younger and older dialysis patients and examination of non-linear relationships. When data is grouped sensitivity can be lost and making results less robust. However, categorizing age provides additional information through analyses that categorical variables allow for, such as cross-tabulation and regression with dummy variables. In addition, this study contains large amounts of data making interpretation and discernment of the differences between older and younger patients more understandable.[697]

Change over time to elicit whether the ESRD QIP has influenced the selected outcome variables is also a variable of interest, and will be achieved by examining the pattern of year dummy coefficients. The earliest year (2012) is selected as the base or reference category, and years 2013 through 2019 are the dummy variables. These time dummies are used to model and test for differences in slope coefficients and intercept terms between years to provide statistical analysis of change in any of the variables over time.[698]

The covariates sex, race and ethnicity are included in the model as these factors have been shown to impact dialysis patient outcomes. While African Americans compared to Whites in older age categories survive longer on dialysis, they are less likely to receive access to care and

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[697] Walker and Almond, *Interpreting Statistical Findings*.
[698] Wooldridge, *Introductory Econometrics*.

less likely to achieve targeted interventions that are associated with improved outcomes. In addition, kidney disease disparities have been identified among dialysis patients who are female, Hispanic and African American.[699,700,701] For example, catheter use is independently associated with race and sex. The use of catheters for hemodialysis is discouraged because of the high risk for catheter related complications leading to poorer health outcomes.[702,703,704] African Americans are more likely than Whites to have a catheter, and women are more likely than men to have a catheter. African Americans and Hispanics are also less likely than Whites to receive a transplant.[705,706,707]

Race is a categorical variable that USRDS provided with six values: White=1; African American=2; American Indian/Alaskan Native=3; Asian=4; Pacific Islander=5 and other/multiracial=6. Diagnostic and logistic regression analysis including these categories demonstrated expected frequencies for each cell of categories 3, 4, 5 and 6 to be small resulting in inadequate power for the analyses. Regression analyses generated large coefficient estimates and standard errors.[708] Therefore, the categories were collapsed in into three categories: African American; White and other. Sex is a dichotomous variable with the values of 1=male and 2=female. Hispanic is a categorical variable with the values of 1=Hispanic, 2=non-Hispanic and 9=unknown. The variable Hispanic had the fewest available observations. *Employment status* includes the categories unemployed, employed and retired.

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[699] William F. Owen et al., "Dose of Hemodialysis and Survival."
[700] Rhee et al., "Impact of Age, Race and Ethnicity on Dialysis Patient Survival and Kidney Transplantation Disparities."
[701] Kucirka et al., "Age and Racial Disparities in Dialysis Survival."
[702] Wang et al., "Epidemiology of Haemodialysis Catheter Complications."
[703] Steward, "The Relationship Between Bloodstream Infections and Hemodialysis Catheters in Hospital-Based Hemodialysis Units."
[704] Hopson et al., "Variability in Reasons for Hemodialysis Catheter Use by Race, Sex, and Geography."
[705] Hopson et al.
[706] Pisoni et al., "Trends in US Vascular Access Use, Patient Preferences, and Related Practices."
[707] Rhee et al., "Impact of Age, Race and Ethnicity on Dialysis Patient Survival and Kidney Transplantation Disparities."
[708] Mertler and Reinhart, *Advanced and Multivariate Statistical Methods*.

The number of hemodialysis sessions per week and the number of hours of dialysis per treatment are important components to dialysis care that have been associated with improved health outcomes. Better health outcomes, such as a lower risk for death, improved clinical outcomes and mental health, occur with longer or more frequent dialysis.[709,710] Morbidity and mortality are associated with dialysis duration and frequency, and these components of dialysis care have demonstrated statistically significant health related quality of life improvements, therefore they will be added into the models as covariates.[711,712]

Data Collection and Cleaning

The USRDS data had the largest volume of data and required IRB approval and a Data Use Agreement with USRDS. These files were store on George Mason University's Controlled Unclassified Information research computing environment required for the protection of USRDS's data. The individual data files were SAS files formatted as "sas7bdat" file extension and came in about twenty ZIP files. After unzipping the files, I converted each of the datasets into "dta" files to be read and analyzed in STATA 15. As STATA only works with one dataset at a time, I went through each file and isolated the variables relevant to my research. After noting the files which contained the data I needed, I went back to each file and cleaned it.

The data cleaning process consisted of screening for errors or missing values, and removing duplicates, then treating the problematic observations.[713] This consisted of deleting columns with variables not relevant to the research, deleting data from the years prior to 2012,

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[709] Unruh et al., "Effects of 6-Times-Weekly Versus 3-Times-Weekly Hemodialysis on Depressive Symptoms and Self-Reported Mental Health."
[710] Rivara et al., "Extended-Hours Hemodialysis Is Associated with Lower Mortality Risk in Patients with End-Stage Renal Disease."
[711] Lacson and Brunelli, "Hemodialysis Treatment Time."
[712] Garg et al., "Patients Receiving Frequent Hemodialysis Have Better Health-Related Quality of Life Compared to Patients Receiving Conventional Hemodialysis."
[713] Van den Broeck et al., "Data Cleaning."

deleting extra spaces, examining missing data, selecting and treating blank cells, converting numbers stored as text into numbers, and changing variable text for consistency with upper and lower cases. I also identified 25 duplicate observations of the same patient for the same year. These 25 rows were subsequently removed.

Examining and cleaning the data also consisted of filtering each variable column to display all observations and evaluate whether the data needs manipulation or further examination. For example, a hemoglobin level observation of 92.0 grams per deciliter was recognizably incorrect as that level is too high to be an accurate observation. An average hemoglobin level for a dialysis patient is 9.5 grams per deciliter.[714] Based on known information about hemoglobin levels, I concluded that the decimal point was erroneously placed and I changed the observation to be 9.20 grams per deciliter.

Different files contained the same variable but with different names. For example, the variable containing "yes" or "no" on whether the renal replacement therapy was discontinued prior to death was identified as *REPLTHEDS* in one file and *RXSTOP* in another file. Because these files contained data on the same variable from different years, I made both variable names *RRTdcd* (renal replacement therapy discontinued) and merged the two files on the USRDS unique identification number and the year. For this merged file containing data on death, no age was provided. However, a birthdate and a date of death was provided. I created a new age variable by subtracting the death date from the birthdate to get the patient's age at death.

For the two variables *dialysis type* and *modality type*, I combined all types of peritoneal dialysis. USRDS differentiates between Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cycler-assisted Peritoneal Dialysis (CCPD). Since the objective of the ESRD QIP is

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[714] United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."

to encourage more patients to use any type of peritoneal dialysis, combining CAPD and CCPD is appropriate. I then merged *dialysis type* and *modality type* because these variables contain the same values, but were labeled as different variable names in different data sets.

Once I identified the files with the variables I needed, I merged two files at a time until all the files were combined. Merge joins corresponding observations from a dataset open in STATA (called the master dataset) with a file saved in the CUI environment (called the using dataset). The files were matched on the USRDS unique identifiers, which were in each file. matching on one or more key variables.[715] The merges incrementally added new variables from each dataset to existing observations and the final file resulted in over one million observations and twenty-two variables. The merge of the first file (containing clinical data including patient hemoglobin levels) and second file (containing clinical data including employment status and dialysis modality type) resulted in 670,152 observations matched on the key variables (year and USRDS unique identifier) and 140,330 observations not matched. The newly combined file was merged with a third file containing information about death (such as place of death), and resulted in 999,423 observations matched and 837,892 observations not matched. This newly merged file merged with the last file that contained transplant data, which resulted in 25,420 observations matched and 1,905,863 observations not matched.

Missing Data

While the USRDS has data on the entire ESRD population in the US; special studies from which this data was collected contains a random sampling of patients. Combining data from several different USRDS studies demonstrated that patients do not have data for all USURDS studies. The missing data does not appear to be related to observed data as the most common missing data pattern is patients randomly selected for different studies. For example, the

[715] StataCorp, "Merge Datasets."

Hospitalization Dataset has complete observations for each patient. However, none of these patients had data in the Medical Evidence Dataset. In addition, many variables can only be collected one time. For example, type of dialysis modality, such as hemodialysis, is collected once when the patient begins the therapy. If the patient receives a transplant, then renal replacement status of the patient is collected once, after the patient receives a transplant. Most patients receive the same type of renal replacement for many years and will therefore not have annually collected data on renal replacement therapy type.[716,717] The missing data points do not appear to be related to the missing data or to the observed data. Rather, the missing data seems to be a random subset of the data. While missing data may threaten statistical power by reducing sample size, this dataset contains thousands of observations, which affords a smaller margin of error. See Table 24 for descriptive statistics of missing USRDS data.

Table 22. Missing Data from United States Renal Data System

Variable	Missing Data	Non-Missing Data	% Missing Data	Unique Values	Min	Max
Year	1917568	1,042,069	64.8	9	2,012	2020
Sex	1104451	1,855,186	37.3	2	1	2
Hispanic	2869184	90,453	96.9	4	0	9
Age	1104244	1,855,393	37.3	120	0	119
Employment Status	2152219	807,418	72.7	3	1	3
HD Treatments per Weeek	2231224	728,413	75.4	8	0	7
HD Hours per Treatment	2231237	728,400	75.4	43	0	10
Access Type	2248533	711,104	76.0	4	1	4
Hemoglobin Level	2291663	667,974	77.4	275	0.2	19.9
Transplant	2816442	143,195	95.2	2	0	1
Modality Type	2139238	820,399	72.3	4	1	4
Number of Diagnoses	2928876	30,761	99.0	26	1	26
Number of Surgeries	2928876	30,761	99.0	26	0	25
ICU Days	2928876	30,761	99.0	78	0	161
Age Categories	2008387	951,250	67.9	4	1	4
Hospice	2926543	33,094	98.9	2	0	1
Place of Death	2925416	34,221	98.8	4	1	4
Discontinued Treatment Prior to Death	2925416	34,221	98.8	2	0	1

[716] Jain, Haddad, and Goel, "Choice of Dialysis Modality Prior to Kidney Transplantation."
[717] United States Renal Data System, "2017 Researcher's Guide to the USRDS Database Appendix A: USRDS Products and Services."

To examine the missing data pattern, I generated indicators for missingness. The new variables created begin with the prefix “miss” and correspond to the original variables in the data set. Logistic regression models are conducted to evaluate whether any of the variables predict missingness. See Tables 25, 26 and 27 for variables that predict missingness. Variables associated with missingness that are statistically significant are identified as missing at random instead of missing completely at random. The majority of variables associated with missingness are not statistically significant. Hospice is statistically significantly associated with missingness of access type, and penalty is statistically significantly associated with missingness of hemoglobin. While the reason for missing data cannot be confirmed through statistical analysis, the regression analyses supports that the propensity for patient-level data points to be missing at random. Regression would not run for certain variables because the outcomes did not vary. STATA yields results when running the same regression only using variables that are not missing any observations. When conducting logit regression for missingness, STATA only uses those observations that do not contain missing values. See Appendix B for additional logistic regression models examining missing data.

Table 23. Logistic Regression Model for Missing Data: Access Type

Missing Access Type	Coef.	P>z	[95% Conf.Interval]	
Sex	-1.27	0.09	-2.75	0.21
Race	-0.77	0.26	-2.10	0.56
HD Hours	-0.62	0.34	-1.89	0.65
Number of Diagnoses	0.07	0.27	-0.06	0.20
Hospice	2.38	0.03	0.27	4.49
Place of Death	0.35	0.31	-0.32	1.02
Penalty	-3.12	0.14	-7.27	1.03
Hispanic	0.02	0.98	-1.54	1.58

Table 24. Logistic Regression Model for Missing Data: Hemoglobin

Missing Hemoglobin	Coef.	P>z	[95% Conf.Interval]	
Sex	2.54	0.06	-0.12	5.20
Race	-0.02	0.98	-1.58	1.54
HD Hours	-0.40	0.69	-2.37	1.57
Access Type	-0.03	0.97	-1.74	1.68
Number of Diagnoses	0.01	0.94	-0.16	0.18
Hospice	-0.68	0.67	-3.75	2.40
Place of Death	0.52	0.43	-0.77	1.80
Penalty	6.11	0.02	1.04	11.17
Hispanic	-1.32	0.28	-3.69	1.05
Age Categories	0.97	0.25	-0.68	2.63

Table 25. Logistic Regression Model for Missing Data: Modality Type

Missing Modality Type	Coef.	P>z	[95% Conf.Interval]	
Sex	0.33	0.40	-0.44	1.11
Race	-0.41	0.32	-1.23	0.41
Age Categories	0.25	0.21	-0.14	0.65
Number of Diagnoses	0.02	0.53	-0.05	0.10
Year	-0.12	0.43	-0.43	0.18
Hispanic	-0.61	0.41	-2.07	0.85

Data Analysis and Model Specifications

To answer whether associations exist between the key predictor variable Age Category and non-targeted and targeted measures, I will use pooled regression analyses with year dummies. Pooled cross-sectional data are obtained from USRDS, which provides random samples of dialysis patients that are independent of each other at different points in time. Time dummies will be used to model and test for differences in slope coefficients and intercept terms between years.[718] Each year the time dummies allow the intercept to have a different value. In the year

[718] Ward and Leigh, "Pooled Time Series Regression Analysis in Longitudinal Studies."

with the omitted dummy, which is 2012, the estimated intercept term in the model with time dummies is the estimated intercept. Similarly, the estimated coefficient of the time dummy corresponding to a particular year is an estimate of the difference between the intercept in that period and the intercept in the omitted year (2012).[719,720] Time dummy variables are used as controls to help describe change of over time associated with the ESRD QIP, and allow for evaluation of the program.

Descriptive and inferential statistics are first conducted to examine the data. This includes summary statistics of individual variables, and graphical depictions of individual variables and the relationship between two variables are executed. Contingency tables with Pearson Chi-Square hypothesis tests of independence between *Age Category* and the dependent variables are also conducted. Preliminary regression analyses in STATA resulted in numerous iterations of models that never converge, which indicates the model is not well specified. To identify the problem, I added “iter (20)” to the STATA command. This instructs STATA to stop iterating after twenty iterations, even though the model has not converged. STATA provides a table of output including the coefficients and standard errors. Some of the coefficients and standard errors were abnormally large or had a dot (“.”) instead of a number, which identified the problem variable. A large standard error is large in relation to the statistic, and generally indicates that the statistic will be non-significant.[721] The problem appears to be the categorical predictor variables with too many categories, which can diminish the model’s performance.[722] The following variables have too many categories to be practical or meaningful: *employment status, race* and *place of death*. To

719 Dielman, “Pooled Cross-Sectional and Time Series Data.”
720 Gerdtham et al., “The Determinants of Health Expenditure in the OECD Countries.”
721 McHugh, “Standard Error.”
722 Jones et al., “Visualising and Modelling Changes in Categorical Variables in Longitudinal Studies.”

avoid unnecessary levels in these variables, and to handle categories with a very small number of observations, I collapsed categories of these variables.[723]

Employment status is collapsed into three categories: unemployed, employed and retired. Retired is a combination of the category 'retired based on age' and 'retired based on disability.' Employed is a combination of 'employed full-time' and 'employed part-time.' Student and homemaker are collapsed into the 'unemployed category.' *Race* is condensed into three categories White, African American, and other. 'Other' consisted of American Indian, Asian and Pacific Islander, which are a very small subset of the dialysis population and of the overall percent of the variable *race* that it created large standard errors and coefficients. The *race* category 'unknown' was merged with the *race* category 'other' because the standard error was a ".," and the coefficient large (708.35).

Place of death is collapsed into four categories: hospital; dialysis unit, home and nursing home. The number of data points in the dialysis unit category and nursing home category appeared insufficient. Dialysis unit had 0 deaths for the two age categories corresponding to patients age 65 and over, and 9 deaths for the two age categories for patients under age 65. The nursing home category contained 9 data points for age category 3, and 9 data points for age category 4. To elicit whether the lack of data points would be problematic, multinomial logistic regression of *place of death* containing four categories was conducted. While convergence of the majority of models was achieved (see Appendix B), these models contained large negative coefficients and standard errors. The estimates associated with categories containing very few data points were imprecise and the data appeared to not be representative of the true mean, which created irregularities in the output and poorly fitting models.[724] Therefore, *place of death* was

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[723] Roy et al., "Evaluation of Unplanned Dialysis as a Predictor of Mortality in Elderly Dialysis Patients."
[724] Christley and Diggle, "Statistical Modelling."

further collapsed into two categories: hospital and/or facility death and home death. Regression analyses results which incorporated the independent variable *dual eligible,* also had irregularities. Convergence with the variable included in the model was never achieved, and the variable is therefore removed from the analyses. Convergence of some of the models was not achieved with the variable *Hispanic*. Therefore, *Hispanic* is only kept in models where convergence is achieved and the variable generated statistical significance.

The explanatory variables have been chosen based on a review of the literature and correlation analyses, therefore they have a demonstrated relationship with the dependent variables. Control variables are included as inputs to separate their effects from the explanatory variables and exclude alternative explanations about the relationship between the explanatory variables and the outcome variables. Statistically significant control variables changing the coefficient estimates of the explanatory variables are maintained. Forward and backward stepwise selection was used to make a selection from the original 18 variables. For each step, a variable is considered for addition to or removal from the model based on the following criteria: P values, adjusted R^2, standard error, goodness of fit tests, Akaike Information criterion, Bayesian information criterion.[725] Four types of regression analyses are used to evaluate two ESRD QIP targeted measures and the non-targeted measures: binary logistic regression, multinomial logistic regression, negative binomial regression and multiple linear regression. The first two outcome variables are ESRD QIP targeted measures and the remaining five outcome variables are non-targeted performance measures. The key predictor variable is age and the outcome variables are used as control variables when not being used as outcome variables. See Table 26.

[725] Zhang, "Variable Selection with Stepwise and Best Subset Approaches."

Table 26. Variables and Types of Regression

Outcome Variable	Outcome Variable Type	Explanatory and Control Variables	Regression
Access Type	Categorical	Year, Age Category, Sex, Race, Ethnicity, Number of Diagnoses, HD hours per Treatment, HD Treatments per Week, Hospice, Discontinued Treatment prior to Death, Transplant, Place of Death, Modality Type, Access Type, Employment Status, ICU Days, Hemoglobin Level	Multinomial Logistic
Hemoglobin Level	Continuous		Multiple Linear
Hospice	Binary		Logistic
Discontinued Treatment prior to Death	Binary		Logistic
Place of Death	Binary		Logistic
Modality Type	Categorical		Multinomial Logistic
ICU Days	Count		Negative Binomial

Binary Logistic Regression

Logistic Regression is first performed for each of the binary outcomes, which have values of one or zero reflecting whether the event occurs or not. The dependent binary variables include: *hospice* (received hospice or did not receive hospice); *RRTdcd* (renal replacement therapy discontinued prior to death or renal replacement therapy not discontinued prior to death); and *place of death* (death in the hospital/facility or death at home). In addition to a binary response, binary logistic regression contains a set of explanatory and control variables. The response Y assumes the values 0 or 1 with the expected value of Y being the probability that Y= 1.[726] The success category (Y=1) represents the probability of an event occurring as a function of X explanatory variables.

While the model does not assume a linear relationship, it assumes a linear combination of the explanatory variables, which provides the probability of the response variable through the logit link function.[727] Homogeneity of variance is not required and generally not feasible. While the error terms are not assumed to be normally distributed, they need to be independent. Maximum likelihood estimation estimates the parameters and therefore depends on a large

[726] Walker and Duncan, "Estimation of the Probability of an Event as a Function of Several Independent Variables."
[727] Minium, Clarke, and Coladarci, *Elements of Statistical Reasoning*.

sample of data points.[728,729] The estimated coefficients determine the effect of a one-unit increase in the explanatory variable on the logarithm of the odds ratio, while holding other independent variables unchanged. The odds ratio, which is ascertained by exponentiating the coefficient, is the ratio of two odds: the odds of success related to a unit increase in the explanatory variable and the odds of failure without a unit increase in the explanatory variable.[730,731] Binary logistic regression for *hospice* is specified by the following equation:

Equation 2. Hospice Binary Logistic Regression Model Specification

$$Hospice\left[\frac{p}{1-p}\right] = e^{(\alpha +)\,\beta_1 Age\ Category_2 + \beta_2 Age\ Category_3 + \beta_3 Age\ Category_4 + \beta_4 Year_{2013} + \beta_5 Year_{2014} \ldots + \beta_9 Year_{2018} + \beta_{10} Sex + \beta_{11} Race_2 + \beta_{12} Race_3 + \beta_{13} Race_4 + \beta_{14} Hispanic + \beta_{15} Patient\ Informed + \beta_{16}\ RRTdcd}$$

Reference Category for Age Category dummy variable: Age Category 1
Reference Category for Year dummy variable: 2012
Reference Category for Race dummy variable: White

Binary logistic regression for *RRTdcd* is specified by the following equation:

Equation 3. RRTdcd Binary Logistic Regression Model Specification

$$RRT\ Discontinued\ prior\ to\ Death\left[\frac{p}{1-p}\right] = e^{(\alpha + \beta_1 Age\ Category_2 + \beta_2 Age\ Category_3 + \beta_3 Age\ Category_4 + \beta_4 Year_{2013} + \beta_5 Year_{2014} \ldots + \beta_9 Year_{2018} + \beta_{10} Hispanic + \beta_{11} Race_2 + \beta_{12} Race_3 + \beta_{13} Race_4 + \beta_{14} Hospice)}$$

Reference Category for Age Category dummy variable: Age Category 1
Reference Category for Year dummy variable: 2012
Reference Category for Race dummy variable: White

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728 Braunstein, "How Large a Sample Is Needed for the Maximum Likelihood Estimator to Be Approximately Gaussian?"
729 Ge and Whitmore, "Binary Response and Logistic Regression in Recent Accounting Research Publications."
730 Bland and Altman, "The Odds Ratio."
731 Ge and Whitmore, "Binary Response and Logistic Regression in Recent Accounting Research Publications."

Binary logistic regression for *place of death* is specified by the following equation:

Equation 4. Place of Death Binary Logistic Regression Model Specification

$$Place\ of\ Death\left[\frac{p}{1-p}\right] = e^{(\alpha + \beta_1 Age\ Category_2 + \beta_2 Age\ Category_3 + \beta_3 Age\ Category_4 + \beta_4 Year_{2013} + \beta_5 Year_{2014} \cdots + \beta_9 Year_{2018} + \beta_{10} Hispanic + \beta_{11} Race_2 + \beta_{12} Race_3 + \beta_{13} Race_4 + \beta_{14} Hospice + \beta_{15} EmploymentStatus_2 + \beta_{16} EmploymentStatus_3}$$

Reference Category for Age Category dummy variable: Age Category 1
Reference Category for Year dummy variable: 2012
Reference Category for Race dummy variable: White
Reference Category for Employment Status dummy variable: Unemployed

After each logistic regression analysis, a goodness of fit test is performed. The goodness of fit "estat classification" command reports various summary statistics, including the classification table, and requires that estimation results be from a logistic regression. The classification table contains sensitivity and specificity tests. Sensitivity is the percentage of true positives, while specificity is the percentage of true negatives.[732] Specificity (the true negative rate) ranges from 0 to 100%, and indicates how well a test performs to correctly exclude people for whom the event does not occur. A specificity of 100% indicates that all negatives are true negatives, and no false positives exist. A specificity of 50% indicates that the number of true negatives and false positives are the same. A specificity of 0% indicates no true negatives exist, and all patients with whom the event does not occur are false positives.[733] The cutoff number (0.5) specifies the value for establishing whether an observation has a predicted positive outcome. During the regression model specification process, I used statistical assessments (p value, z score, standard deviation, pseudo R^2 and the goodness of fit classification table) to identify which independent variables to retain and exclude in the regression equation.

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[732] Parikh et al., "Understanding and Using Sensitivity, Specificity and Predictive Values."
[733] Cool and Ockendon, "Stats Book."

Multinomial Logistic Regression

Multinomial regression is conducted to statistically estimate the predicted effect of principal independent variable age category on the categorical dependent variables: *modality type* and *access type*. *Modality type* consists of four categories: in-center hemodialysis (in-center HD), home hemodialysis (home HD), peritoneal dialysis (PD) and transplant. *Access type* includes the categories arteriovenous fistula (AV fistula), arteriovenous graft (AV graft), central venous catheter (CVC) and other. Multinomial logistic regression is an extension of the binary logistic regression, permitting more than two categories of the dependent variable that are not ordinal. The first category of the dependent variable, which is the value with the highest frequency, is selected as the reference category. The reference category for *modality type* is in-center HD, and the reference category for access type is AV fistula. The probability of belonging in the other three categories is compared to the probability of belonging in the reference category.[734,735]

Three dummy variables are used, because m*odality type* and *access type* each contain four categories, and each dummy variable has a value of 1 for its category and 0 for the other categories. The multinomial logistic regression estimates a separate binary logistic regression model for each of the dummy variables. This results in three specification model equations that each estimate the logit equation and assume a log distribution of the probability of the dependent variable category occurring. While multinomial logistic regression does not assume normality, linearity or homoscedasticity, it does assume independence among the dependent variable categories and independence of irrelevant alternatives.[736,737,738] For example, the relative

[734] Campbell and Donner, "Classification Efficiency of Multinomial Logistic Regression Relative to Ordinal Logistic Regression."
[735] Berman & Wang, *Essential Statistics for Public Managers and Policy Analysts*.
[736] Bull and Donner, "The Efficiency of Multinomial Logistic Regression Compared with Multiple Group Discriminant Analysis."
[737] Petrucci, "A Primer for Social Worker Researchers on How to Conduct a Multinomial Logistic Regression."
[738] Berman & Wang, *Essential Statistics for Public Managers and Policy Analysts*.

probability of a patient receiving the modality type PD does not change if the modality type home HD is added as a category. Thus, four alternatives for modality type are modeled as a set of three independent binary outcomes equations.

Multinomial logistic regression is used to model the nominal dependent variable modality type. The log odds of the modality type categories are modeled as a linear combination of the key predictor Age Category and year dummies, while controlling for sex, race and employment status. The base outcome, or reference category, for the key predictor variable Age Category is age category 1 (0-44 years old). The base outcome, or reference category, of modality type is in-center HD and signifies the category that is used for the baseline comparison group. The multinomial logistic regression estimates a separate binary logistic regression model for each of the dummy variables. This results in three specification model equations that each estimate the logit equation and assume a log distribution of the probability of the dependent variable category occurring. The primary interest is the estimation of Age Categories on the dialysis patient's modality type. Age category, year, race and employment status are categorical variables, and included in the model as a series of indicator variables. The reference category for *Age Category* is age category 1 (0-44 years old), the reference category for *year* is 2012, the reference category for *race* is White, and the reference category for *employment status* is unemployed. See Equation 5 for the multinomial logistic regression model specification for modality type.

Equation 5. Modality Type Multinomial Logistic Regression Model Specification

$$\ln\left(\frac{P(ModalityType=HomeHD)}{P(ModalityType=In-CenterHD)}\right)=\beta_0+\beta_1 AgeCategory_2+\beta_2 AgeCategory_3+\beta_3 AgeCategory_4+\beta_4 Year_{2013}+\beta_5 Year_{2014}+\ldots+\beta_9 Year_{2018}+\beta_{10} Sex+\beta_{11} Race_2+\beta_{12} Race_3+\beta_{13} EmploymentStatus_2+\beta_{14} EmploymentStatus_3$$

$$\ln\left(\frac{P(ModalityType=PD)}{P(ModalityType=In-CenterHD)}\right)=\beta_0+\beta_1 AgeCategory_2+\beta_2 AgeCategory_3+\beta_3 AgeCategory_4+\beta_4 Year_{2013}+\beta_5 Year_{2014}+\ldots+\beta_9 Year_{2018}+\beta_{10} Sex+\beta_{11} Race_2+\beta_{12} Race_3+\beta_{13} EmploymentStatus_2+\beta_{14} EmploymentStatus_3$$

$$\ln\left(\frac{P(ModalityType=Transplant)}{P(ModalityType=In-CenterHD)}\right)=\beta_0+\beta_1 AgeCategory_2+\beta_2 AgeCategory_3+\beta_3 AgeCategory_4+\beta_4 Year_{2013}+\beta_5 Year_{2014}+\ldots+\beta_9 Year_{2018}+\beta_{10} Sex+\beta_{11} Race_2+\beta_{12} Race_3+\beta_{13} EmploymentStatus_2+\beta_{14} EmploymentStatus_3$$

Reference Category for Age Category dummy variable: Age Category 1
Reference Category for Year dummy variable: 2012
Reference Category for Race dummy variable: White
Reference Category for Employment Status dummy variable: Unemployed

Multinomial logistic regression is used to model the nominal dependent variable *access type*. The log odds of the *access type* categories are modeled as a linear combination of the key predictor Age Category and dummy year variables controlling for sex, race and HD hours. The base outcome or reference category is AV fistula and signifies the category used for the baseline comparison group. The primary interest is the estimation of age categories on the dialysis patient's access type. Age category, year and race are categorical variables, and included in the model as a series of indicator variables. The reference category for *Age Category* is age category 1, the reference category for *year* is 2012, and the reference category for *race* is White. See Equation 6 for the Multinomial logistic regression model specification for *access type*.

Equation 6. Access Type Multinomial Logistic Regression Model Specification

$$\ln\left(\frac{P(AccessType=AVGraft)}{P(AccessType=AVFistula)}\right)=\beta_0+\beta_1 AgeCategory_2+\beta_2 AgeCategory_3+\beta_3 AgeCategory_4+\beta_4 Year_{2013}+\beta_5 Year_{2014}+\ldots+\beta_9 Year_{2018}+\beta_{10} Sex+\beta_{11} Race_2+\beta_{12} Race_3+\beta_{13} HD\ Hours$$

$$\ln\left(\frac{P(AccessType=CVC)}{P(AccessType=AVFistula)}\right)=\beta_0+\beta_1 AgeCategory_2+\beta_2 AgeCategory_3+\beta_3 AgeCategory_4+\beta_4 Year_{2013}+\beta_5 Year_{2014}+\ldots+\beta_9 Year_{2018}+\beta_{10} Sex+\beta_{11} Race_2+\beta_{12} Race_3+\beta_{13} HD\ Hours$$

$$\ln\left(\frac{P(AccessType=Other)}{P(AccessType=AVFistula)}\right)=\beta_0+\beta_1 AgeCategory_2+\beta_2 AgeCategory_3+\beta_3 AgeCategory_4+\beta_4 Year_{2013}+\beta_5 Year_{2014}+\ldots+\beta_9 Year_{2018}+\beta_{10} Sex+\beta_{11} Race_2+\beta_{12} Race_3+\beta_{13} HD\ Hours$$

Reference Category for Age Category dummy variable: Age Category 1
Reference Category for Year dummy variable: 2012
Reference Category for Race dummy variable: White

Negative Binomial Regression

Negative binomial regression is used for the count dependent variable *ICU_days* (number of days spent in the ICU during one hospital episode). Negative Binomial Regression is used instead of Poisson because distributional qualities of ICU days demonstrate that overdispersion is suspected. A Poisson regression model explains observed heterogeneity with the assumption that the Poisson random variable mean must be equal to its variance. If the assumption that the conditional variance is more than the conditional mean, then the Poisson model standard errors will tend to be underestimated, z values will be inflated and p values will be artificially low. This problem of overdispersion frequently exists with count data because of the unobserved heterogeneity and prevalence of observations having zero frequency.[739,740,741] When overdispersion occurs, a negative binomial distribution is most fitting to use. See Equation 7 for the negative binomial logistic regression model specification.

Equation 7. Negative Binomial Logistic Regression Model Specification

$$\text{ICU Days} = e^{(\beta_0 + \beta_1 \textit{Age Category}_2 + \beta_2 \textit{Age Category}_3 + \beta_3 \textit{Age Category}_4 + \beta_4 \textit{Number of Diagnoses} + \beta_5 \textit{Number of Surgeries} + \beta_6 \textit{Year}_{2013} + \beta_7 \textit{Year}_{2014} + \beta_8 \textit{Year}_{2015} + \beta_9 \textit{Year}_{2016})}$$

Reference Category for Age Category dummy variable: Age Category 1
Reference Category for Year dummy variable: 2012

The regression coefficients are interpreted as a difference between the logs of expected counts. Each regression coefficient is interpreted as its effect on ICU days, controlled for all

739 Gardner, Mulvey, and Shaw, "Regression Analyses of Counts and Rates."
740 Long and Freese, "Predicted Probabilities for Count Models."
741 Cameron and Trivedi, *Microeconometrics Using Stata*.

independent variables in the model. The regression coefficient b_1 shows the effects of x_1 (Age Category) on y (ICU days). The remainder of the variables are covariates and controls. The primary interest is the estimation of Age Categories on the number of ICU days a dialysis patient spends during one hospital episode. Age category is a categorical variable, and included in the model as a series of indicator variables. The reference category for *Age Category* is age category 1 and the reference category for *year* is 2012.

Negative binomial regression is a generalization of Poisson regression, and is formed by the Poisson-gamma mixture distribution. The Poisson parameter accounts for overdispersion and is a random variable, which is distributed according to a gamma distribution. Thus, the negative binomial distribution is known as a Poisson-Gamma mixture.[742] This permits Poisson heterogeneity modelling using a gamma distribution, which includes a parameter to account for overdispersion and estimate the possible deviation of variance from that predicted under the Poisson distribution.[743,744] Negative binomial regression begins with fitting a Poisson model, and then a null model with only the intercept. The iterations begin to end with the Negative binomial model, which employs maximum likelihood estimate, and repeats until the log likelihood is adequately small. The final log likelihood in the iteration log is log likelihood for the full model, which can be used to compare models.[745]

To help assess the goodness of fit of the negative binomial regression models, each model will be compared using Akaike information criterion (AIC) and Bayesian Information Criterion (BIC). AIC and BIC measures goodness of fit and model simplicity. AIC compares models by estimating the likelihood of a model to predict and estimate future values while BIC

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742 Long and Freese, "Predicted Probabilities for Count Models."
743 Cameron and Trivedi, *Microeconometrics Using Stata*.
744 Gardner, Mulvey, and Shaw, "Regression Analyses of Counts and Rates."
745 UCLA: Statistical Consulting Group, "Introduction to SAS."

evaluates the trade-off between model fit and complexity. A lower AIC or BIC value signifies a better fitting model that is more parsimonious.[746,747,748]

Multiple Linear Regression

Multiple linear regression is conducted to examine the relationship between the independent variables (Age Category, year, sex, race and ethnicity) and the continuous dependent variable *hemoglobin*. See Equation 8 for the Multiple Linear Regression model specification.

Equation 8. Multiple Regression Model Specification

$$\text{Hemoglobin} = \beta_0 + \beta_1\text{Age Category}_2 + \beta_2\text{Age Category}_3 + \beta_3\text{Age Category}_4 + \beta_4\text{Year}_{2013} + \beta_5\text{Year}_{2014} + \ldots + \beta_9\text{Year}_{2018} + \beta_{10}\text{Sex} + \beta_{11}\text{Race}_2 + \beta_{12}\text{Race}_3 + \beta_{13}\text{Hispanic} + \varepsilon_i$$

Reference Category for Age Category dummy variable: Age Category 1
Reference Category for Year dummy variable: 2012
Reference Category for Race dummy variable: White

Each regression coefficient is interpreted as its effect on hemoglobin, controlled for all independent variables in the model. The regression coefficient b_1 shows the effects of x_1 (Age Category) on y (hemoglobin) and ε_i is the error term. The remainder of the variables are covariates and controls.[749] The primary interest is the estimation of Age Categories on dialysis patient hemoglobin levels. The reference category for *Age Category* is age category 1, the reference category for *year* is 2012, and the reference category for *race* is White.

A box and whisker plot of hemoglobin levels from years 2012 through 2018 will be conducted to evaluate whether an association exists between hemoglobin levels and age category with the year dummies. The plot will help examine whether the data is skewed, contains outliers,

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[746] Mohammed, Naugler, and Far, "Chapter 32: Emerging Business Intelligence Framework for a Clinical Laboratory Through Big Data Analytics."
[747] Kingdom and Prins, "Chapter 9 - Model Comparisons∗∗This Chapter Was Primarily Written by Nicolaas Prins."
[748] Cameron and Trivedi, *Microeconometrics Using Stata*.
[749] Berman & Wang, *Essential Statistics for Public Managers and Policy Analysts*.

or follows a normal distribution. A standardized normal probability plot for hemoglobin will be conducted to examine whether the distribution of hemoglobin data points is approximately normally distributed. The plot of the data points against a theoretical normal distribution should create an approximate straight line.[750] To test for heteroscedasticity, the Breusch-Pagan Test is performed on the regression model with hemoglobin as the dependent variable. The null hypothesis states that there is constant variance among the residuals. Goodness-of-fit tests are conducted to assess if the data fits the distribution from the dialysis patient population. The goodness of fit tests detects model specification errors to identify the extent to which the model fits the data, and for model evaluation and selection.[751,752]

Results

Descriptive Statistics

Each cross section contains randomly sampled dialysis populations independent from each other at different time points. Table 29 displays the frequency and percentage of each of the four age categories from 2012 through 2018. The number of patients in each age category remains relatively constant over time.

Table 27. Frequency of Dialysis Patients in an Age Category over Time

	Year							
Age Category	2012	2013	2014	2015	2016	2017	2018	Total
1 (0-44)	23550 (18.18%)	23577 (17.84%)	24697 (18.24%)	25780 (18.41%)	25788 (18.14%)	25515 (18.13%)	19868 (15.13%)	168,775
2 (45-64)	58380 (45.07%)	59906 (45.34%)	61459 (45.40%)	63890 (45.62%)	64691 (45.52%)	63618 (45.20%)	63523 (48.38%)	435,467
3 (65-74)	27033 (20.87%)	28311 (21.43%)	28957 (21.39%)	29748 (21.24%)	31314 (22.03%)	31403 (22.31%)	30053 (22.89%)	206819
4 (75+)	20560 (15.87%)	20329 (15.39%)	20266 (14.97%)	20640 (14.74%)	20334 (14.31%)	20199 (14.35%)	17861 (13.60%)	140189
Total	129523	132123	135379	140058	142,127	140735	131305	951250

750 Nisbet, Miner, and Yale, "Chapter 11 - Model Evaluation and Enhancement."
751 Manjón and Martínez, "The Chi-Squared Goodness-of-Fit Test for Count-Data Models."
752 Chen, Zhang, and Li, "Goodness-of-Fit Test for Meta-Analysis."

A contingency table of 20,477 randomly sampled dialysis patients is performed to display the frequency of dialysis patients in a corresponding age category and penalty status. See Table 29. The penalty status indicates how well the facility achieved the ESRD QIP targeted measures by age. The contingency table is contextual information useful to understanding the regression analysis evaluating patient targeted and non-targeted measures. The weak association revealed by the Spearman's correlation examining performance between a facility's penalty status and star-rating demonstrated that facilities achieving the ESRD QIP targeted measures may be deficient in achieving other performance. Therefore, penalty status by age group provides preliminary descriptive information about which age groups are more likely to receive a penalty under the ESRD QIP and whether this will be similar to the age groups deficient in achieving the non-targeted measures evaluated in this dissertation.

The largest age category is 2, which consists of dialysis patients 45-64 years old. Dialysis patients who are age 65-74 years old comprise the second largest age category. The Chi-Square hypothesis examines the effects between penalty and age, and the results demonstrate a significant relationship between the two variables. Most age categories receive no penalty, and frequencies do not show a higher penalty status for older age categories. For dialysis patients age 45-64 years old, 78% are treated at a facility that receives no penalty while 22% are treated at a facility that receives any amount of a penalty. For dialysis patients age 65-74 years old, 81% are treated at a facility that receives no penalty while 19% are treated at a facility that receives any amount of a penalty. For dialysis patients age 75 and older, 81% are treated at a facility that receives no penalty while 19% are treated at a facility that receives any amount of a penalty. Therefore, older dialysis patients (age 65 years and older) compared to younger dialysis patients are marginally more likely to be treated at a facility that receive no penalty.

Table 28. Frequency of Penalty vs Age Category

Penalty	1	2	3	4	Total
0	2,397	6,963	3,738	3,133	16,231
0.5	350	1,051	497	425	2,323
1	121	407	196	162	886
1.5	162	432	153	125	872
2	29	77	29	30	165
Total	3,059	8,930	4,613	3,875	20,477
Pearson	chi2(12) = 47.8711	Pr=0			

Preliminary ordinal logistic regression analysis examining the association of age category and penalty status while controlling for race using patient level data was also conducted. I used race as a control because I believe this variable relates to the outcome variable, previous studies have included the variable and have found statistically significant relationships between race and penalty status, and including race may reflect an alternative explanation to the following results.[753] The findings demonstrate that age category is statistically significant for dialysis patients age 65 and over with weak to moderate strengths of association.

With 20,477 observations, the Likelihood Ratio Chi-Square of 121.2 with a p-value of $\leq$0.001 shows that the model as a whole is statistically significant, as compared to the null model with no predictors. The ordered logit estimate comparing age category 3 (65-74) to age category 1 (0-44) for level of penalty status, given the other variables in the model are held constant, is -0.16 (95% CI -0.27, -0.46) and statistically significant at p<0.001. For a one-unit increase in age category 3, a 0.16 decrease in the log odds of having a higher penalty status is expected, given all of the other variables in the model are held constant. The ordered logit estimate comparing age category 4 (75+) to age category 1 (0-44) for level of penalty status, given the other variables in the model are held constant, is -0.13 (95% CI -0.25, -0.01) and statistically significant at p<0.05.

[753] Bernerth and Aguinis, "A Critical Review and Best-Practice Recommendations for Control Variable Usage."

For a one-unit increase in age category 4, a 0.13 decrease in the log odds of having a higher penalty status is expected, given all of the other variables in the model are held constant.

The ordered logit estimate comparing African Americans to Whites for level of penalty status, given the other variables in the model are held constant, is 0.47 (95% CI 0.37, 0.56) and statistically significant at $p<0.001$. For a one-unit increase in African American (compared to White), a 0.47 increase in the log odds of having a higher penalty status is expected, given all of the other variables in the model are held constant. African Americans are more likely to be patients at dialysis facilities that receive a penalty and/or a higher penalty level, which is consistent with previous research.[754,755] The key predictor, dialysis patients age 65 years and older, are marginally less likely to receive treatment at a facility that incurs a penalty and/or receive a lower penalty level. See Table 29.

Table 29. Ordered Logistic Regression Penalty and Age Category with Race

Ordered Logistic Regression		Number of obs	=	20,477		
		LR chi2(5)	=	121.2		
		Prob > chi2	=	0		
Log likelihood = -15097.118		Pseudo R2	=	0.004		
Penalty	**Coef.**	**Std. Err.**	**z**	**P>z**	**[95% Conf.**	**Interval]**
Race						
2	0.467	0.049	9.55	0	0.371	0.563
3	0.186	0.047	3.98	0	0.094	0.277
Age Categories						
2	0.031	0.051	0.61	0.542	-0.068	0.130
3	-0.159	0.058	-2.76	0.006	-0.272	-0.046
4	-0.132	0.060	-2.2	0.028	-0.249	-0.014

[754] Saunders, Lee, and Chin, “Early Winners and Losers in Dialysis Center Pay-for-Performance.”
[755] Qi, Butler, and Joynt Maddox, “The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program.”

Contingency tables for the categorical dependent variables demonstrated relationships between age category and patient level targeted and non-targeted measures. About 5% of patients age 75+ receive a transplant and about 10% of patients 65-74 years old receive a transplant. Patients 45-64 years old receive 52% of the transplants, which is the age category that has historically been the most likely to have this modality. About 44% of patients age 75+ do not receive hospice care, while 54% do receive hospice care. About 54% of patients age 75+ do not discontinue dialysis prior to death, while about 44% of patients 75+ discontinue dialysis prior to death. For the outcome variable place of death (death in the hospital/facility or death at home) not enough evidence exists to suggest a relationship exists. Since the p-value is greater than 0.05, I fail to reject the null that no relationship exists between age category and place of death in the population.

About 15% of patients age 75+ have an AV fistula as a means of access, which is an ESRD QIP targeted measure. For patients age 65-74 years old, about 25% have an AV fistula as a means of access. About 45% of those 45-64 years old have a fistula as a means of access and are most likely to have a fistula compared to the other age categories. About 16% of patients age 75+, 24% of patients age 65-74 years old and 44% age 45-64 years old use in-center HD. While about 13% of patients age 75+, 18% of patients age 65-74 years old and 45% age 45-64 years old use in-center HD. See Table 30, which include the contingency tables for the chi squared test of significance for all outcome variables.

Table 30. Contingency Tables of Patient Level Data

Age Category	Hospice 0	Hospice 1	Total
1	2,326	567	2,893
2	1,522	522	2,044
3	90	39	129
4	4	5	9
Total	3,942	1,133	5,075

Pearson chi2(3) = 34.9492 Pr = 0.000

Age Category	Discontinued Dialysis Prior to Death 0	Discontinued Dialysis Prior to Death 1	Total
1	2,268	648	2,916
2	1,522	556	2,078
3	95	38	133
4	5	4	9
Total	3,890	1,246	5,136

Pearson chi2(3) = 16.9794 Pr = 0.001

Age Category	Place of Death 0	Place of Death 1	Total
1	1,935	1,126	3,061
2	1,003	598	1,601
3	64	34	98
4	248	124	372
Total	3,259	1,882	5,132

Pearson chi2(3) = 2.2860 Pr = 0.515

Age Category	Access Type 1	Access Type 2	Access Type 3	Access Type 4	Total
1	17,972	2,561	88,218	229	108,980
2	56,778	9,322	249,562	516	316,178
3	31,430	5,792	131,150	274	168,646
4	18,697	4,114	94,162	210	117,183
Total	124,877	21,789	563,092	1,229	710,987

Pearson chi2(9) = 849.6126 Pr = 0.000

Age Category	Modality Type: In-Center HD	Home HD	PD	Transplant	Total
1 (0-44)	108,814	8,373	10,147	885	128,219
2 (45-64)	315,939	17,403	18,468	1,171	352,981
3 (65-74)	168,571	7,529	7,444	238	183,782
4 (75+)	117,138	3,738	5,174	25	126,075
Total	710,462	37,043	41,233	2,319	791,057

Pearson chi2(9) = 6.2e+03 Pr = 0.000

Summary statistics for the indicator variable *HD Treatment Sessions per Week* and *Age Categories* reveals a marginal decrease in the number of treatments a dialysis patient receives each week for each successive older age category. Therefore, the older a dialysis patient becomes, the fewer treatments per week he or she receives. See Table 31.

Table 31. Summary Statistics for HD Treatments per Week

Diagnostics
Summary for variables: HD Treatments per Week
by categories of: Age_Cats (RECODE of age)

Age Categories	mean	sd	N
1	3.01	0.25	113403
2	3.00	0.22	323303
3	3.00	0.22	170151
4	2.99	0.23	118024
Total	3.00	0.23	724881

The number of surgeries per hospital episode, another indicator variable, have marginally decreased since 2012 from 3.53 to 3.42. The oldest age category (75 years old and over) has an average of 2.66 surgeries per hospital episode, while younger age categories have, on average, a little over 3 surgeries per hospital episode. On average, older patients have few surgeries per hospital episode. See Table 32 for the number of surgeries per hospital stay by year and age category.

Table 32. Number of Surgeries per Hospital Episode by Year and Age Category

Number of Surgeries	Obs	Mean	Std. Dev.	Min	Max
Year					
2012	7545	3.53	3.36	0	25
2013	6587	3.56	3.47	0	25
2014	6019	3.53	3.48	0	25
2015	5750	3.57	3.68	0	25
2016	4860	3.42	3.72	0	25

Number of Surgeries	Obs	Mean	Std. Dev.	Min	Max
Age Category					
1	6294	3.01	2.85	0	25
2	5292	3.09	2.98	0	25
3	477	3.08	2.83	0	24
4	793	2.66	2.70	0	25

Regression Analysis

ESRD QIP Targeted Measures

Multinomial Logistic Regression for Access Type

Multinomial logistic regression is an extension of binary logistic regression and used to model the log odds of the nominal dependent variable *access type*. Similar to binary and ordered logistic regression, multinomial logistic regression uses maximum likelihood estimation, which determines the distribution parameters that best explains the data. The iterative process for determining the maximum likelihood estimates begins with iteration zero, which is the log likelihood of the null model containing no explanatory variables.[756,757] The subsequent iterations include the explanatory variables. With each iteration, the log likelihood is decreased, which is the objective of the iterative process. The iteration process ends when the difference between consecutive iterations has become very small, and the model converges.[758] See Appendix B for all

[756] Harter and Moore, "Iterative Maximum-Likelihood Estimation of the Parameters of Normal Populations from Singly and Doubly Censored Samples."
[757] Kohler and Kreuter, *Data Analysis Using Stata*.
[758] UCLA: Statistical Consulting Group, "Introduction to SAS: Multinomial Logistic Regression."

of the multinomial logistic regression models and selection criteria, which reflects the iterative model fitting process.

Multinomial logistic regression is used to examine the relationship between *Access Type* and *Age Categories*. The final model contains the following independent variables: *Race, Sex, Year* and *HD hours*. *Access type* has four categories: AV fistula, AV graft, CVC and other. The reference category is AV fistula, which has the largest number of observations. The coefficients for the three other categories (AV graft, CVC and other) explain how the explanatory variables are associated with the probability of being in one of the three categories versus the reference category. The model summary has 710,113 observations, and the Likelihood Ratio (LR) Chi-Square tests that for all three equations (CVC relative to AV fistula, CVC relative to AV graft and CVC relative to other) at least one of the predictors' regression coefficient is not equal to zero. The null hypothesis is that all of the regression coefficients across the models are simultaneously equal to zero, which is the probability of obtaining the LR Chi-Square statistic (7781.92) if no effect of the predictor variables exists. With a small p-value from the LR Chi Square test ($p < 0.001$), I conclude that at least one of the regression coefficients in the model is not equal to zero.

The multinomial logit estimate comparing 45-64 years old, 65-74 years old and 75 years and older to 0-44 years-old dialysis patients for having an AV fistula versus a CVC, given the other variables in the model are held constant are 0.10 (95% CI: 0.08, 0.12), 0.15 (95% CI: 0.13, 0.17) and -0.06 (95% CI: -0.09, -0.04) respectively. The statistically significant ($p < 0.001$) coefficients demonstrate that 45-64 years old and 65-74 years old are marginally more likely to have an AV fistula than 0-44 years old dialysis patients; while patients 75 years and older are marginally less likely to have an AV fistula than 0-44 years old dialysis patients.

The multinomial logit for females relative to males is decreased by 0.29 (95% CI: -0.31, -0.28), for fistula versus catheter, given all other predictor variables in the model are held constant. Statistically significant at $p < 0.001$, the multinomial logit estimate comparing females to males is 0.29 unit lower for having an AV fistula relative to having a CVC given all other predictor variables in the model are held constant. The multinomial logit estimate comparing African Americans to Whites for having an AV fistula versus having a CVC, given the other variables in the model are held constant is -0.08 (95% CI: -0.10, -0.07) and statistically significant at $p < 0.001$. Therefore, African Americans are marginally less likely than Whites to have an AV fistula.

The multinomial logit estimate comparing years 2013 through 2018 to 2012, given the other variables in the model are held constant, are statistically significant at $p < 0.05$. The multinomial logit estimate comparing 2018 to 2012 for having an AV fistula versus having a CVC, given the other variables in the model are held constant is 0.08 (95% CI: 0.05, 0.11). Therefore, for the year 2018 dialysis patients are marginally more likely to have an AV fistula than a CVC. For years 2013 through 2017, the coefficient estimates range from 0.02 to 0.04. These results also indicate a marginal increase in the use of an AV fistula, compared to a CVC. Since the year 2012, patients are more likely to have an AV fistula compared to a CVC. However, the statistically significant coefficients demonstrate weak relationships between access type and the year. The multinomial logit for HD hours is decreased by 0.19 (95% CI: -0.21, -0.18), for having an AV fistula versus a CVC, given all other predictor variables in the model are held constant. The multinomial logit estimate for HD hours is 0.19 units lower for having an AV fistula relative to having a CVC given all other predictor variables in the model are held constant. Therefore, dialysis patients with an AV fistula receive a lower duration of treatment time than dialysis patients with a CVC.

The multinomial logit for females relative to males is increased by 0.44 (95% CI: 0.42, 0.47), for having an AV graft versus a CVC, given all other predictor variables in the model are held constant. The multinomial logit estimate comparing females to males is 0.47 unit higher for having an AV graft relative to having a CVC given all other predictor variables in the model are held constant. The multinomial logit estimate comparing African Americans to Whites for having an AV graft versus having a CVC, given the other variables in the model are held constant is 0.65 (95% CI: 0.63, 0.68) and statistically significant at $p < 0.001$. Therefore, African Americans are more likely than Whites to have an AV graft versus a CVC.

The multinomial logit estimate comparing 45-64 years old, 65-74 years old and 75 years and over to 0-44 years-old dialysis patients for having an AV graft versus a CVC, given the other variables in the model are held constant are 0.30 (95% CI: 0.25, 0.35) , 0.49 (95% CI: 0.45, 0.54) and 0.49 (95% CI: 0.44, 0.54), respectively. The statistically significant ($p < 0.001$) coefficients demonstrate that older age groups are more likely than the youngest age group to have an AV graft versus a CVC. Dialysis patients age 65 and older compared to dialysis patients younger than 65 are the most likely to have an AV graft versus a CVC. Statistically significant at the $p < 0.001$, the multinomial logit for HD hours is decreased by 0.22 (95% CI: -0.25, -0.20) for having an AV graft versus a CVC, given all other predictor variables in the model are held constant. The multinomial logit estimate for HD hours is 0.19 units lower for having an AV fistula relative to having a CVC, therefore, dialysis patients with an AV graft have a lower duration of treatment time than dialysis patients with a CVC. See Table 41.

Table 33. Multinomial Logistic Regression for Access Type

	Multinomial Logistic Regression	Number of obs	=		710,113
		LR chi2(39)	=		7781.92
		Prob > chi2	=		0.00
	Log Likelihood = -427327.05	Pseudo R2	=		0.01

	Access Type	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
1	Sex	-0.29	0.001	-0.31	-0.28
	Race				
	2	-0.08	0.001	-0.10	-0.07
	3	0.10	0.001	0.08	0.13
	Age Categories				
	2	0.10	0.001	0.08	0.12
	3	0.15	0.001	0.13	0.17
	4	-0.06	0.001	-0.09	-0.04
	Year				
	2013	0.03	0.003	0.01	0.06
	2014	0.03	0.02	0.004	0.05
	2015	0.04	0.001	0.02	0.07
	2016	0.02	0.05	-0.0003	0.04
	2017	0.03	0.01	0.01	0.05
	2018	0.08	0.001	0.05	0.11
	HD Hours	-0.19	0.001	-0.21	-0.18
	_cons	-0.44	0.001	-0.50	-0.38
2	Sex	0.44	0.001	0.42	0.47
	Race				
	2	0.65	0.001	0.63	0.68
	3	0.21	0.001	0.15	0.26
	Age Categories				
	2	0.30	0.001	0.25	0.34
	3	0.49	0.001	0.45	0.54
	4	0.49	0.001	0.44	0.54
	Year				
	2013	0.001	0.999	-0.05	0.05
	2014	0.03	0.24	-0.02	0.08
	2015	0.07	0.01	0.02	0.11
	2016	0.07	0.003	0.03	0.12
	2017	0.09	0.001	0.04	0.14
	2018	0.19	0.001	0.14	0.25
	HD Hours	-0.22	0.001	-0.25	-0.20
	_cons	-3.69	0.001	-3.82	-3.56

3	(Base Outcome)				
4	Sex	0.03	0.68	-0.09	0.14
	Race				
	2	-0.06	0.41	-0.19	0.08
	3	0.09	0.48	-0.15	0.33
	Age Categories				
	2	-0.20	0.02	-0.36	-0.03
	3	-0.17	0.08	-0.35	0.02
	4	-0.14	0.18	-0.34	0.06
	Year				
	2013	-0.01	0.95	-0.22	0.20
	2014	0.05	0.65	-0.16	0.25
	2015	0.002	0.99	-0.21	0.21
	2016	-0.21	0.06	-0.43	0.01
	2017	-0.11	0.30	-0.33	0.10
	2018	-0.23	0.10	-0.50	0.05
	HD Hours	-0.19	0.002	-0.31	-0.07
	_cons	-5.33	0.001	-5.88	-4.79

Multiple Linear Regression for Hemoglobin

The following analyses evaluates whether an association exists between hemoglobin levels and age categories with year dummies. Figure 7 displays a box and whisker plot of hemoglobin levels from years 2012 through 2018. The figure demonstrates that the data does not appear to be skewed or contain outliers. The median weights for each year are similar, and the box plots are symmetrical. Therefore, the data appears to follow a normal distribution.

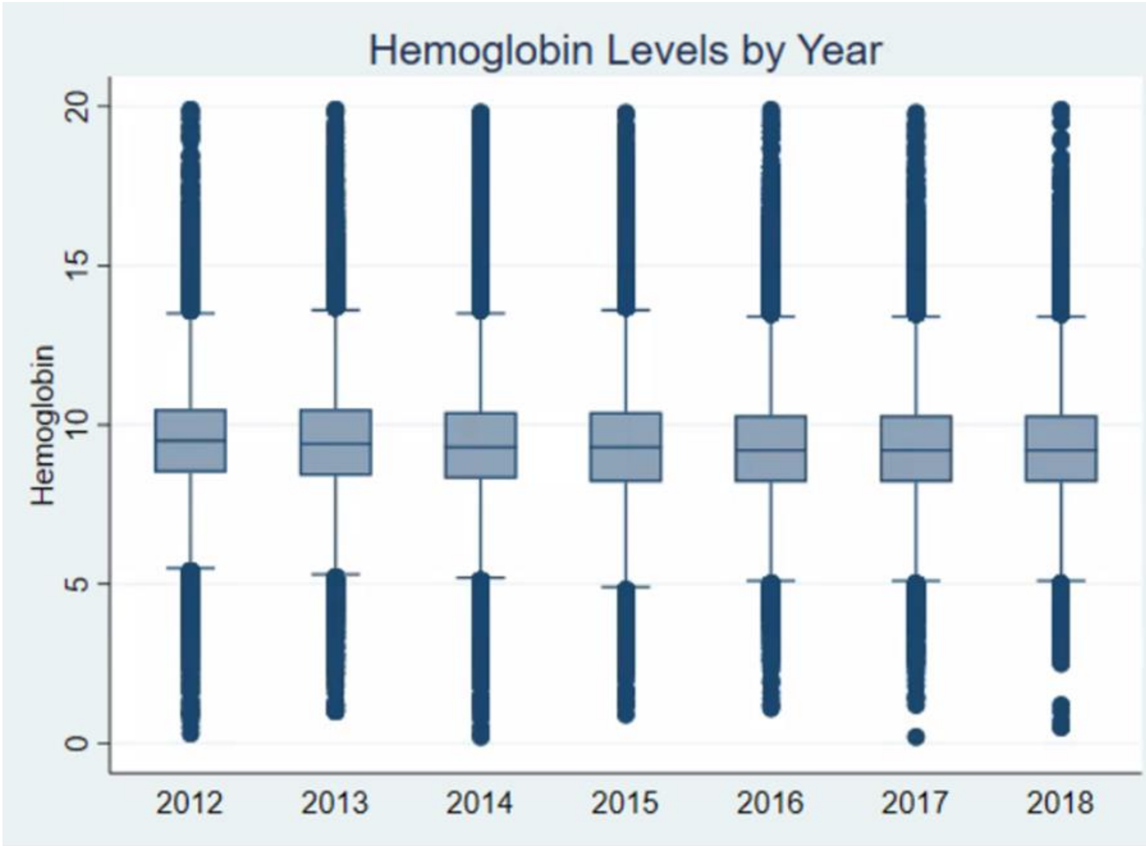

Figure 8. Box Plot for Hemoglobin Levels by Year

Figure 8 displays the standardized normal probability plot a for the dependent variable hemoglobin. The majority of the adjusted residuals appear to be with the 95% confidence limits of normally expected values. The probability plot points for hemoglobin form a nearly linear pattern, which indicates that the normal distribution is a good model for the data set.

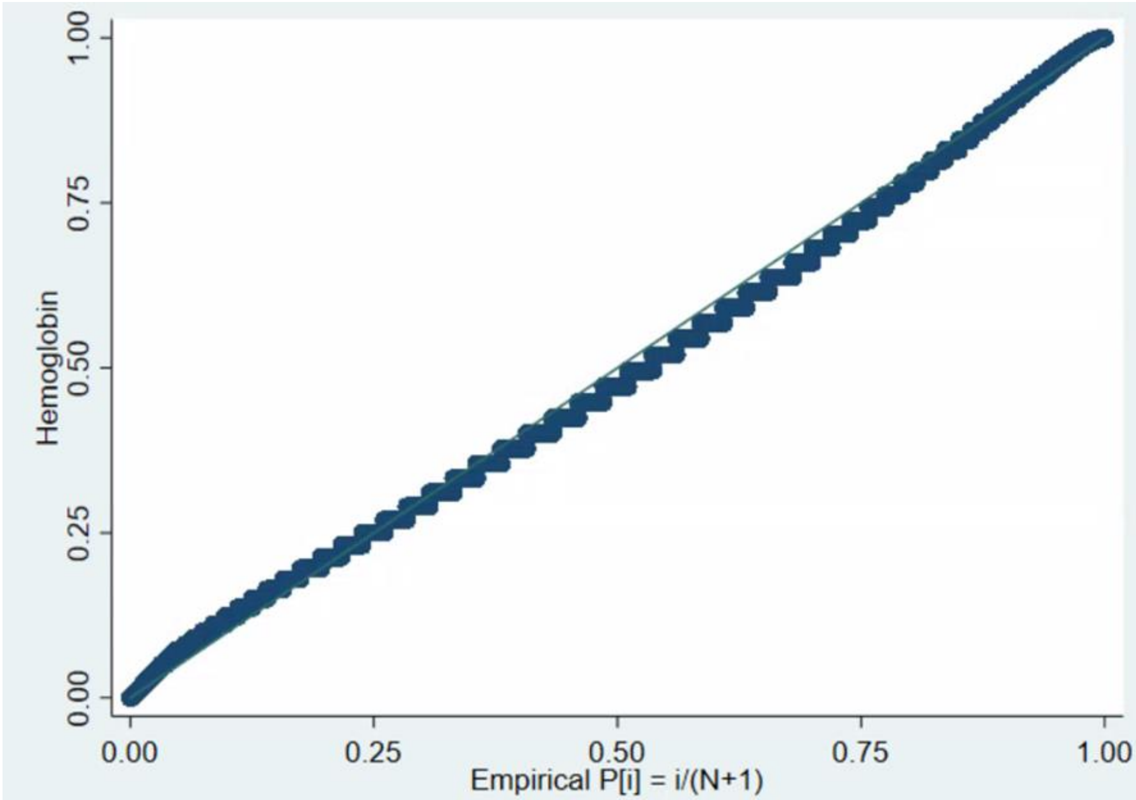

Figure 9. Standardized Normal Probability Plot for Hemoglobin

The linear regression model has 7,715 observations. The p-value associated with the F value is very small (0.001), which indicates that the independent variables reliably predict hemoglobin levels. The R-Squared value specifies the proportion of variance in hemoglobin levels, which can be predicted from the independent variables (HD hours, Access Type, Year, Sex, Race, Hispanic, and the key predictor variable Age Categories). The R-squared for this model indicates that 3% of the variance in hemoglobin levels can be predicted from the variables: HD hours, Access Type, Year, Sex, Race, Hispanic, and Age Categories. While the overall measure of the strength of association is weak, it does not reflect the extent to which any particular independent variable is associated with hemoglobin levels.

The key predictor variable age category demonstrated statistical significance for each category. Age Category 2 is statistically significant at $p < 0.001$, Age Category 3 is statistically significant at $p < 0.001$, and Age Category 4 is statistically significant at $p < 0.05$.

For every one-unit increase in Age Category 2 (45-64 years old) compared to Age Category 1(0-44 years old), *hemoglobin level* is predicted to be higher by 0.22 (CI: 0.12, 0.32), holding all other variables constant. For every one-unit increase in Age Category 3 (65-74 years old) compared to Age Category 1(0-44 years old), *hemoglobin level* is predicted to be higher by 0.41 (CI: 0.28, 0.54), holding all other variables constant. For every one-unit increase in Age Category 4 (75 year and older) compared to Age Category 1(0-44 years old), *hemoglobin level* is predicted to be higher by 0.18 (CI: 0.03, 0.34), holding all other variables constant.

The independent variable *HD hours* is statistically significant at $p < 0.05$. For every increase of one-unit of HD hours, *hemoglobin level* is predicted to be lower by 0.07 (CI: -0.15, 0.001), holding all other variables constant. CVC, a dialysis access type category, is statistically significant at $p < 0.001$. For every-unit increase in CVC compared to AV fistula, *hemoglobin level* is predicted to be lower by 0.21 (CI: -0.29, -0.12), holding all other variables constant.

For every one-unit increase in 2015 compared to 2012, *hemoglobin level* is predicted to be lower by 0.32 (CI: -0.51, -0.13), holding all other variables constant and is statistically significant at $p < 0.001$. For every one-unit increase in 2016 compared to 2012, *hemoglobin level* is predicted to be lower by 0.23 (CI: -0.44, -0.01), holding all other variables constant and is statistically significant at $p < 0.05$. For every increase of one point on 2018 compared to 2012, *hemoglobin level* is predicted to be lower by 0.55 (CI: -0.75, -0.36), holding all other variables constant and is statistically significant at $p < 0.001$.

The independent variable *sex* is statistically significant at $p < 0.001$. For every one-unit increase in female, *hemoglobin level* is predicted to be lower by 0.14 (CI: -0.18, -0.04), holding all other variables constant. *African American,* a category of the independent variable *race,* is statistically significant at p < 0.001. For every one-unit increase of *African Americans* compared to *Whites*, *hemoglobin level* is predicted to be lower by 0.34 (CI: -0.43, -0.26), holding all other variables constant. See Table 46 for hemoglobin level regression output.

Table 34. Linear Regression for Hemoglobin

Source	SS	df	MS			
				Number of obs	=	7175.00
				F(17, 7157)	=	10.94
Model	477.04	17.00	28.06	Prob > F	=	0.00
Residual	18351.59	7157.00	2.56	R-squared	=	0.03
				Adj R-squared	=	0.02
Total	18828.64	7174.00	2.62	Root MSE	=	1.60

Hemoglobin	**Coef.**	**P>t**	**[95% Conf.**	**Interval]**
HD Hours	-0.07	0.04	-0.15	0.00
Access Type				
2	0.00	1.00	-0.17	0.17
3	-0.21	0.001	-0.29	-0.12
4	0.10	0.76	-0.56	0.76
Year				
2013	-0.09	0.32	-0.25	0.08
2014	-0.10	0.27	-0.28	0.08
2015	-0.32	0.001	-0.51	-0.13
2016	-0.23	0.04	-0.44	-0.01
2017	-0.25	0.08	-0.53	0.03
2018	-0.55	0.001	-0.75	-0.36
Sex	-0.14	0.001	-0.22	-0.07
Race				
2	-0.27	0.001	-0.36	-0.19
3	-0.19	0.03	-0.35	-0.02
Hispanic	0.01	0.88	-0.08	0.09
Age Categories				
2	0.22	0.001	0.12	0.32
3	0.41	0.001	0.28	0.54
4	0.18	0.02	0.03	0.34

During the process of fitting the regression model, two variables that were not statistically significant (*HD Sessions* and *Modality Type*) were removed. See Appendix B for original model. After removal of the variables, the final model's adjusted R2 improves marginally. Compared to the original model, the final model's AIC value decreased, which also helped confirm the variables should be removed. See Table 47 for the final model's selection criteria test and Appendix B for the original model's selection criteria test.

Table 35. Selection Criteria for Hemoglobin

Akaike's Information Criterion and Bayesian Information Criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	7,175	-13642.02	-13549.95	18	27135.91	27259.72

To test for heteroscedasticity, the Breusch-Pagan Test is performed on the regression model with hemoglobin as the dependent variable. See Table 48. The null hypothesis states that there is constant variance among the residuals. The Chi-Square test statistic of the test 0.31. The Prob > chi2, which is the p-value that corresponds to the Chi-Square test statistic, is 0.58. Therefore, I fail to reject the null hypothesis and conclude that heteroscedasticity is not present in the data and interpreting the output for the regression model is appropriate.

Table 36. Test for Heteroskedasticity

Breusch-Pagan / Cook-Weisberg test for heteroskedasticity

Ho: Constant variance
Variables: fitted values of hemoglobin

chi2(1) = 0.31
Prob > chi2 = 0.5787

Non-targeted Measures

Binary Logistic Regression

The odds ratio for binary logistic regression is used to model the dichotomous outcome variables: *hospice*, *RRTdcd (*renal replacement therapy discontinued prior to death) and *place of death*. The odds ratio compares the odds of *hospice* and *RRTdcd* occurring or not occurring (1=occurring, 0=not occurring). Logistic regression will also model the dichotomous dependent variable *place of death* occurring in the home or not occurring in the home (hospital=0, home=1). While the logit command in STATA uses the log odds of the outcome modeled as a linear combination of the predictor variables and generates coefficients, the logistic command in STATA generates the odds ratios. Odds ratio are generated by exponentiating the coefficient parameters. Compared to the logit function, the odds ratio excludes the intercept term because the exponentiated intercept is not an odds ratio. Therefore, a meaningful interpretation cannot be obtained because there is nothing to compare.[759,760]

The binary dependent variable logistic models will estimate odds ratios for categorical independent variables. The primary explanatory variable of interest is *Age Category*, which is comprised of four levels (Age Category 1 = 0-44 years old; Age Category 2 = 45-64 years old; Age Category 3 = 65-74 years old; and Age Category 4 = 75+ years old). The expectation is that older dialysis patients will be more likely to use hospice, discontinue renal replacement therapy prior to death and die in the home. The regression models designate Age Category 1 as the reference category because it has the largest number of observations. Each age category is interpreted with respect to the reference category (Age Category 1). The odds ratio is the ratio of the respective odds for each age category to the odds of the reference category.[761] For all

[759] Ge and Whitmore, "Binary Response and Logistic Regression in Recent Accounting Research Publications."
[760] Hilbe, *Logistic Regression Models*.
[761] Hilbe.

successive binary logistic regression models conducted to obtain the best and final fitting model, see Appendix B. These regression models reflect the iterative model fitting process for the dependent variables (*hospice*, *RRTdcd.* and *place of death)*.

Hospice

The regression model with *hospice* as an outcome variable has a likelihood ratio chi-square of -1447.03 with a p-value of 0.0001, which indicates the model, as a whole, fits significantly better than an empty model. One indicator variable for *Age Categories* is statistically significant. The control variables: *Sex; Race;* and *Place of death* are also statistically significant. The odds ratio (OR) of receiving hospice care is 1.76 for A*ge Category 2 compared to Age Category 1* with a 95% Confidence Interval (CI) of [1.43, 2.17], and is statistically significant at $p<0.001$. No statistical significance was found between older age groups and hospice care.

The odds ratio (OR) of receiving hospice care is 1.31 for *Sex* (95% CI: 1.09, 1.57), and is statistically significant at $p<0.01$. For female dialysis patients, the odds of receiving hospice are 1.31 times as large as the odds for male dialysis patients. The odds ratio of receiving hospice care for African Americans versus Whites is 0.63 (95% CI: 0.50, 0.80), and is statistically significant at $p<0.001$. The odds ratio is a 0.63 change in the odds ratio when there is a one-unit change in African American versus White. For patients who receive hospice, the odds ratio for African Americans is smaller (OR < 1) than Whites. Thus, an odds ratio of 0.63 signifies that African Americans are less likely receive hospice than Whites.

The odds ratio of receiving hospice care is 5.40 for *Place of Death* (95% CI: 4.49, 6.49), and is statistically significant at $p<0.001$. For patients who die in the home, the odds of receiving hospice are 5.40 times as large as the odds for patients dying in the hospital. Therefore, patients who receive hospice are much more likely to die at home than the hospital. See Table 33 for final model depicting Hospice Logistic Regression Model results.

Table 37. Logistic Regression Model for Hospice versus no Hospice

Logistic Regression		Number of obs	=	3057
		LR chi2(15)	=	424.42
		Prob > chi2	=	0.00
Log Likelihood = -1447.0272		Pseudo R2	=	0.13

Hospice	Odds Ratio	P>z	[95% Conf.	Interval]
Age Categories				
2	1.76	0.001	1.43	2.17
3	0.88	0.75	0.39	1.98
4	0.81	0.25	0.57	1.16
Year				
2013	0.88	0.35	0.68	1.15
2014	0.95	0.72	0.72	1.25
2015	1.03	0.86	0.77	1.37
2016	1.07	0.69	0.77	1.47
2017	1.28	0.24	0.85	1.94
2018	1.66	0.35	0.57	4.86
Sex	1.31	0.01	1.09	1.57
Race				
2	0.63	0.001	0.50	0.80
3	0.55	0.02	0.33	0.90
Patient Informed	0.82	0.28	0.58	1.17
Place of Death	5.40	0.001	4.49	6.49
Hispanic	0.75	0.06	0.56	1.01
_cons	0.12	0.001	0.07	0.19

The goodness of fit test demonstrates that the overall rate of correct classification is estimated to be 77.92% with 96.33% of the non-hospice group correctly classified (specificity) and only 17.28% of the hospice group correctly classified (sensitivity). The table displays that 712 patients are on hospice, and among those, 123 are found to be with Pr (y=1) > 0.5. Thus, the model reproduced 17.28% of the true cases. The table also displays that 2,345 patients did not receive hospice. Among those, 86 are found to be with Pr (y=1) < 0.5. Therefore, the model reproduced 96.33% of the true cases. The model correctly classifies R^2_{count} = (123 + 2259)/3057 = 77.92% of the observation.[762] See Table 34.

[762] Kohler and Kreuter, *Data Analysis Using Stata*.

Table 38. Goodness of Fit Test for Hospice Logistic Regression Model

	TRUE		
Classified	D	~D	Total
+	**123**	**86**	**209**
-	**589**	**2259**	**2848**
Total	**712**	**2345**	**3057**

Classified + if predicted Pr(D)>= .5
True D defined as Hospice != 0

Sensitivity	Pr(+ D)	**17.28%**
Specificity	Pr(-~D)	**96.33%**
Positive predictive value	Pr(D +)	**58.85%**
Negative predictive value	Pr(~D -)	**79.32%**
False + rate for true ~D	Pr(+~D)	**3.67%**
False - rate for true D	Pr(- D)	**82.72%**
False + rate for classified +	Pr(~D +)	**41.15%**
False - rate for classified -	Pr(D -)	**20.68%**
Correctly classified		**77.92%**

Renal Replacement Therapy Discontinued Prior to Death

The regression model with *RRTdcd* (renal replacement therapy discontinued prior to death) as an outcome variable has a likelihood ratio chi-square of 1664.63 with a p-value of 0.001, which indicates the model, as a whole, fits significantly better than an empty model. *Sex*, *Hospice* and *Hispanic* are statistically significant, as is the indicator variable (African American) for *race*. STATA automatically omitted *employment status*, *ICU_days* and *modality type*, which was initially included in the original model, because of collinearity. A correlation among these explanatory variables in the original model exists and is confirmed by the regression analysis output which specified these omitted variables exhibit collinearity. The dummy variables *year* and *age categories* are not statistically significant.

The odds of discontinuing renal replacement therapy prior to death for Hispanics versus non-Hispanics is 0.62 (95% CI:0.45, 0.87), and is statistically significant at $p<0.01$.

The odds of discontinuing renal replacement therapy is 0.62 that of the odds of not discontinuing renal replacement therapy for Hispanics compared to non-Hispanics. Thus, the odds of discontinuing renal replacement therapy prior to death are reduced for Hispanics. This indicates that non-Hispanics, compared to Hispanics, are more likely to discontinue renal replacement therapy prior to death.

The odds ratio of discontinuing renal replacement therapy prior to death for African Americans versus Whites is 0.49 (95% CI:0.38,0.65), and is statistically significant at $p<0.001$. The odds of discontinuing renal replacement therapy is 0.49 that of the odds of not discontinuing renal replacement therapy for African Americans versus Whites. Thus, the odds of discontinuing renal replacement therapy prior to death are reduced for African Americans. The odds ratio of discontinuing renal replacement therapy prior to death is 1.32 for *sex* with (CI: 1.07,1.63), and is statistically significant at $p<0.01$. Therefore, the odds of discontinuing renal replacement therapy prior to death for females is 1.32 times more than that of males.

The odds ratio of the control variable discontinuing renal replacement therapy prior to death for hospice versus no hospice is 40.52 (95% CI: 32.61, 50.30), and is statistically significant at $p < 0.001$. Therefore, the odds of discontinuing renal replacement therapy prior to death for hospice versus no hospice is 40.52 times that of not discontinuing renal replacement therapy prior to death. While this outcome supports the literature that patients on hospice are more likely to discontinue renal replacement therapy prior to death, the actual strength of the relationship is questionable due to the large odds ratio, standard error, and wide confidence interval. See Table 35.

Table 39. Logistic Regression for RRT Discontinued prior to Death

Logistic Regression		Number of o	=	3687.00
		LR chi2(14)	=	1664.63
		Prob > chi2	=	0.001
Log Likelihood = -1255.45		Pseudo R2	=	0.40
RRTdcd	**Odds Ratio**	**P>z**	**[95% Conf.**	**Interval]**
Year				
2013	1.05	0.75	0.78	1.42
2014	1.03	0.83	0.76	1.41
2015	1.08	0.65	0.78	1.50
2016	0.74	0.13	0.51	1.09
2017	1.19	0.46	0.75	1.89
2018	1.36	0.59	0.44	4.20
Hispanic	0.62	0.01	0.45	0.87
Race				
2	0.49	0.00	0.38	0.65
3	0.88	0.62	0.54	1.45
Sex	1.32	0.01	1.07	1.63
Age Categories				
2	1.08	0.54	0.85	1.38
3	1.25	0.60	0.54	2.90
4	0.85	0.41	0.58	1.25
Hospice	40.50	0.001	32.61	50.30

The goodness of fit test for the logistic regression model discontinuing renal replacement therapy prior to death demonstrates that the overall rate of correct classification is estimated to be 74.82% with 100.00% of the non-renal replacement therapy prior to death group correctly classified (specificity) and only 0.21% of the renal replacement therapy prior to death group correctly classified (sensitivity). Classification is sensitive to the relative sizes of each group, and always prefers classification into the larger group, which occurred here.[763] The table displays that 939 discontinued renal replacement therapy prior to death, and among those, 2 are found to be with Pr (y=1) > 0.5. Thus, the model reproduced 0.21% of the true cases. The display indicates

[763] Minium, Clarke, and Coladarci, *Elements of Statistical Reasoning*.

that 2782 failed to discontinue renal replacement therapy prior to death. Among those, 0 are found to be with Pr (y=1) < 0.5. Therefore, the model reproduced 100.00% of the true cases. The model correctly classifies R^2_{count} = (2 + 2782)/3721 = 74.82% of the observation.[764] See Table 36.

Table 40. Goodness of Fit Test RRT Discontinued Prior to Death Logistic Regression Model

	TRUE		
Classified	D	~D	Total
+	**2**	**0**	**2**
-	**937**	**2782**	**3719**
Total	**939**	**2782**	**3721**
Classified + if predicted Pr(D) >= .5			
True D defined as RRTdcd != 0			
Sensitivity		Pr(+ D)	**0.21%**
Specificity		Pr(-~D)	**100.00%**
Positive predictive value		Pr(D +)	**100.00%**
Negative predictive value		Pr(~D -)	**74.81%**
False + rate for true ~D		Pr(+~D)	**0.00%**
False - rate for true D		Pr(- D)	**99.79%**
False + rate for classified +		Pr(~D +)	**0.00%**
False - rate for classified -		Pr(D -)	**25.19%**
Correctly classified			**74.82%**

Place of Death

Place of death is a dichotomous dependent variable with two values: death in the hospital and death at home. These values are coded as hospital = 0 and home = 1. The regression model with *place of death* as a dependent variable has a likelihood ratio chi-square of 485.40 with a p-value of 0.001, which indicates the model, as a whole, fits significantly better than an empty model. *Race*, *Hispanic*, *employment status* and *hospice* are statistically significant. *Age categories* and the dummy variables *year* and are not statistically significant.

[764] Kohler and Kreuter, *Data Analysis Using Stata*.

The odds of dying at home for African Americans versus Whites is 0.75 (95% CI: 0.62, 0.89), and is statistically significant at $p < 0.001$. The odds of dying at home is 0.75 that of the odds of dying in the hospital for African Americans compared to Whites. This indicates that African Americans compared to Whites, are more likely to die in the hospital than at home. The odds of dying at home for the race category ‘other’ versus Whites is 0.58 (95% CI: 0.40, 0.84), and is statistically significant at $p < 0.004$. The category ‘other’ includes Asians, Native Americans and Hawaiians. The odds of dying at home is 0.58 that of the odds of dying in the hospital for other race compared to Whites. This indicates that other race compared to Whites, are more likely to die in the hospital than at home. The odds of dying at home for Hispanics versus non-Hispanics is 0.67 (95% CI: 0.53, 0.84), and is statistically significant at $p < 0.001$. The odds of dying at home is 0.62 that of the odds of dying in the hospital for Hispanics compared to non-Hispanics. This indicates that Hispanics, compared to non-Hispanics, are more likely to die in the hospital than at home.

The odds of dying at home for employed versus unemployed is 1.35 (95% CI: 1.03, 1.76), and is statistically significant at $p < 0.05$. The odds of dying at home for employed is 1.35 times that of unemployed. This indicates that employed dialysis patients compared to unemployed dialysis patients, are more likely to die at home than in the hospital. The odds of dying at home for retired versus unemployed is 1.24 (95% CI: 1.04, 1.48), and is statistically significant at $p < 0.05$. The odds of dying at home for retired is 1.24 times that of unemployed. This indicates that retired dialysis patients compared to unemployed dialysis patients, are more likely to die at home than in the hospital. The odds ratio of dying at home is 5.35 for *hospice* (95% CI: 4.52, 6.33), and is statistically significant at $p < 0.001$. Therefore, the odds of dying at home for hospice is 5.35 times that of dying in the hospital. See Table 37.

Table 41. Logistic Regression for Place of Death

Logistic Regression		Number of obs	=	3673
		LR chi2(15)	=	485.40
		Prob > chi2	=	0.00
Log Likelihood = -2167.87		Pseudo R2	=	0.10
Place of Death	**Odds Ratio**	**P>z**	**[95% Conf.**	**Interval]**
Race				
2	0.75	0.001	0.62	0.89
3	0.58	0.004	0.40	0.84
Hispanic	0.67	0.001	0.53	0.84
Employment Status				
2	1.35	0.03	1.03	1.76
3	1.24	0.02	1.04	1.48
Hospice	5.35	0.001	4.52	6.33
Year				
2013	1.02	0.84	0.83	1.26
2014	0.98	0.89	0.79	1.23
2015	1.04	0.74	0.82	1.31
2016	1.16	0.26	0.90	1.51
2017	1.05	0.77	0.76	1.46
2018	0.51	0.14	0.21	1.25
Age Categories				
2	0.84	0.07	0.71	1.01
3	0.64	0.18	0.34	1.23
4	0.94	0.67	0.72	1.23
_cons	0.37	0.001	0.30	0.46

The goodness of fit test for *place of death* demonstrates that the overall rate of correct classification is estimated to be 71.60%, with 88.29% of the dying in the hospital group correctly classified (specificity) and only 42.58% of the dying at home group correctly classified (sensitivity). Classification is sensitive to the relative sizes of each component group, and always favors classification into the larger group. The table displays that 1341 died at home, and among those, 571 are found to be with Pr (y=1) > 0.5. Thus, the model reproduced 42.58% of the true cases. The display indicates that 2332 die in the hospital. Among those, 273 are found to be with Pr (y=1) < 0.5. Therefore, the model reproduced 88.29% of the true cases. The model correctly classifies R^2_{count} = (551 + 2059)/3673 = 71.60% of the observation.[765] See Table 38.

[765] Kohler and Kreuter.

Table 42. Goodness of Fit Test for Place of Death

	TRUE		
Classified	D	~D	Total
+	**571**	**273**	**844**
-	**770**	**2059**	**2829**
Total	**1341**	**2332**	**3673**
Classified + if predicted Pr(D) >= .5			
True D defined as placedeath != 0			
Sensitivity		Pr(+ D)	**42.58%**
Specificity		Pr(-~D)	**88.29%**
Positive predictive value		Pr(D +)	**67.65%**
Negative predictive value		Pr(~D -)	**72.78%**
False + rate for true ~D		Pr(+~D)	**11.71%**
False - rate for true D		Pr(- D)	**57.42%**
False + rate for classified +		Pr(~D +)	**32.35%**
False - rate for classified -		Pr(D -)	**27.22%**
Correctly classified			**71.60%**

Multinomial Logistic Regression for Modality Type

Multinomial logistic regression is an extension of binary logistic regression and used to model the log odds of the nominal dependent variable *modality type*. Similar to binary and ordered logistic regression, multinomial logistic regression uses maximum likelihood estimation, which determines the distribution parameters that best explains the data. The iterative process for determining the maximum likelihood estimates begins with iteration zero, which is the log likelihood of the null model containing no explanatory variables.[766,767] The subsequent iterations include the explanatory variables. With each iteration, the log likelihood is decreased, which is the objective of the iterative process. The iteration process ends when the difference between consecutive iterations has become very small, and the model converges.[768] See Appendix B for all

[766] Harter and Moore, "Iterative Maximum-Likelihood Estimation of the Parameters of Normal Populations from Singly and Doubly Censored Samples."
[767] Kohler and Kreuter, *Data Analysis Using Stata*.
[768] UCLA: Statistical Consulting Group, "Introduction to SAS: Multinomial Logistic Regression."

of the multinomial logistic regression models and selection criteria, which reflects the iterative model fitting process.

The final model for the multinomial logistic regression examines the relationship between *modality type* and *age categories, year, race, employment status,* and *sex*. *Modality type* has four categories: in-center HD, home HD, PD and transplant. The reference category is in-center HD, which has the largest number of observations. The coefficients for the three other categories (home HD, PD and transplant) explain how the explanatory variables are associated with the probability of being in one of the three categories versus the reference category. The model summary has 788,816 observations, and the Likelihood Ratio (LR) Chi-Square tests that for all three equations (in-center HD relative to home HD, in-center HD relative to PD and in-center HD relative to transplant) at least one of the predictors' regression coefficient is not equal to zero. The null hypothesis is that all of the regression coefficients across the two models are simultaneously equal to zero, which is the probability of obtaining the LR Chi-Square statistic (22209.84) if no effect of the predictor variables exists. With a small p-value from the LR Chi Square test (<0.001), I can conclude that at least one of the regression coefficients in the model is not equal to zero.

The multinomial logit estimate comparing 45-64 years old, 65-74 years old and 75 years old and over to 0-44 years-old dialysis patients for home HD versus in-center HD, given all other predictor variables in the model are held constant are -0.22 (95% CI: -0.25, -0.19), -0.32 (95% CI: -0.35, -0.28), and -0.65 (95% CI: -0.70, 0.61), respectively. The statistically significant ($p < 0.001$) coefficients demonstrate that older dialysis patients are less likely to receive home HD compared to in-center HD. The strongest statistically significant association is between age category 4 (75 years and older) and receiving home HD compared to in-center HD. The relative log odds of receiving home HD versus in-center HD will decrease by 0.65 if moving from the lowest age category (0-44 years old) to the highest age category (75 and older).

The statistically significant ($p < 0.001$) multinomial logit for females relative to males is increased by 0.14 (95% CI: 0.12, 0.16), for home HD versus in-center HD, given all other predictor variables in the model are held constant. The relative log odds of receiving home HD versus in-center HD will increase by 0.14 for females compared to males. In other words, females are more likely than males to receive home HD. The multinomial logit estimate comparing African Americans to Whites for receiving home HD to in-center HD, given the other variables in the model are held constant, is -0.45 (95% CI: -0.48, -0.42) and statistically significant at $p<0.001$. The relative log odds of receiving home HD versus in-center HD will decrease by 0.45 for African Americans compared to Whites. Therefore, African Americans are less likely than Whites to receive home HD.

The multinomial logit estimate comparing employed to unemployed for receiving home HD to in-center HD, given the other variables in the model are held constant, is 1.04 (95% CI: 1.01, 1.07) and statistically significant at $p < 0.001$. The relative log odds of receiving home HD versus in-center HD will increase by 1.04 for employed compared to unemployed. Thus, dialysis patients who are employed are much more likely to receive home HD than in-center HD. For the year dummies, the multinomial logit estimate comparing years 2013 through 2018 to year 2012 for receiving home HD to in-center HD, given the other variables in the model are held constant, range from 0.05 to 0.18 and are all statistically significant at $p < 0.001$. The relative log odds of receiving home HD versus in-center HD will increase by 0.11 in the year 2018 compared to the 2012. Therefore, during the year 2018 compared to the year 2012, dialysis patients are marginally more likely to receive home HD.

For the PD category versus the in-center HD category, the results are relatively similar to the home HD category versus the in-center HD category. That is, the predictor variable's coefficients and p-values are similar in strength and direction. The multinomial logit estimates comparing 45-64 years old, 65-74 years old and 75 years old and over to 0-44 years-old dialysis patients for PD versus in-center HD, given all other predictor variables in the model are held constant are -0.26 (95% CI: -0.28, -0.23), -0.29 (95% CI: -0.33, -0.26), and -0.28 (95% CI: -0.32, -0.25), respectively. The statistically significant ($p<0.001$) coefficients demonstrate that older dialysis patients are less likely to receive PD compared to in-center HD. That is, the relative log odds of receiving PD versus in-center HD will decrease if moving from the lowest age category (0-44 years old) to age categories 2, 3, and 4. Dialysis patients age 65 and older, compared to ages 45-64 years old, are marginally (about 0.02) less likely to receive PD compared to in-center HD.

The multinomial logit for females relative to males is increased by 0.09 (95% CI 0.07, 0.11), for PD versus in-center HD, given all other predictor variables in the model are held constant. Therefore, females are 0.09 more likely than males to receive PD. The multinomial logit estimate comparing African Americans to Whites for receiving PD relative to in-center HD, given the other variables in the model are held constant, is -0.31 (95% CI: -0.34, -0.29) and statistically significant at $p < 0.001$. That is, the relative log odds of receiving PD versus in-center HD will decrease by 0.31 for African Americans compared to Whites. Therefore, African Americans are less likely than Whites to receive PD than in-center HD.

The multinomial logit estimate comparing employed to unemployed for receiving PD to in-center HD, given the other variables in the model are held constant, is 1.09 (95% CI: 1.06, 1.12) and statistically significant at $p < 0.001$. The relative log odds of receiving PD versus in-center HD will increase by 1.09 for employed compared to unemployed. Thus, dialysis patients who are employed are much more likely to receive PD than in-center HD. The multinomial logit estimate comparing retired to unemployed for receiving PD to in-center HD, given the other variables in the model are held constant, is -0.32 (95% CI: -0.34, -0.29) and statistically significant at $p < 0.001$. The relative log odds of receiving PD versus in-center HD will decrease by 0.32 for retired compared to unemployed. Thus, dialysis patients who are retired are less likely to receive PD than in-center HD.

The multinomial logit estimates comparing 45-64 years old, 65-74 years old and 75 years old and over to 0-44 years-old dialysis patients for a transplant versus in-center HD, given all other predictor variables in the model are held constant are -1.89 (95% CI: -2.24, -1.54), -1.98 (95% CI: -2.48, -1.48), and -4.76 (95% CI: -6.74, -2.78), respectively. The statistically significant ($p < 0.001$) coefficients demonstrate that older dialysis patients are less likely to receive a transplant compared to in-center HD. That is, the relative log odds of receiving a transplant versus in-center HD will significantly decrease if moving from the lowest age category (0-44 years old) to age categories 2, 3, and 4. Dialysis patients age 75 and older are the least likely to receive transplant versus to in-center HD.

The year dummies are statistically significant except for year 2018. For the year 2013 compared to year 2012, the relative log odds of receiving a transplant versus in-center HD will increase by 1.29 (95% CI: 0.39, 2.19). For the year 2014 compared to year 2012, the relative log odds of receiving a transplant versus in-center HD will increase by 1.15 (95% CI: 0.23, 2.06). For the year 2015 compared to year 2012, the relative log odds of receiving a transplant versus in-center HD will increase by 2.26 (95% CI: 1.43, 3.10). For the year 2016 compared to year 2012, the relative log odds of receiving a transplant versus in-center HD will increase by 1.84 (95% CI: 0.99, 2.70). For the year 2017 compared to year 2012, the relative log odds of receiving a transplant versus in-center HD will increase by 1.39 (95% CI: 0.50, 2.27).

For the transplant category of modality type, age categories and the year dummies had statistically significant coefficient estimates, however the coefficient estimates are large and the width of the confidence intervals are large. This may be related to the smaller number of dialysis patients who receive transplants compared to dialysis and the overall smaller sample size of transplant patients, which may result in a larger margin of error. The multinomial logit for females relative to males is increased by 0.37 (95% CI: 0.08, 0.66) and is statistically significant at $p < 0.01$, for receiving a transplant versus in-center HD, given all other predictor variables in the model are held constant. Therefore, females are 0.37 more likely than males to receive a transplant. The multinomial logit estimate comparing African Americans to Whites for receiving a transplant relative to in-center HD, given the other variables in the model are held constant, is -1.12 (95% CI: -1.52, -0.72) and statistically significant at $p < 0.001$. That is, the relative log odds of receiving a transplant versus in-center HD will decrease by 1.12 for African Americans compared to Whites. Therefore, African Americans are significantly less likely than Whites to receive a transplant versus in-center HD.

The multinomial logit estimate comparing employed to unemployed for receiving a transplant to in-center HD, given the other variables in the model are held constant, is 1.07 (95% CI: 0.71, 1.42) and statistically significant at $p < 0.001$. The relative log odds of receiving a transplant versus in-center HD will increase by 1.07 for employed compared to unemployed. Thus, dialysis patients who are employed are much more likely to receive a transplant than in-center HD. See Table 39.

Table 43. Multinomial Logistic Regression for Modality Type

	Multinomial Logistic Regression		Number of obs	=	788,816
			LR chi2(42)	=	22209.84
			Prob > chi2	=	0.00
	Log Likelihood = -299824.63		Pseudo R2	=	0.04

	Modality Type	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
1		(Base Outcome)			
2	Year				
	2013	0.07	0.001	0.03	0.11
	2014	0.05	0.01	0.01	0.09
	2015	0.18	0.001	0.14	0.22
	2016	0.08	0.001	0.04	0.12
	2017	0.06	0.001	0.03	0.10
	2018	0.11	0.001	0.06	0.15
	Sex	0.14	0.001	0.12	0.16
	Race				
	2	-0.45	0.001	-0.48	-0.42
	3	0.23	0.001	0.19	0.27
	Employment Status				
	2	1.04	0.001	1.01	1.07
	3	-0.001	0.97	-0.03	0.03
	Age Categories				
	2	-0.22	0.001	-0.25	-0.19
	3	-0.32	0.001	-0.35	-0.28
	4	-0.65	0.001	-0.70	-0.61
	_cons	-3.06	0.001	-3.11	-3.01
3	Year				
	2013	0.14	0.001	0.10	0.18
	2014	0.18	0.001	0.14	0.22
	2015	0.09	0.001	0.06	0.13
	2016	0.21	0.001	0.17	0.24
	2017	0.28	0.001	0.24	0.32
	2018	0.38	0.001	0.34	0.43
	Sex	0.09	0.001	0.07	0.11
	Race				
	2	-0.31	0.001	-0.34	-0.29
	3	-0.01	0.53	-0.05	0.03
	Employment Status				
	2	1.09	0.001	1.06	1.12
	3	-0.32	0.001	-0.34	-0.29
	Age Categories				
	2	-0.26	0.001	-0.28	-0.23
	3	-0.29	0.001	-0.33	-0.26
	4	-0.28	0.001	-0.32	-0.25
	_cons	-2.88	0.001	-2.93	-2.83

4	Year				
	2013	1.29	0.01	0.39	2.19
	2014	1.15	0.01	0.23	2.06
	2015	2.26	0.001	1.43	3.10
	2016	1.84	0.001	0.99	2.70
	2017	1.39	0.002	0.50	2.27
	2018	0.87	0.11	-0.19	1.93
	Sex	0.37	0.01	0.08	0.66
	Race				
	2	-1.12	0.001	-1.52	-0.72
	3	-0.95	0.01	-1.71	-0.19
	Employment Status				
	2	1.07	0.001	0.71	1.42
	3	0.12	0.55	-0.27	0.51
	Age Categories				
	2	-1.89	0.001	-2.24	-1.54
	3	-1.98	0.001	-2.48	-1.48
	4	-4.76	0.001	-6.74	-2.78
	_cons	-8.90	0.001	-9.85	-7.96

The initial model explaining *modality type* contained the independent variables: *year; sex; race; number of diagnoses; age category;* and *place of death.* See Appendix B for all model iterations. Based on the AIC and BIC selection criteria test; the variables *HD sessions* and *HD hours* were added. The models each contained 2,376 observations. Based on the coefficient estimates, standard errors, p values and the goodness of fit test, *sex, HD hours, HD sessions, number of diagnoses* and *place of death were removed;* which greatly increased the number of observations to 788,925. This model had better p-values and stronger coefficient estimates. The next model replaced *sex*, which provided stronger coefficient estimates and p values, and lower AIC and BIC values. This became the best fitting and final model compared to the previous models. The improved goodness of fit test, reflected by the lower AIC and BIC values, signifies a better fitting model that is more parsimonious. See Table 40 for the selection criteria test assessing model fit.

Table 44. Model Selection Criteria for Modality Type

Akaike's Information Criterion and Bayesian Information Criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
	788,816	-310929.6	-299824.6	45	599739.3	600260.3

The original model explaining *access type* contained the independent variables: *year; sex; race; age category; Hispanic; employment status; HD hours; HD sessions* and *ICU days.* See Appendix B for all model iterations. Based on p-values, coefficient estimates and the goodness of fit selection criteria test; the variables *HD sessions* and *employment status* were removed. The models each contained 2,376 observations. The next model removed *HD hours; Hispanic* and *ICU days*, and added *modality type;* which greatly increased the number of observations to 710,817. This model had better p-values and stronger coefficient estimates. The next model removed *modality type*, and the goodness of fit improved. The final model added *HD hours* back into the model and removed *modality type*, which resulted in better p-values, coefficient estimates and lower AIC and BIC values compared to the previous model. The improved goodness of fit test, reflected by the lower AIC and BIC values, signifies a better fitting model that is more parsimonious. See Table 42 for the selection criteria test assessing model fit.

Table 45. Model Selection Criteria for Access Type

Akaike's Information Criterion and Bayesian Information Criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
	710,113	-431218	-427327.1	42	854738.1	855220

Negative Binomial Regression for ICU Days

The following analyses examines whether the number of ICU days varies with different age categories. Summary Statistics for *ICU Days* and *Age Categories* shows that compared to younger age categories, the oldest age category (75 years old and over) experiences the least amount of days averaging 1.32 days per hospital admission in the ICU. See Table 43.

Table 46. Number of ICU Days by Age Category

Diagnostics

Summary for variables: icu_days

by categories of: Age_Cats (RECODE of age)

Age Categories	mean	sd	N
1	1.90	4.76	6294
2	2.19	4.71	5292
3	2.14	4.45	477
4	1.32	3.39	793
Total	2.00	4.66	12856

Negative binomial regression is used to examine the relationship between the count dependent variable *ICU Days* and *Age Categories.* The full model included eighteen explanatory and control variables. After seven iterations of model refining based on statistical tests including the AIC and BIC goodness of fit tests, I validated the best fitting model. This final model includes the independent variables: *Age Categories; Number of Diagnoses; Number of Surgeries* and *year* as a dummy variable. Negative binomial regression is used instead of Poisson because overdispersion is suspected and negative binomial regression handles overdispersion better. The graphical display of *ICU Days* demonstrates greater variability than expected. The variance is greater than the mean and the distribution of *ICU Days* therefore shows overdispersion. See Figure 6.

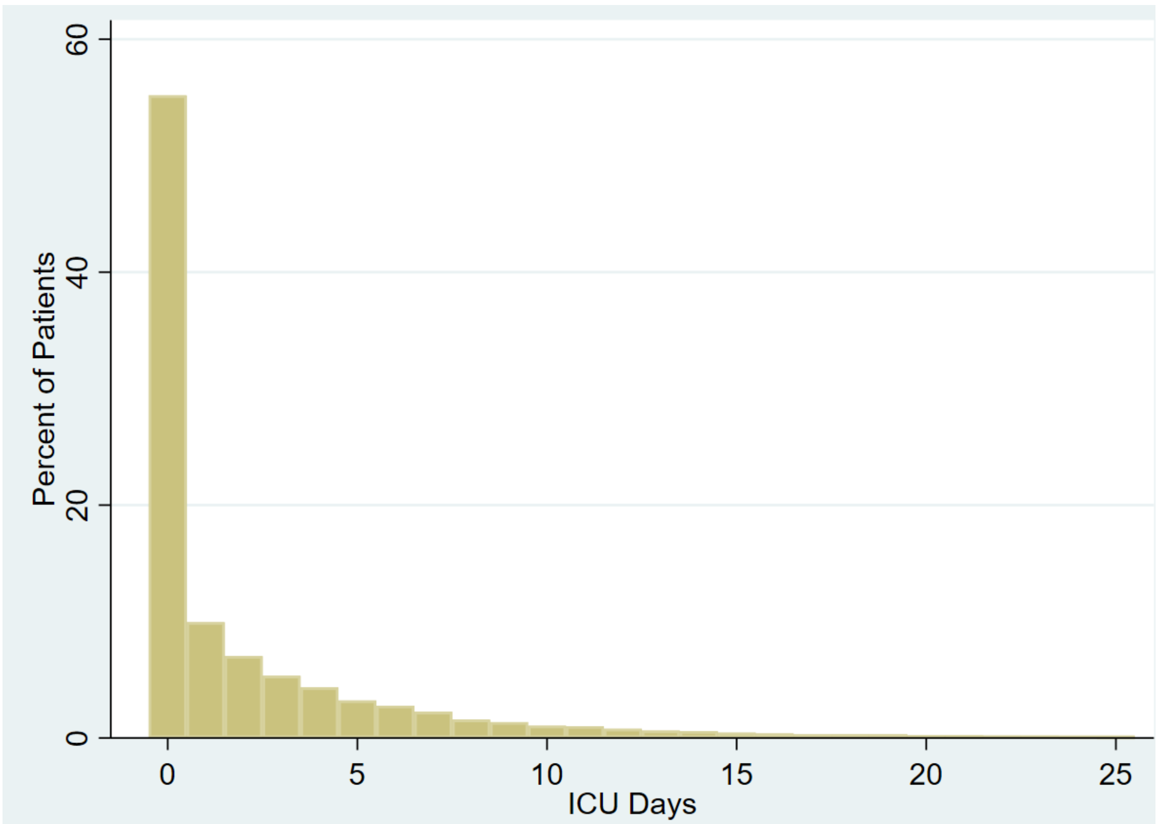

Figure 10. ICU Days by Patient Percent

The final model contains 12,856 observations from the years 2012 through 2016. The Likelihood Ratio (LR) Chi-Square is 1513.82, which tests that all regression coefficients in the model are simultaneous equal to zero, is calculated as negative two times the difference of the likelihood for the null and fitted model. The null hypothesis is that all of the regression coefficients are simultaneously equal to zero, which is the probability of obtaining the Chi-Square statistic of 1513.82 if no effect of the predictor variables exists. The small p-value from the LR Chi Square test (< 0.001), indicates that at least one of the regression coefficients in the model is not equal to zero.[769] See Table 44 for the final model and see Appendix B for the binomial regression model selection process, which involves backward elimination and forward selection and model selection criterion tests.

The negative binomial regression estimates for Age Categories, given the other variables are held constant in the mode, are statistically significant. The estimated negative binomial regression coefficient comparing Age Category 2 (45-64 years old) to the reference group Age Category 1 (0-44 years old), given the other variables are held constant in the model, is statistically significant at $p < 0.001$. The difference in the logs of expected counts of ICU Days is expected to be 0.12 units higher (CI: 0.05, 0.20) for Age Category 2 compared to Age Category 1, while holding the other variables constant in the model. Therefore, Age Category 2, compared Age Category 1, is more likely to spend more days in the ICU.

The estimated negative binomial regression coefficient comparing Age Category 3 (65-74 years old) to the reference group Age Category 1 (0-44 years old), given the other variables are held constant in the model, is statistically significant at $p < 0.05$. The difference in the logs of expected counts of ICU Days is expected to be 0.24 units higher (CI: 0.05, 0.43) for Age Category 3 compared to Age Category 1, while holding the other variables constant in the model. The estimated negative binomial regression coefficient comparing Age Category 3 (75 years old and over) to the reference group Age Category 1 (0-44 years old), given the other variables are held constant in the model, is statistically significant at $p<0.01$. The difference in the logs of expected counts of ICU Days is expected to be 0.22 units lower (CI: -0.38, -0.06) for Age Category 3 compared to Age Category 1, while holding the other variables constant in the model.

[769] UCLA Institute for Digital Research and Education, "Negative Binomial Regression: Stata Annotated Output."

While Age Category 3 spends more days in the ICU than Age Category 1; Age Category 4 spends less days in the ICU than Age Category 1.

The negative binomial regression estimates for the control variables (number of diagnoses and number of surgeries), given the other variables are held constant in the model, are statistically significant at $p<0.0001$. If a dialysis patient has a one-unit increase in number of diagnoses, given the other variables are held constant in the model, then the difference in the logs of expected counts of the number of ICU days would be expected to increase by 0.04 (CI: 0.03, 0.05). If a dialysis patient has a one-unit increase in number of surgeries, given the other variables are held constant in the model, then the difference in the logs of expected counts of the number of ICU days would be expected to increase by 0.20 (CI: 0.18, 0.21).

Table 47. Negative Binomial Regression for ICU Days

Negative Binomial Regression	Number of obs	=	12856
	LR chi2(9)	=	1513.82
Dispersion = mean	Prob > chi2	=	0.00
Log likelihood = -20435.07	Pseudo R2	=	0.04

ICU Days	Coef.	Std. Error	z	P>z	[95% Conf.	Interval]
Number of Diagnoses	0.04	0.00	12.48	0.00	0.03	0.05
Number of Surgeries	0.20	0.01	26.64	0.00	0.18	0.21
Age Categories						
2	0.12	0.04	3.18	0.00	0.05	0.20
3	0.24	0.10	2.43	0.02	0.05	0.43
4	-0.22	0.08	-2.71	0.01	-0.38	-0.06
Year						
2013	-0.02	0.05	-0.31	0.75	-0.12	0.09
2014	-0.09	0.06	-1.64	0.10	-0.20	0.02
2015	-0.04	0.06	-0.77	0.44	-0.15	0.07
2016	-0.05	0.06	-0.78	0.43	-0.16	0.07
_cons	-0.81	0.06	-12.94	0.00	-0.93	-0.69
/lnalpha	1.27	0.02			1.23	1.31
LR test of alpha=0	chibar2(01)=	31000.00	Prob>=	chibar2= 0.000		

During the process of fitting the regression model, multiple variables were not statistically significant and removed. See Appendix B for original model and iteration process.

After removal of the variables, the final model's adjusted R2 improves marginally. Compared to the original model, the final model's AIC value decreased, which also helped confirm the variables should be removed. See Table 45 for the final model's selection criteria test and Appendix B for iteration of models and corresponding selection criteria tests.

Table 48. ICU Days: Model Selection Criteria for Negative Binomial Regression

Akaike's information criterion and Bayesian information criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	12,856	-21191.98	-20435.07	11	40892.14	40974.21

CHAPTER SIX

Principal Findings and Discussion

This chapter contains two sections: the principal findings of the above analyses, followed by a discussion of the results. While the primary purpose of this study is to examine the impact of the ESRD QIP on the elderly, incidental findings related to the program emerged that may have program policy implications will also be discussed.

Principal Findings

Chapter 3

- 11 studies examined the impact of the ESRD QIP
  - 2 articles evaluated the ESRD QIP and non-targeted patient level data
  - 9 articles evaluated facility ratings and aggregated facility level data
  - 11 cross-sectional studies
- Facilities with a greater proportion of African Americans are more likely to receive a penalty
- Most facilities achieve the targeted measures and avoid a penalty
- Conflicting results from different articles
  - Mostly negative and some positive results associated with the ESRD QIP
  - Discrepancy among studies associating for-profit/larger facilities/ neighborhood poverty/ethnicity and incurring a penalty

Chapter 4

- Structural characteristics of a dialysis facility associated with receiving a penalty

    - Non-chain facilities
    - Greater number of dialysis machines per facility
    - Facilities offering PD instead of HD
    - Dialysis Facility Network 2 (New York) and Network 7 (Florida)
- Sociodemographic factors associated with a dialysis facility receiving no penalty
    - 65 years and older (marginally decreased likelihood)
    - Native Hawaiians
    - High school diploma
- Sociodemographic factors associated with a dialysis facility receiving a penalty
    - Uninsured individuals
    - African Americans living below the FPL
- Dialysis Facility Penalty Status and Dialysis Facility Star-rating relationship
    - As the star-rating increases, penalty amount decreases
    - Overall strength of relationship is not strong
    - Strength of the relationship is weakly correlated 2015-2018
    - Strength of the relationship increases in 2019-2020

Chapter 5

- ESRD QIP Targeted Measures
    - Older dialysis patients (75+) are marginally less likely to have a fistula (than a CVC)
    - Older dialysis patients (65+) are more likely to have a graft (than a CVC)
    - Older patients are more likely to have higher hemoglobin levels
    - African Americans are more likely to have lower hemoglobin levels

    - African Americans are marginally less likely to have a fistula
    - Over time use of a fistula (compared to a CVC) has marginally increased

- Non-targeted Measures
    - Receiving end-of-life care was not statistically significant for older patients
    - Older patients are less likely to receive home HD, PD and transplant
    - Older patients are more likely to spend less days in the ICU
    - Older patients are more likely to have the fewest number of surgeries
    - African Americans are less likely to receive home HD and PD; and significantly less likely to receive a transplant
    - African Americans are more likely to die in the hospital
    - African Americans are more likely to be unemployed
    - African Americans/Hispanics are less likely to receive hospice care, and less likely to discontinue dialysis prior to death.
    - Men are more likely to be employed
    - Females are more likely to receive hospice care
    - Females and employed are more likely to receive a transplant
    - Since 2012 a marginal increase receiving home HD, PD, transplant

Discussion

Chapter 3

For Chapter three, I hypothesized that the collective empirical evidence of the ESRD QIP would have a range of positive to negative findings associated with the ESRD QIP. Surprisingly, only 11 research studies examine the impact of the ESRD QIP. The majority of these studies reported negative effects of the ESRD QIP on dialysis patients. All of the researchers used a cross-sectional design to examine dialysis patient or facility characteristics associated with a facility's ESRD QIP performance. This type of design is useful to provide information about associations between a facility's performance and what explains the variations in those scores. However, the one-time measurement of the facility's performance prevents supporting a causal relationship and can be disposed to biases. The year of the snapshot may not be representative or sufficient to understand the pattern of the ESRD QIP over time.[770] The variation in years that the researchers used to evaluate the ESRD QIP may have caused the inconsistency in findings amongst studies examining the same variables.

The small volume of research output precludes a convincing picture of the ESRD QIP effects and impedes rigorous conclusions about the program's current status. The small size of the penalty incurred by facilities and the small proportion of dialysis facilities receiving a penalty may be a rationale for policymakers and researchers to overlook thorough and frequent evaluations of the ESRD QIP. In addition, while morbidity, mortality, and economic costs of the ESRD patients are among the highest for all Medicare beneficiaries, this subset represents a very small proportion of the overall Medicare population. Further, a sizeable proportion of the ESRD patient population is part of a socioeconomically disadvantaged group of healthcare consumers that generally possesses few resources to influence the policy making process. This may lead to fewer political and financial resources allocated to the ESRD program and its evaluation.

Some of the findings of the systematic review are consistent with the results of the quantitative analysis portion of this dissertation. Specifically, dialysis facilities in poorer neighborhoods with a greater proportion of African Americans are more likely to incur a penalty.

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[770] Setia, "Methodology Series Module 3."

A common theme highlighted throughout the studies from the systematic review was the racial and socio-economic disparities that exist for lower performing facilities.[771,772,773,774,775,776] Dialysis facilities in predominantly African American communities and lower-income communities had a greater likelihood to have worse performance on individual measures and total performance scores.[777,778,779,780,781,782,783,784] These findings are consistent with the results from questions two and three of this dissertation.

Chapter 4

For Chapter four, I hypothesized that dialysis facilities in poorer neighborhoods with a greater proportion of elderly will be more likely to receive facility payment reductions. My hypothesis that dialysis facilities with a greater proportion of elderly will be more likely to receive a payment reduction is proved false for the final best fitting regression model. However, bivariate analyses indicated that the elderly are less likely to receive care at a dialysis facility incurring a penalty. Using facility level data, the bivariate association of age 65+ and penalty status exhibited concurrent variations. As penalty amount increases, the proportion of elderly in the dialysis facility

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[771] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[772] Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
[773] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
[774] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[775] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[776] Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."
[777] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[778] Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
[779] Brady et al., "Patient-Reported Experiences of Dialysis Care Within a National Pay-for-Performance System."
[780] Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
[781] Kshirsagar et al., "Area-Level Poverty, Race/Ethnicity & Dialysis Star Ratings."
[782] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[783] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[784] Zhang, "The Association Between Dialysis Facility Quality and Facility Characteristics, Neighborhood Demographics, and Region."

neighborhood decreases. The bivariate analysis demonstrated that the association of the proportion of elderly in the dialysis facility neighborhood and penalty status has a statistically significant strong negative relationship. That is, dialysis facilities in neighborhoods with a greater proportion of individuals age 65 years and older, are marginally less likely to receive a penalty. While this finding is the proportion of individuals in the neighborhood and not the dialysis facility itself, dialysis patients generally receive dialysis care that is close to their home.[785] This finding is also supported by regression analysis examining patient level data of age within a facility and the facility's penalty status. While the patient data sample size is smaller, the results demonstrate a statistically significant association between age variation and penalty status. Facilities with a greater proportion of patients 65 years and older are marginally less likely to receive a penalty.

The initial ordinal regression analyses models using facility level data indicated that facilities in neighborhoods with a greater proportion of elderly are less likely to incur a penalty. However, as the models became more refined through subtraction and addition of variables, the age variable was no longer statistically significant and the coefficients became considerably weaker. That is, the estimated coefficients for the proportion of elderly in dialysis facility neighborhoods and facility penalty status are not statistically significant in the majority of the models and results in a poorer model fit when left in the model. While the hypothesis that older age groups are more likely to receive care at facilities that incur a penalty is not supported by the final ordinal regression model, bivariate analyses supported an association between age and penalty status. It is interesting to note that as model refinement of the ordinal regression models occurred, the regression coefficient for age becomes statistically insignificant. The ordinal regression models reveal that once factors such as race and poverty are taken into account, the impact of the elderly

[785] Eliason et al., "How Acquisitions Affect Firm Behavior and Performance."

on penalty amount ceases to exist. This may suggest that penalty status has less to do with the proportion of patients who are elderly and more to do with poverty and race.

The regression analysis also demonstrated significant associations between penalty amount and other facility and neighborhood characteristics. Applying Donabedian's framework to the ESRD QIP helps explain how facility and neighborhood level structure, mediated by the ESRD QIP process measures, impacts dialysis patient health outcomes.[786] Structural aspects of the dialysis facility and characteristics of the organization are markers of the healthcare provider's capacity to deliver quality care. While structure does not directly measure the care received or whether it has improved patient health, it is associated with the environment which provides services essential to patient care.[787] The findings of this research suggest that in-center dialysis facilities which are affiliated with a chain organization are much more likely to perform better on clinical outcomes. The results are similar to previous ESRD QIP studies and findings from other Medicare incentive program studies.[788,789]

Similar to Medicare's Electronic Health Record Incentive Program and the Hospital Readmission and Reduction Program, facilities unaffiliated with a chain organization are more at risk for failing to achieve the targeted measures and receiving a penalty.[790] An explanation for this may be that chain organizations have established policies that promote standardization of processes which support achieving targeted metrics. Non-chain dialysis facilities tend to be smaller and may be poorly equipped with resources to implement the ESRD QIP and achieve its targeted measures. Compared to larger chain organizations, small independent dialysis facilities do not benefit from economies of scale and may contend with inefficiencies and increased costs

[786] Donabedian, "Evaluating the Quality of Medical Care."
[787] Donabedian, "The Quality of Care."
[788] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[789] Zhang, Cotter, and Thamer, "The Effect of Dialysis Chains on Mortality among Patients Receiving Hemodialysis."
[790] DesRoches, Worzala, and Bates, "Some Hospitals Are Falling Behind In Meeting 'Meaningful Use' Criteria And Could Be Vulnerable To Penalties In 2015."

related to coordinating and administering the ESRD QIP.[791] In addition, chain organizations may tend to incorporate profit as a top priority into operational decisions, which may motivate dialysis facility providers to avoid a penalty more than providers at independently managed non-profit facilities.

Descriptive statistics demonstrated the number of chain-owned and for-profit dialysis facilities increased from 83% to 89%. This illustrates the continued change in the dialysis industry's market structure over the eight years, which similarly follows decades of growth and consolidation. For-profit dialysis facility providers and dialysis chain organizations have been a principal source of growth since the 1980s when a proliferation in the numbers of facilities and patients receiving treatment occurred. While the number of dialysis facilities across the country has increased over time, the number of independent dialysis facilities has decreased and overall market concentration has increased.[792,793] Comparisons before and after ownership change of independently owned facilities that have been acquired by a for-profit chain organization have demonstrated poorer dialysis patient health outcomes that include increased hospitalization and mortality rates and fewer patients on the transplant waitlist. Chain acquisitions of independently owned facilities frequently result in cost reduction mechanisms that pursue profit at the expense of quality care. For-profit chain-owned dialysis facilities are more likely to increase the number of dialysis patient treatments per machine; transition to more expensive medications; provide care to more patients relative to the number of staff; and replace registered nurses with low-skilled technicians.[794,795]

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791 Conrad, "The Theory of Value-Based Payment Incentives and Their Application to Health Care."
792 Erickson et al., "Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition."
793 Program, Rettig, and Levinsky, "Structure of the Provider Community."
794 Eliason et al., "How Acquisitions Affect Firm Behavior and Performance."
795 Erickson et al., "Association of Hospitalization and Mortality Among Patients Initiating Dialysis With Hemodialysis Facility Ownership and Acquisitions."

Even though certain quality of care measures has shown to decline when a facility is acquired by a for-profit chain organization, most chain dialysis facilities achieve the ESRD QIP targeted measures. This incongruity may occur because large chain organizations are more efficient at procedural changes required to achieve the targeted measures. In addition, when facilities fail to achieve targeted ESRD QIP measures or fail to deliver quality care related to other metrics, patients are not likely to change facilities in response to these quality issues. The demand for dialysis care is not elastic as patients choose a facility that has available capacity and is nearby their home. Travel costs, especially for dialysis patients who are more likely to be in a lower income bracket and suffer multiple comorbidities, frequently overshadow issues about quality care.[796] Thus, whether a facility delivers below average care, or safe effective care, patients generally do not change dialysis providers. Despite having access to a dialysis facility star-rating system that reports on quality of care, patients are not likely to change the facility where they receive care. While the increasing number of for-profit and chain organizations may be associated with better ESRD QIP performances, these facilities may have a reduced incentive to provide quality care beyond the ESRD QIP targeted measures.

In neighborhoods with a greater proportion of Native Hawaiians, dialysis facilities are much more likely to achieve ESRD QIP measures and avoid a penalty. Considering that kidney disease is a significant health problem for Native Hawaiians, this outcome was unexpected. Compared to other races, Native Hawaiians have the highest rate of ESRD and are the most likely to receive no pre-ESRD nephrology care, the least likely to receive a kidney transplant, and have the highest average level of blood sugars over the past three months.[797] A possible explanation for this unusual finding is that Hawaii has been touted as a state that provides higher quality

[796] Eliason et al., "How Acquisitions Affect Firm Behavior and Performance."
[797] United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."

healthcare compared to other states in the country. Based on metrics that included Medicare quality, Hawaii was ranked number one by US News and World Report for healthcare quality.[798] While Hawaii, which is part of ESRD Network 17, is less likely to receive a penalty, dialysis facilities in Networks 2, 4, 5, 7 and 9 have the strongest statistically significant association with a higher penalty amount. Network 7, which consists of dialysis facilities in the state of Florida, is the most likely of all ESRD networks to receive a penalty. The fact that elderly patients were marginally less likely to receive care at a facility that received a penalty make this an unexpected finding, given the high proportion of elderly individuals residing in Florida.

Dialysis facilities located in census tracts serving a greater proportion of uninsured individuals and African Americans living below the FPL had poorer ESRD QIP performance scores and were thus more likely to receive a penalty. These results concur with previous studies that evaluated characteristics of dialysis facilities and the ESRD QIP penalty status or targeted measures.[799,800,801,802] An interaction effect exists between the two independent variables proportion of African Americans and the proportion of individuals with an income below the FPL, on the dependent variable dialysis facility penalty amount. The combined effect of the interaction term on penalty status is considerably greater than the sum of the individual variables.[803] African Americans living below the FPL have a negative impact on ESRD QIP facility performance and penalty amount. The mechanism underlying the relationship between social disparities by race and socioeconomic status, and health outcomes frequently appear in the literature. African Americans tend to live in the poorest of neighborhoods and suffer worse health

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[798] Debenport, "These U.S. States Have the Best Healthcare Quality."
[799] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[800] Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
[801] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[802] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[803] Berman & Wang, *Essential Statistics for Public Managers and Policy Analysts*.

outcomes than other races.[804] Similar to other ESRD QIP studies, analyses have demonstrated that caring for patients of lower socioeconomic status places the dialysis facility at a higher risk of incurring a penalty.[805] Reducing payments to dialysis facilities with a greater proportion of disadvantaged patients may result in decreased resources for facilities that need them the most.

Disentangling whether lower scores on the ESRD QIP performance measures are associated with serving more disadvantaged groups or lower scores are the result of poorer quality care is complex. The interplay between patient, provider and community factors have all been shown to impact health and create disparities.[806,807] However, the role each of these entities plays in producing low ESRD QIP scores remains unclear. In neighborhoods where a dialysis facility is located, approximately 17% of the population lives below the federal poverty level (FPL). In contrast, approximately 12% of the US population lives below the FPL.[808] The fact that dialysis facilities are more likely to be located in a neighborhood below the FPL, which tend to have less resources, social organization and access to healthcare, may be an additional barrier to improving dialysis patient health outcomes.

For the second part of Chapter 4, I predicted that dialysis facilities receiving no ESRD QIP penalty are more likely to be characterized by a higher star-rating; and lower star-rating facilities will more likely have receive a penalty. While an aim of the ESRD QIP is to improve health care delivery and patient outcomes, the star-rating program similarly awards facilities a one to five-star scale rating based on patient outcomes and surveys. This simple and patient-friendly reporting system aims to better inform a patient about the quality of care provided at a

[804] Noonan, Velasco-Mondragon, and Wagner, "Improving the Health of African Americans in the USA."
[805] Qi, Butler, and Joynt Maddox, "The Role Of Social Risk Factors In Dialysis Facility Ratings And Penalties Under A Medicare Quality Incentive Program."
[806] Thornton et al., "Evaluating Strategies For Reducing Health Disparities By Addressing The Social Determinants Of Health."
[807] Ryvicker and Sridharan, "Neighborhood Environment and Disparities in Health Care Access Among Urban Medicare Beneficiaries With Diabetes."
[808] US Census Bureau, "Poverty Status."

dialysis facility.[809,810] Both reporting systems involve similar metrics. A little over half of the metrics used in the ESRD QIP overlap with the star-rating system.[811] Therefore, the variation in ESRD QIP penalty status and the variation in the star-rating should be congruent.

The analyses supported this prediction, however, the association between the ESRD QIP and the star-rating program was not strong. The results demonstrate that the star-rating increases when the penalty status decreases. The relationship between star-rating and penalty amount is negative, however, the strength of the relationship is weak for the years 2015 through 2018. In 2019 and 2020 the statistically significant negative correlation becomes stronger.

The overall weak relationship between the ESRD QIP and star-rating may present a problem for patients and be an indicator of a flawed design. The purpose of the star-rating system is to offer dialysis patients an easy to interpret consumer friendly summary of a dialysis facility's performance. Therefore, the star-ratings should accurately reflect facilities of poor and high quality so patients can distinguish differences in facility quality when making decisions about care.[812] However, dialysis facility star-ratings are weakly aligned with dialysis facility ESRD QIP performance. Both programs are indicators of a dialysis facility's quality, but this is not reflected in the analyses results.

Even though the ESRD QIP is an accountability program and the star-rating program is better described as a reporting system to provide transparency and inform patients of their choices, the two programs are not clearly delineated from each other. Similar to Medicare's hospital quality incentive program, overlapping payment systems with reporting programs produce unnecessary complexity. When assessing ESRD QIP penalties for dialysis facilities, the

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809 Kidney Epidemiology and Cost Center, "Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release."
810 Pozniak and Pearson, "The Dialysis Facility Compare Five-Star Rating System at 2 Years."
811 Kidney Epidemiology and Cost Center, "Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release."
812 Pozniak and Pearson, "The Dialysis Facility Compare Five-Star Rating System at 2 Years."

complication of repeated requirements for an additional program, such as the star-rating program, may be burdensome and problematic both for healthcare facilities and for Medicare.[813]

Aggregating all years since the inception of the ESRD QIP in 2012 through 2020 indicates that 19% of dialysis facilities have received a penalty. Medicare views the low percent of penalized facilities as an indication that the majority of dialysis patients are receiving quality healthcare and achieving targeted measures that are associated with improved health outcomes. In the first year of the ESRD QIP, only 5% of facilities received a penalty, however, this increased to 40% in 2020. Over the past nine years the program has evolved and additional, more complex measures have been added, and may explain why more facilities in recent years are receiving penalties than in the early years of the program years. While the percentage of facilities receiving a penalty has gradually increased over the past nine years, overall, the majority of dialysis facilities still do not receive a penalty.

Compared to similar Medicare penalty programs, the ESRD QIP assesses far fewer penalties to facilities. Under the Hospital Readmission Reduction Program, approximately 70% of hospitals received a penalty and under the Skilled Nursing Facility Value-based Purchasing Program about 73% of facilities received a penalty.[814,815] In contrast to these incentive programs, the ESRD QIP appears to have achieved much greater success. The easily achievable measures, specifically in the earlier years, may not have been reflective of a high standard of clinically meaningful patient-centered care. To achieve improvement in patient health, the Institute of Medicine asserts that easily attainable measures should not be used as a proxy for quality indicators.[816] While most dialysis facilities achieve the standards that Medicare matched with

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[813] Medicare Payment Advisory Commission, "The Hospital Value Incentive Program: Measuring and Rewarding Meaningful Hospital Quality."
[814] McIlvennan, Eapen, and Allen, "Hospital Readmissions Reduction Program."
[815] Castellucci, "Most Skilled-Nursing Facilities Penalized by CMS for Readmission Rates."
[816] Micheel and Ball, *Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease*.

high-quality care, researchers question whether the reporting measures are indicative of quality dialysis care and improved patient outcomes.[817] Critics of the ESRD QIP measures argue that rationales for a measure's endorsement are derived from observational studies and neglect to obtain a scientifically proven association with improved patient outcomes.[818,819]

Even though most facilities attain the ESRD QIP metrics, the maximum penalty is minimal. Thus, facilities incurring a payment reduction receive a marginal penalty. This design may provide a safeguard against negative impacts such as a major financial losses or avoidance of high-risk patients. However, the weakness of this design, especially for facilities incurring penalties, is that the penalty may not be a large enough incentive to change provider behavior. For low-performing facilities, especially smaller non-profit facilities, a considerable alteration in delivery of care, in addition to the administrative burden and cost for physical, organizational and technological modifications, may diminish or preclude the motivation required to avoid a penalty.[820]

Chapter 5

ESRD QIP Targeted Measures

For Chapter 5, I hypothesized that older age groups will be less likely to achieve targeted measures and for outcome measures not related to the ESRD QIP, I hypothesized that the elderly will perform poorer than their younger counterparts, with the exception of the end-of-life care measures. The hypothesis is partially supported for the AV fistula measure and not supported for the hemoglobin level. For the targeted measures, the AV fistula was slightly less likely to be

[817] Weiner and Watnick, "The ESRD Quality Incentive Program—Can We Bridge the Chasm?"
[818] Hogan, "ESRD QIP: The Good, the Not So Good, and the Mysterious."
[819] Gupta and Wish, "Do Current Quality Measures Truly Reflect the Quality of Dialysis?"
[820] Chung and Shauver, "Measuring Quality in Healthcare and Its Implications for Pay-for-Performance Initiatives."

achieved for the oldest age category of dialysis patients (75 years and older), while 65-74 years old are more likely to have a fistula than younger age groups. Older dialysis patients are marginally less likely to have an AV fistula, but more likely to have an AV graft than a catheter. AV fistula placement, a targeted clinical measure, is the surgical connection of an artery to a vein. Based on the literature this is an unexpected result because an AV fistula requires vessels with a larger diameter. Older people have smaller vessels, and AV fistulas fail in the elderly more often than in the overall ESRD population.[821,822] AV fistula placement was selected as a targeted measure because of its association with lower patient infection rates, better survival and lower costs. However, the benefit of an AV fistula is significantly reduced for specific subsets of the ESRD population.

While the average failure rate of an AV fistula within the first year is 40%, older patients, and those with diabetes or peripheral vascular disease have been associated with even lower AV fistula success rates and lower life expectancy. This results in added surgeries to place another type of access, greater morbidity and higher long-term costs.[823,824,825,826] Healthier older patients may have a greater likelihood for AV fistula success; however, studies have demonstrated that older patients in general have a higher mortality rate associated with an AV fistula placement. That is, a functioning AV fistula in these age groups has shown to increase the likelihood of death. Additionally, the literature supports use of an AV graft for vascular access for older dialysis patients to maximize life expectancy.[827,828] While an AV fistula placement in the elderly may be counted towards the ESRD QIP targeted measure achievement, they have a greater

[821] U.S. Department of Health and Human Services, "Hemodialysis."
[822] Tucker and Mahajan, "Anatomy, Blood Vessels."
[823] Drew et al., "Vascular Access Choice in Incident Hemodialysis Patients."
[824] Smith, Gohil, and Chetter, "Factors Affecting the Patency of Arteriovenous Fistulas for Dialysis Access."
[825] Thamer et al., "Medicare Costs Associated with Arteriovenous Fistulas Among US Hemodialysis Patients."
[826] United States Renal Data System, "2017 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."
[827] Richardson et al., "Should Fistulas Really Be First in the Elderly Patient?"
[828] DeSilva et al., "Fistula First Is Not Always the Best Strategy for the Elderly."

likelihood to die with an AV fistula placement. A possible rationale for my finding that elderly ESRD patients, compared to younger ESRD patients, were only slightly less likely to achieve the AV fistula targeted measure, could be that some dialysis providers may prioritize achievement of targeted measures for every patient rather than tailoring treatment protocols to individual patient situations. The ESRD QIP incentivizes AV fistula placement for all ESRD patients, however this targeted performance measure does not always translate into best care practices, especially for the elderly.[829]

While older patients are marginally less likely to have an AV fistula, they are more likely to have an AV graft than a CVC. An AV graft is a type of vascular access that is not measured in the ESRD QIP, but was included in my analysis as a comparison to the CVC, which is measured in the ESRD QIP. The study observed that older age groups compared to younger age groups are much more likely to have an AV graft than a CVC. While national guidelines recommend an AV fistula as a first choice for access type, an AV graft is less expensive and for older adults has been associated with better health outcomes.[830,831] A CVC, which is included in the ESRD QIP, is the least optimal choice for vascular access because patients with a CVC are more prone to clotting, infections and overall poorer health outcomes.[832] Compared to younger patients, older patients are less likely to have a CVC. Regardless of patient mix, dialysis facilities are rewarded for a high AV fistula prevalence and penalized for high CVC prevalence.[833] Therefore, younger patients compared to older patients received worse scores for the CVC measure. Conversely, older

[829] Drew et al., "Vascular Access Choice in Incident Hemodialysis Patients."
[830] Murea et al., "A Randomized Pilot Study Comparing Graft-First to Fistula-First Strategies in Older Patients with Incident End-Stage Kidney Disease."
[831] Al-Balas et al., "Choice of a Second Vascular Access in Hemodialysis Patients Whose Initial Arteriovenous Fistula Failed to Mature."
[832] Quarello et al., "Do Central Venous Catheters Have Advantages over Arteriovenous Fistulas or Grafts?"
[833] Wish, "Catheter Last, Fistula Not-So-First."

patients performed worse on the AV fistula, which is the higher rewarded measure, and performed better on the CVC.

Even though the advantage of an AV fistula is significantly less for older dialysis patients, the ESRD QIP continues to include it in the program without adjusting for a facilities patient mix.[834] This dissertation demonstrates, however, that older dialysis patients are more likely to have an AV graft, which is consistent with studies showing that an AV graft is often the best choice for elderly dialysis patients. This could indicate that some dialysis providers encounter cases with elderly patients where an AV graft is the safest and most effective means of vascular access, and recommend an AV graft instead of an AV fistula. While an AV fistula is a better choice for younger healthier patients, promoting this metric for all patients under the ESRD QIP precludes a patient-centered approach to care that may be detrimental to different patient mixes.

The second ESRD QIP targeted measured analyzed was hemoglobin levels, which I hypothesized would be more difficult for older dialysis patients to achieve. This proved false as the hemoglobin targeted measure was more likely to be achieved by older dialysis patients than younger dialysis patients. The majority of dialysis patients have anemia, a hemoglobin deficiency, that is associated with the inability of deteriorating kidneys to make an adequate amount of erythropoietin. Therefore medication is used as a proxy for the hormone erythropoietin to increase hemoglobin levels.[835] The ESRD QIP initially incentivized providers to maintain patient hemoglobin levels between 10-12 g/dl by calculating the performance score based on the least number of patients with a score of less than 10g/dl and the least number of patients with a score greater than 12g/dl. The vast majority of providers achieved patient levels above 10g/dl and

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[834] Drew et al., "Vascular Access Choice in Incident Hemodialysis Patients."

[835] Juárez-Cedillo et al., "Prevalence of Anemia and Its Impact on the State of Frailty in Elderly People Living in the Community."

that component of the hemoglobin level was removed.[836] Currently, the goal for hemoglobin is to have as few patients over 12g/dl, which corresponds to current nephrology practice guidelines, and is considerably lower than the normal range for healthy patients.[837] While naturally occurring hemoglobin levels of >12g/dl among dialysis patients are not linked to adverse events, such as increased mortality, dialysis patients with high hemoglobin levels because of high doses of medication, have an increased risk for cardiovascular events.[838]

While previous research has demonstrated that elderly patients have a greater risk for lower, not higher, hemoglobin levels,[839] this study finds that older dialysis patients are more likely to have higher hemoglobin levels than younger age groups. This is an unexpected finding considering that older patients are more vulnerable and susceptible to adverse outcomes, such as lower hemoglobin levels. A possible rationale is that older dialysis patients, who tend to have lower baseline hemoglobin levels, are more likely to receive higher doses of anemia treatment to increase these levels.[840] While older patients are more susceptible to naturally occurring lower hemoglobin levels, increased levels of hemoglobin are a result of the medication given. In contrast, younger dialysis patients may be more likely to have higher levels of naturally occurring hemoglobin levels, and may receive lower doses or less frequent doses of the medication. Thus, older dialysis patients may have higher levels of hemoglobin because they are receiving more frequent or higher doses of the medication.

The analyses yielded additional statistically significant results for hemodialysis treatment practices, socio-demographics and change over time. Dialysis patients who receive longer

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[836] Centers for Medicare & Medicaid Services, "ESRD QIP Summary: Payment Years 2012 - 2016."
[837] Berns, "Should the Target Hemoglobin for Patients with Chronic Kidney Disease Treated with Erythropoietic Replacement Therapy Be Changed?"
[838] Mimura, Tanaka, and Nangaku, "How the Target Hemoglobin of Renal Anemia Should Be?," 2015.
[839] Anand, Tamura, and Chertow, "The Elderly Patients on Hemodialysis."
[840] St. Peter et al., "Prevalence, Treatment Patterns, and Healthcare Resource Utilization in Medicare and Commercially Insured Non-Dialysis-Dependent Chronic Kidney Disease Patients with and without Anemia in the United States."

treatment times per session are marginally more likely to have lower hemoglobin levels, which may be correlated with the loss of blood during the extended duration of hemodialysis treatments. Patients with a CVC for dialysis access are also more likely to have lower hemoglobin levels. These results correspond to previous studies that find CVCs to be associated with lower hemoglobin levels. CVCs have been shown to contribute to higher levels of inflammation, which are associated with lower hemoglobin levels. Furthermore, studies have demonstrated that dialysis patients who transition from a CVC to an AV fistula will have higher hemoglobin after changing to an AV fistula.[841,842,843] The ESRD QIP encourages providers to restrict CVC placement by reducing dialysis facility performance scores for patients with a CVC instead of an AV fistula. The literature and ESRD guidelines support the avoidance of CVCs because of adverse outcomes such as infection and sepsis.[844] Another rationale for avoiding CVCs, which this study demonstrates, is the increased likelihood for lower hemoglobin levels.

The analysis also showed that hemoglobin levels are found to be lower in African Americans compared to Whites. The results correspond to previous studies which found that African Americans, compared to Whites, have an approximate 0.5g/dl lower adjusted mean hemoglobin level.[845,846] Malnutrition, genetics and increased rates of inflammation are believed to contribute to the lower hemoglobin levels which African Americans experience.[847,848,849] While

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841 Hung and Alp Ikizler, "Hemodialysis Central Venous Catheters as a Source of Inflammation and Its Implications."
842 DeSilva et al., "Fistula First Is Not Always the Best Strategy for the Elderly."
843 Gluba-Brzózka et al., "The Influence of Inflammation on Anemia in CKD Patients."
844 Hung and Alp Ikizler, "Hemodialysis Central Venous Catheters as a Source of Inflammation and Its Implications."
845 McFarlane et al., "Prevalence and Associations of Anemia of CKD."
846 Lea, Norris, and Agodoa, "The Role of Anemia Management in Improving Outcomes for African-Americans with Chronic Kidney Disease."
847 Derebail et al., "Variant Hemoglobin Phenotypes May Account for Differential Erythropoiesis-Stimulating Agent Dosing in African-American Hemodialysis Patients."
848 Rattanasompattikul et al., "Association of Malnutrition–Inflammation Complex and Responsiveness to Erythropoiesis-Stimulating Agents in Long-Term Hemodialysis Patients."
849 Beutler and West, "Hematologic Differences between African-Americans and Whites."

the ESRD QIP does not make adjustments for hemoglobin levels, considering the social determinants of health for African Americans may be beneficial to decreasing health disparities.

Hemoglobin levels also decreased over time. The years 2015, 2016 and 2018 demonstrated a statistically significant decrease in dialysis patient hemoglobin levels. The decrease in hemoglobin levels corresponds to the change in the targeted measure levels for hemoglobin. Initially, the ESRD QIP reduced performance scores to facilities that had patients with a hemoglobin levels of <10g/dl and/or >12g/dl. The bottom measure became topped-out, as the majority of providers were able to achieve hemoglobin levels for their patients that were >10g/dl, and was removed from the ESRD QIP in 2013. Dialysis providers were then incentivized to have as few dialysis patients over >12g/dl. This may have resulted in a reduction in hemoglobin levels during the subsequent years of the ESRD QIP.

Non-targeted Measures

For outcome measures not related to the ESRD QIP, I hypothesized that the elderly will perform poorer than their younger counterparts, with the exception of the end-of-life care measures. The analyses suggest that older dialysis patients perform better on certain quality indicators and lag behind on others. The analyses show a non-significant effect for older dialysis patients and the end-of-life care measures: hospice; discontinues renal replacement therapy prior to death; and death in the home versus the hospital. While I did not expect a change over time between older patients receiving end-of-life care measures, I was incorrect to hypothesize that a statistically significant effect would exist among older patients (compared to younger patients) receiving end-of-life care. In addition, I expected more older patients to die in the hospital. Based on the literature, elderly dialysis patients spend more of their remaining life years in the hospital, and while in the hospital elderly patients are much more likely to die.[850,851] However, older dialysis patients dying in the hospital was not found to be a statistically significant effect.

End-of-life care that transitions from aggressive treatment to symptom management is an important option for patients. It cost-effectively provides physical and emotional support at end of life, and allows patients to die more comfortably than if receiving invasive treatments.[852] Researchers believe the option for end-of-life care, such as hospice, offers an important part of healthcare as a patient approaches death. This research found that African Americans compared to Whites, and males compared to females are less likely to receive hospice care and less likely to discontinue renal replacement therapy prior to death. End-of-life care for Medicare patients suffering from cancer share similar results. Comparable to dialysis patients, cancer patients at the end of life often receive aggressive treatment, and this occurrence is more common in African Americans and males.[853] In addition, the analyses indicate that Hispanics are less likely to discontinue renal replacement therapy prior to death; and African Americans are considerably more likely than Whites to die in the hospital. These findings are consistent with previous studies addressing disparities in end-of-life care that have demonstrated African Americans are more likely to die in the hospital; and African Americans and Hispanics are less likely to use hospice or palliative care because of cultural and language barriers.[854,855,856] The outcomes conform to the broader literature on end-of-life care for minorities, specifically African Americans. Such underrepresented groups experience obstacles to end-of-life care such as lack of insurance,

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[850] Carson et al., "Is Maximum Conservative Management an Equivalent Treatment Option to Dialysis for Elderly Patients with Significant Comorbid Disease?"
[851] Schmidt and Moss, "Dying on Dialysis."
[852] DeVore, "The Humanity In End-Of-Life Care."
[853] Miesfeldt et al., "Association of Age, Gender, and Race with Intensity of End-of-Life Care for Medicare Beneficiaries with Cancer."
[854] Miesfeldt et al.
[855] Carrion and Bullock, "A Case Study of Hispanics and Hospice Care."
[856] Rhodes et al., "Barriers to End-of-Life Care for African Americans From the Providers' Perspective."

knowledge deficiency about end-of-life care, provider cultural insensitivity and distrust towards medical providers.[857]

The analyses also indicate that older dialysis patients are much less likely to receive home HD and PD as a renal replacement therapy, which conforms to the literature about challenges of older patients on home HD and PD. Problems associated with aging, such as frailty, manual dexterity, visual and hearing impairment and cognitive dysfunction can make self-administering home dialysis difficult.[858] While PD and home HD is preferred over in-center HD because of lower costs, commensurate health outcomes and patient independence,[859] PD and home HD for many older patients may be less practical. Older patients are also less likely to receive a transplant. While an upper age limit for a kidney transplant does not exist, older patients are significantly less likely to receive a transplant. This is an expected finding as older age is often indicative of other health issues associated with a higher risk for adverse outcomes. In addition, since the beginning of the ESRD QIP an increase in transplantation has occurred. The years 2013 through 2017, compared to 2012, were statistically significant for an increase in transplantation. The strongest increase occurred in 2015. While these finding may have been associated with the ESRD QIP, the occurrence of the new kidney allocation system (KAS), which was implemented in 2014 by the Organ Procurement and Transplant Network (OPTN), may have impacted the increase in transplantation. KAS was created to decrease the rate of usable discarded kidneys and provide improved access for transplant candidates who are more difficult to match.[860]

Patients age 65 and over were found to be less likely to receive a transplant, and those 75 and older were significantly less likely to receive a transplant. While age itself is not a contraindication for transplantation, the majority of elderly dialysis patients have a high burden of

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[857] Rhodes et al.
[858] Hurst and Figueiredo, “The Needs of Older Patients for Peritoneal Dialysis.”
[859] Arrieta et al., “Peritoneal Dialysis Is the Best Cost-Effective Alternative for Maintaining Dialysis Treatment.”
[860] Organ Procurement and Transplantation Network, “Kidney Allocation System.”

chronic diseases, which can make them ineligible for a transplantation.[861] The decrease in kidney transplantation for the elderly during the inception of the ESRD QIP may have also been associated with the implementation of KAS, which contained policy components that made receiving a deceased donor kidney more restrictive for older ESRD patients. During the first five months of the new KAS, a small reduction in deceased donor kidneys given to patients over age 65 occurred.[862,863,864] In the following years, the proportion of 65 and older kidney transplant recipients decreased from 23% to 18%, but by 2018 had returned to near pre-KAS levels.[865] Considering the increasing prevalence of older ESRD patients, and the significant decrease in mortality rates and graft loss for older transplant recipients over the past decades[866] further research on the benefits of receiving a transplant relative to age, functional status, comorbidities and expected life years gained will valuable.[867]

Since the inception of the ESRD QIP the proportion of patients selecting in-center HD, PD, home HD and transplant has marginally changed over time. Compared to in-center HD, patients using PD and receiving a transplant have steadily increased; and patients receiving home HD has marginally increased. This is consistent with previous research examining changes in home dialysis use, which has been historically underutilized.[868,869] In an effort to reduce costs and improve treatment options, attempts to increase the use of home dialysis for all dialysis patients have occurred over the years. The ESRD Prospective Payment System (PPS) enacted in 2011 aimed to reduce costs by increasing the number of dialysis patients on home dialysis, which includes home HD and PD. Reimbursement for dialysis treatment was adjusted so that

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[861] Lønning et al., "Are Octogenarians With End-Stage Renal Disease Candidates for Renal Transplantation?"
[862] Abecassis et al., "Solid-Organ Transplantation in Older Adults."
[863] Organ Procurement and Transplantation Network, "Kidney Allocation System."
[864] Stewart, Wilk, and Klassen, "KAS Turns Four."
[865] Stewart, Wilk, and Klassen.
[866] McAdams-DeMarco et al., "Trends in Kidney Transplant Outcomes in Older Adults."
[867] Randall, Cao, and deVera, "Transplantation in Elderly Patients."
[868] Sloan et al., "Trends in Peritoneal Dialysis Use in the United States after Medicare Payment Reform."
[869] Arrieta et al., "Peritoneal Dialysis Is the Best Cost-Effective Alternative for Maintaining Dialysis Treatment."

medications and supplementary care would be bundled into a single payment. The PPS separately added home dialysis training to incentivize providers to increase training use because the service is paid for separately.[870] The PPS increased home dialysis reimbursement by $330 per month and decreased in-center HD by $117 per month. The expectation was that dialysis providers would shift more patients to home dialysis.[871,872]

Although change has been minimal, payment reform efforts have helped to increase home HD and transplantation, and the results of my analyses concur with this marginal shift. While home dialysis and transplants are generally more optimal than in-center HD, overall, they continue to be underutilized. Renewed attempts to increase the use of PD and home HD; and increase the supply of kidneys for transplantation has become a national priority. The 2019 executive order *Advancing American Kidney Health* was signed by the President to help improve ESRD care and refocus efforts to increase home HD and transplantation.[873,874]

Another health outcome measure not targeted by the ESRD QIP that was evaluated is the number of ICU days a dialysis patient spends per hospital episode. The analyses demonstrated that older patients (75+) experience the least number of days in the ICU and have the fewest number of surgeries per episode of hospital care. Patients age 45-74 years old, compared to the youngest age group, spend more days in the ICU. Patients who receive more surgeries also tend to spend more days in the ICU, which is an expected finding. A possible rational that 45-74 years old spend more days in the ICU and 75+ spend less days in the ICU may be a result of dialysis patients age 75+ receiving less surgeries, especially high-risk surgeries. Often high-risk surgeries

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[870] Department of Health and Human Services, "Medicare Program; End-Stage Renal Disease Prospective Payment System."
[871] Hornberger and Hirth, "Financial Implications of Choice of Dialysis Type of the Revised Medicare Payment System."
[872] Lin et al., "Home Dialysis in the Prospective Payment System Era."
[873] Sau Fan Chow et al., "RENEW—a Renal Redesign Project in Predialysis Patient Care."
[874] U.S. Department of Health and Human Services, "HHS Launches President Trump's 'Advancing American Kidney Health' Initiative."

require admittance into the ICU, and because patients 75+ are at higher risk for complications, they are less likely to receive more surgeries. Another possible explanation could be that more patients 75+ die in the ICU, so they are not necessarily discharged in a shorter period of time.

Examining variation in outcomes by age for ESRD QIP targeted and non-targeted measures is the main motivation for this research, however, analyses also reveal poorer outcomes for African Americans and Hispanics.[875,876,877] This study has demonstrated that poorer health outcomes are minimally associated with older dialysis patients, and significantly associated with minority dialysis patients. While the aim of this study was not to examine health outcomes for minorities, disparities with achieving targeted and non-targeted measures were found to exist for this subset of the population. Minorities are less likely to use end-of-life care, have lower hemoglobin levels and are less likely to receive home dialysis or a transplant. Future research to examine a broader range of measures to determine whether minority ESRD patients are performing poorly in other areas would be beneficial. Also, studies to understand why this is happening and the most optimal approach to addressing health disparities among minorities would be useful.

For older dialysis patients compared to other age groups, health disparities exist, however the correlation is weak. The large sample size may produce a statistically significant difference for older patients compared to younger patients, however, the effect appears minimal.[878] While caution is needed when interpreting these results, the fundamental issue remains unchanged, that elderly patient outcomes are an area in need of continued improvement. This is especially the case when addressing end-of-life issues, which are not included in the ESRD QIP and have been

875 Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
876 Almachraki et al., "Socioeconomic Status of Counties Where Dialysis Clinics Are Located Is an Important Factor in Comparing Dialysis Providers."
877 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
878 Chung and Shauver, "Measuring Quality in Healthcare and Its Implications for Pay-for-Performance Initiatives."

shown to be inadequate.[879,880,881,882] These issues may be associated with suboptimal treatment goals, communication about prognosis and advance care planning for elderly ESRD patients.[883,884] As the incidence and prevalence of older ESRD patients continues to increase, challenges with dialysis initiation at an advanced age become more apparent. Initiating dialysis in the elderly, especially for those 75 years and older, generally affords a small probability of improved quality of life or long-term survival.[885] For dialysis patients, especially those nearing the end of life, a myriad of severe symptoms creates various negative physical and emotional challenges. Such responses are often caused by the treatment itself, making the final months or years of life more burdensome and distressing.[886,887] Providing patient-centered holistic care, especially for dialysis patients with a limited life expectancy, regardless of age, race or ethnicity is important and would be beneficial for inclusion in future quality incentive program adjustments.[888] The findings have implications for policymakers to ensure that ESRD QIP targeted outcomes are beneficial for all subsets of the dialysis population, especially those who are most vulnerable.

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879 Russon and Mooney, "Palliative and End-of-Life Care in Advanced Renal Failure."
880 Wong, Kreuter, and O'Hare, "Treatment Intensity at the End of Life in Older Adults Receiving Long-Term Dialysis."
881 Finnegan-John and Thomas, "The Psychosocial Experience of Patients with End-Stage Renal Disease and Its Impact on Quality of Life."
882 Grubbs et al., "A Palliative Approach to Dialysis Care."
883 Saeed et al., "Outcomes of In-Hospital Cardiopulmonary Resuscitation in Maintenance Dialysis Patients."
884 Holley, "Advance Care Planning in CKD/ESRD."
885 Rosansky, "The Sad Truth about Early Initiation of Dialysis in Elderly Patients."
886 Grubbs et al., "System-Level Barriers and Facilitators for Foregoing or Withdrawing Dialysis: A Qualitative Study of Nephrologists in the United States and England."
887 Grubbs et al., "A Palliative Approach to Dialysis Care."
888 Kennedy, "The Importance of Patient Dignity in Care at the End of Life."

CHAPTER SEVEN

Study Significance and Policy Implications

This study is the first to link the ESRD QIP penalty status to dialysis facility and neighborhood characteristics using census tract data from the program's inception to the current year; and the first study to examine the impact of the ESRD QIP for targeted and non-targeted measures among the elderly. The significant findings of this research provide evidence that vulnerable subsets of the dialysis population are more likely to have negative outcomes despite the program's aim to improve quality of care. The main focus of this study, the impact of the ESRD QIP on the elderly, revealed a marginally negative impact associated with quality metrics. However, statistically significant and strong associations between race and performance on ESRD QIP targeted and non-targeted measures were found. Consistent with a large number of existing studies in the broader literature addressing health disparities by race, this study found substantial differences in health outcomes of African American dialysis patients.[889,890,891] In addition, racial disparities in health, activities of daily living and mortality have been shown to exist among the elderly.[892,893] Future research that addresses whether an interaction exists among African Americans and the elderly exists to elicit whether racial disparities increase or decrease with age would be valuable.

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889 Thornton et al., "Evaluating Strategies For Reducing Health Disparities By Addressing The Social Determinants Of Health."
890 Kucirka et al., "Age and Racial Disparities in Dialysis Survival."
891 Goodman et al., "Disparities in TKA Outcomes."
892 Kucirka et al., "Age and Racial Disparities in Dialysis Survival."
893 Anderson, Bulatao, and Cohen, "Racial and Ethnic Disparities in Health and Mortality Among the U.S. Elderly Population."

Previous studies have expressed concern that the ESRD QIP disproportionately penalizes dialysis facilities serving vulnerable patients.[894,895] This study confirms that vulnerable patients, such as African Americans, Hispanics and the elderly, can be negatively affected. The elderly ESRD patient population faces a unique set of challenges. The elderly population is the fastest growing segment of patients initiating dialysis. Specifically, dialysis patients 75 years of age and older are the largest subset of ESRD patients initiating dialysis. In addition, those 65-74 years old have the highest prevalence rate and are the second fastest growing population. Secondly, studies have demonstrated the quality of care and quality of life for elderly dialysis patients nearing death is poor. Almost half of all ESRD patients will die in a hospital. Even though no statistically significant effect between the elderly and death in the hospital was shown, the large proportion of ESRD patients dying in the hospital versus the home is significant. Receiving optimal end of life care when dying in the hospital is often impractical, and generally not a patient's preferred place of death.[896] While the purpose of dialysis is to restore kidney functioning and maintain life, vulnerable patients such as the elderly often become more disabled, suffer greater physical burden and an increased risk for mortality after dialysis initiation.[897,898,899] Developing a policy that promotes a model of end-of-life care for dialysis patients would be beneficial to delivering quality care by fostering patient autonomy and active involvement in the decision-making process.

Healthcare for the elderly is distinct from the care given to younger patients because of a higher occurrence of mental and physical debilitation, larger resource demands and ethical

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[894] Ajmal et al., "Association between Freestanding Dialysis Facility Size and Medicare Quality Incentive Program Performance Scores."
[895] Dad et al., "Evaluation of Non-Response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey."
[896] Virdun et al., "Dying in the Hospital Setting."
[897] Tamura, Tan, and O'Hare, "Optimizing Renal Replacement Therapy in Older Adults."
[898] Roy et al., "Evaluation of Unplanned Dialysis as a Predictor of Mortality in Elderly Dialysis Patients."
[899] United States Renal Data System, "2019 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States."

challenges.[900] This makes policy decisions for elderly dialysis patients complicated. With older patients living longer and life sustaining therapies available, financial and technological issues become interwoven with ethical concerns.[901] While survival has considerably increased since the inception of the ESRD Program, for those 75 and older morbidity frequently complicates the benefit of living longer. This subset of patients experiences the lowest life expectancy and the greatest costs of care.[902] A need exists to support and treat older dialysis patients separate from younger dialysis patients, however, the ESRD QIP is not tailored to meet the singular mental and physical health needs of the elderly. As the number of dialysis patients age 65 and older continues to multiply compared to their younger cohorts, a reevaluation of the program's assumptions, measures and financing should be considered.

The widespread implementation of federally sponsored pay for performance programs has emerged to create cost-effective approaches that improve quality care and patient health outcomes. The number of federally assisted healthcare programs that employ financial incentives to reward or penalize providers has continued to increase over the last decade. While the evidence that these types of programs are successful is limited, the overall literature shows that the research does not strongly support or oppose such payment schemes.[903,904] Research demonstrating positive results has generally presented small improvements with recommendations to adjust the incentive program's design for better success.[905,906,907] Conversely, some research also demonstrates that

900 National Research Council., "The Health of Aging Populations."
901 National Research Council.
902 Tamura, Tan, and O'Hare, "Optimizing Renal Replacement Therapy in Older Adults."
903 Scott et al., "The Effect of Financial Incentives on the Quality of Health Care Provided by Primary Care Physicians."
904 Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
905 Figueroa et al., "Association between the Value-Based Purchasing Pay for Performance Program and Patient Mortality in US Hospitals."
906 Jha et al., "The Long-Term Effect of Premier Pay for Performance on Patient Outcomes."
907 Shih et al., "Does Pay-for-Performance Improve Surgical Outcomes?"

these programs are ineffective in improving patient health outcomes, and conclude that unintended consequences can negatively impact sicker, more vulnerable patients.[908,909,910]

While the majority of dialysis facilities are able to successfully respond to the ESRD QIP by meeting Medicare's criteria for quality, this care may not be compatible for patients at the most risk for adverse outcomes, such as the elderly and African Americans. Furthermore, healthcare interventions that are population based have been shown to increase health disparities of these more vulnerable patients.[911] Better understanding the relationship between the achievement of targeted measures and socioeconomic factors is necessary to better serve the dialysis population. For patients living in economically disadvantaged neighborhoods, especially those living below the FPL, poorer conditions can be a key determinant of the mental and physical well-being of older individuals. Studies have demonstrated that the elderly living in poor neighborhoods, compared to wealthier communities, have a much higher probability of suffering multiple comorbidities, not being able to perform activities of daily living and dying earlier.[912]

For dialysis facilities to improve delivery of care and health outcomes for all patients, ensuring the targeted measures promote equity and addressing neighborhood-level conditions may be helpful. Not accounting for socioeconomic factors disproportionately punishes dialysis facilities that provide care for disadvantaged patients and could potentially increase the disparity gap in dialysis patient healthcare. Efforts to improve care for patients at dialysis facilities incurring penalties may be more effective if corrective measures or specific actions are offered to improve the deficiencies. These issues have ongoing ESRD policy implications for novel approaches to improve health outcomes for all ages and races of dialysis patients.

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908 Roland and Dudley, "How Financial and Reputational Incentives Can Be Used to Improve Medical Care."
909 Doran, Maurer, and Ryan, "Impact of Provider Incentives on Quality and Value of Health Care."
910 Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
911 Frohlich and Potvin, "Transcending the Known in Public Health Practice."
912 Wen and Christakis, "Neighborhood Effects on Posthospitalization Mortality: A Population-Based Cohort Study of the Elderly in Chicago."

Since the ESRD QIP implementation in 2012, a limited number of studies has examined the program. Additionally, very few studies have evaluated whether the program has improved patient outcomes or monitored the effect of the program's increasing complexity and number of targeted measures. Yet, the ESRD QIP continues to be recognized by the CMS as a valuable means of providing quality care.[913,914] While the efficacy of the ESRD QIP remains uncertain, the program continues to evolve and become more complex. Clinical measures annually change and technical specifications for the ESRD QIP have been proposed through 2024.[915] Since the inception of the ESRD QIP, the majority (81%) of dialysis facilities have not received a penalty, however, the percentage of facilities receiving a penalty has gradually increased over the past nine years (from 5% to 40%). Before continuing to add new measures, further research about the long-term effects of the program is warranted. Consistent monitoring of non-targeted and targeted patient outcomes would be helpful to confirm that the ESRD QIP is successfully achieving its objectives.[916] This is especially important for disadvantaged patients, such as the elderly, who are more challenged by the physical and psychosocial burdens of ESRD; and minorities, who are more likely to receive dialysis at facilities incurring penalties.

Limitations

The dissertation analyses were constrained by limitations. First, the data was secondary analysis of observational panel data. Analysis of quantitative data previously collected can be problematic when reusing the data for new research purposes. The data was not collected or targeted to achieving this dissertation's a priori objective of examining the impact of the ESRD QIP on the elderly.[917] Second, the panel data included incomplete data across and within groups.

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[913] Wanchoo, Hazzan, and Fishbane, "Update on the End-Stage Renal Disease Quality Incentive Program."
[914] Hogan, "ESRD QIP: The Good, the Not So Good, and the Mysterious."
[915] Centers for Medicare & Medicaid Services, "Centers for Medicare & Medicaid Services End-Stage Renal Disease Quality Incentive Program Payment Year 2024 Proposed Measure Technical Specifications."
[916] Saunders, Lee, and Chin, "Early Winners and Losers in Dialysis Center Pay-for-Performance."
[917] CHENG and PHILLIPS, "Secondary Analysis of Existing Data."

Missing data can lead to a reduction in statistical power and biased estimates, which can be associated with invalid conclusions.[918] The aim of addressing missing data was to most accurately estimate the true value of the coefficient for each term in the model. The problem with addressing missing data is the inability to test the type of missing data because the value of the missing data is unknown.[919] In addition, the assumptions of the type of missing data is based on the literature and my interpretation of the patterns of missing data. Based on the assumptions of missing data, the data used for the analyses was missing at random. Therefore, listwise deletion was performed as studies demonstrate that modeling the missing data as part of the estimation process is unnecessary.[920,921]

Using longitudinal data, this dissertation examined patterns of change and the direction and magnitude of that change over time. However, data prior to the ESRD QIP's implementation was unavailable and therefore the patterns of change were only examined after the program's implementation. In addition, no control group was available as data on every dialysis patient is submitted to Medicare and USRDS. Thus, no group of dialysis patients can be used as the standard which comparisons are made. Being an observational study without a control group, along with analyzing data only after the program was enacted, impedes the ability to identify a causal effect.[922,923,924]

The dissertation demonstrates that quality of care is associated with dialysis facility and neighborhood level characteristics, and that patient outcomes, especially for those more vulnerable, do not appear to have improved over time. These structural and outcome

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918 Kang, "The Prevention and Handling of the Missing Data."
919 Hsiao, "Panel Data Analysis—Advantages and Challenges."
920 Kang, "The Prevention and Handling of the Missing Data."
921 Langkamp, Lehman, and Lemeshow, "Techniques for Handling Missing Data in Secondary Analyses of Large Surveys."
922 Salthouse, "All Data Collection and Analysis Methods Have Limitations."
923 Hsiao, "Panel Data Analysis—Advantages and Challenges."
924 "Panel Data Analysis."

domains describe the context in which care is delivered and are an aspect of Donabedian's framework used to infer the quality of dialysis facility care. The analyses demonstrate a variation in the quality of care among different age groups and races based on variables within the structural and outcome domains. However, variables representing Donabedian's process domain, such as a provider's competency level or dissatisfaction about being compelled to focus on specific patient targeted measures, are lacking. Capturing provider intentions and behavioral changes as variables for analysis can be challenging, however it would have benefitted this research.

Provider attitude and behavior can impact the achievement of ESRD QIP targeted measures. Whether targeted measures are attained can be impacted by the provider's attitude about the ESRD QIP, degree of competency, effort required to change healthcare delivery practices to achieve the targeted measures and job satisfaction. Variables in the statistical model that represent process measures, specifically these unobserved provider behavior changes, were inadequate.[925] To effectively evaluate the quality of care, Donabedian asserts the process of interactions between patients and providers, and how providers deliver care, is necessary to understand prior to attributing a value judgment about how provider interventions contribute to patient health outcomes.[926] Failing to obtain measures that reflect provider attitudes was an additional limitation of the research. Further research to understand provider behavior in association with achieving targeted measures would be valuable.

In addition, the analyses of Chapter four that examines what characteristics are associated with a facility receiving a penalty, was at the facility and neighborhood level. The proxy of census tract data for neighborhood characteristics may not accurately reflect the dialysis facility's

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925 Donabedian, "The Quality of Care."
926 Donabedian, "Evaluating the Quality of Medical Care."

patient population. Based on the literature, dialysis patients tend to receive treatment at facilities in their immediate geographic area because of transportation challenges, the inconvenience for medically compromised individuals to travel long distances or the nephrologist assigns the patient to a facility closest to where they live.[927,928] About 90% of dialysis patients receive treatment at a facility within seven miles of where they live. Patients reported a disinclination and capability to travel extended distances to receive treatment.[929] Therefore, the assumption that dialysis facility census tract data is representative of the dialysis facility population should be interpreted with caution. Including patient level data in future research would provide a clearer representation of the relationship between penalty status and patient characteristics.

Another limitation of Chapter 4 was the analysis did not include the number of years a dialysis facility has been in operation. This may be an important variable because the number of dialysis facilities has increased over the decades. About 2,000 new facilities have been opened since the ESRD QIP was implemented.[930] The performance of these new dialysis facilities may differ from established facilities, and number of years a facility is in operation may have been a confounding variable and failing to include it may have biased the results. Few studies have evaluated the association between length of operation and patient level outcomes. One study found a dialysis facility's length of operation was not associated with performance, and another study found the number of years a facility was Medicare certified was positively associated with home dialysis use, which is an equally effective and less costly modality.[931,932] While newer facilities may differ in performance to more established facilities, since the implementation of the

[927] Yazawa et al., "The Effect of Transportation Modality to Dialysis Facilities on Health-Related Quality of Life among Hemodialysis Patients."
[928] Erickson et al., "Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition."
[929] Erickson et al.
[930] Centers for Medicare & Medicaid Services, "Dialysis Facility Compare."
[931] Saunders and Chin, "Variation in Dialysis Quality Measures by Facility, Neighborhood, and Region."
[932] Walker et al., "Dialysis Facility and Patient Characteristics Associated with Utilization of Home Dialysis."

ESRD QIP the majority of dialysis facilities new to the market were largely chains organizations.[933] Based on the descriptive statistics of this dissertation, most chains achieve the ESRD QIP targeted measures. While dialysis care has been shown to vary for non ESRD QIP measures, the system wide standards and practices of care employed to achieve the targeted measures enable most chain facilities to have similar ESRD QIP performance outcomes.[934,935,936] Therefore, the measure was not entered as an explanatory or control variable. However, excluding the variable was a limitation and future research would benefit to clarify whether the number of years a facility is in operation has an impact on dialysis care and patient outcomes.

Conclusions

While this dissertation demonstrates that the ESRD QIP has a marginally negative impact on elderly patients, further research to examine other outcome measures important to older patients, such as activities of daily living, would be beneficial. As the aging of the ESRD population continues, additional challenges with delivering care that is tailored to the needs of the elderly may arise. This dissertation empirically showed differences in quality metric performance by age group during the ESRD QIP.

The effectiveness and benefits of providing dialysis care to older patients can be complex. Delivery of care should be individualized and address functional improvement for activities of daily living, the burden of treatment, patient preference and quality of life.[937] The ESRD QIP aims to improve quality of care, which is especially crucial for older patients, who have historically received less than adequate care towards the end of life. While the ESRD QIP

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[933] Centers for Medicare & Medicaid Services, "Dialysis Facility Compare."
[934] Zhang, Cotter, and Thamer, "The Effect of Dialysis Chains on Mortality among Patients Receiving Hemodialysis."
[935] Ozgen, "Does Chain Affiliation Make a Difference in Efficiency of Dialysis Providers in the USA."
[936] Eliason et al., "How Acquisitions Affect Firm Behavior and Performance."
[937] Bell et al., "Care of Older Adults."

aims to cost-effectively improve quality of care for all dialysis patients, Medicare should identify approaches to addressing demographic and socioeconomic disparities. In addition, enhancing program transparency, with more methodological evaluations to monitor the ESRD QIP impact on the health of all patients, would be beneficial.

Creating payment incentives for quality healthcare services is an attractive idea, and has led to the proliferation of various incentive payment models throughout federally sponsored entitlement programs. However, financial incentives for providers have not been definitively shown to result in better value or care for patients. Since a reward is not provided for attaining the ESRD QIP targeted measures, the payment reductions will potentially afford Medicare savings. However, most dialysis facilities have achieved the targeted measures, and for those facilities that receive a penalty, very few incur the full 2% penalty. This means most dialysis facilities are achieving the standards that Medicare defined as high-quality care. However, evidence suggests that vulnerable patients, such as African Americans and Hispanics, continue to experience relatively poorer ESRD health outcomes, despite the ESRD QIP implementation.

The design of an incentive program requires that a provider has substantial control in influencing the outcome for a targeted measure to be effective. This can be especially problematic for the ESRD population, who are a vulnerable group of diverse individuals. When delivery of care requires the provider to adapt to a patient's individual needs, maximizing quality of life for that individual transcends achieving pre-established quality measures.[938] Aimed to improve dialysis care and reduce costs, the QIP was designed to monitor the quality of dialysis care and patient outcomes for a population of high-cost Medicare beneficiaries who experience significant physical and psychosocial burdens.[939] Whether achieving the clinical measure standards and high

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938 Donabedian, "The Quality of Care."
939 Centers for Medicare & Medicaid Services, "Dialysis Facility Compare."

performance scores aligns with the overall goal of cost-effectively improving patient outcomes remains unclear and are areas for further research.

Given both the high cost of ESRD treatment for dialysis patients to the federal government and the significant toll it takes on the health of older adults, additional research to better understand how the program affects older adults should be considered. This problem suggests the importance of implementing policies that direct individualized treatment strategies and patient centered decision-making for all vulnerable patients. As the ESRD QIP expands, it is critical to continually monitor whether the targeted measures are cost-efficiently improving patient health outcomes across all socioeconomic and age groups.

APPENDIX A

Chapter 4 Missing Data Regression Model

The logistic regression models to examine the missing data patterns. The below tables assess whether any of the variables predict missingness. Variables associated with missingness and are statistically significant are identified as missing at random instead of missing completely at random.

Missing Education No HS	Coef.	P>|z|	[95% Conf.	Interval]
Offers In-Center HD	1.30	0.20	-0.68	3.29
Offers In-Center PD	-0.34	0.01	-0.60	-0.09
Offers Home HD Training	-0.53	0.002	-0.87	-0.19
Year	-0.18	0.001	-0.22	-0.13
Penalty	0.01	0.94	-0.27	0.29
Profit	0.73	0.001	0.32	1.15
Chain	-1.37	0.001	-1.74	-1.01
Late Shift	0.15	0.29	-0.13	0.42
Dialysis Station	0.01	0.08	-0.001	0.03

Missing Unemployed	Coef.	P>|z|	[95% Conf.	Interval]
Offers In-Center PD	0.83	0.03	0.09	1.57
Year	0.15	0.03	0.01	0.29
Penalty	-0.57	0.31	-1.66	0.52
Profit	0.43	0.46	-0.71	1.56
Chain	-1.30	0.02	-2.41	-0.19
Late Shift	1.89	0.001	1.14	2.63
Dialysis Station	-0.01	0.80	-0.05	0.04
Age 65 and Over	-55.12	0.001	-64.43	-45.80
Education No HS	6.04	0.001	3.71	8.37

Missing African American	Coef.	P>|z|	[95% Conf.	Interval]
Offers In-Center PD	-0.36	0.01	-0.61	-0.11
Offers Home HD Training	-0.54	0.002	-0.88	-0.20
Year	-0.18	0.001	-0.22	-0.13
Penalty	0.005	0.97	-0.27	0.28
Profit	0.71	0.001	0.30	1.12
Chain	-1.36	0.001	-1.72	-0.99
Late Shift	0.15	0.28	-0.12	0.42
Dialysis Station	0.01	0.04	0.001	0.03

Chapter 4 Ordered Logistic Regression Models with Selection Criteria

Bivariate analysis demonstrates that the age variable is strongly associated with penalty status and statistically significant.

penalty	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
age_65_and_over	-.8069756	.2151129	-3.75	0.000	-1.228589	-.3853622
/cut1	1.620055	.0394092			1.542815	1.697296
/cut2	2.754059	.041829			2.672075	2.836042
/cut3	3.690759	.0460133			3.600575	3.780943
/cut4	4.901524	.0583126			4.787233	5.015814
/sigma2_u	1.035636	.0440195			.9528555	1.125608

Random effects ordered logistic regression using facility level data demonstrates that the age variable coefficient becomes weaker and statistically insignificant when African American is added as a control variable into the model.

penalty	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
age_65_and_over	-.2207047	.2135873	-1.03	0.301	-.6393281	.1979188
African_American	1.089583	.0672142	16.21	0.000	.9578451	1.22132
/cut1	1.918178	.0434942			1.83293	2.003425
/cut2	3.051854	.0459012			2.961889	3.141819
/cut3	3.987914	.0498506			3.890209	4.085619
/cut4	5.197629	.0614477			5.077194	5.318064
/sigma2_u	.9561153	.0420393			.8771704	1.042165

The below regression models correspond to the output for the first part of objective two. The output consists of the model selection process beginning with the first model (Model 1), which contains all the variables.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Profit	0.01	0.06	0.24	0.81	-0.095	0.12
Chain	-0.73	0.05	-15.38	0.00	-0.826	-0.64
Late Shift	0.00	0.04	0.05	0.96	-0.081	0.09
Dialysis Stations	0.01	0.00	6.98	0.00	0.010	0.02
Offers In-Center HD	-0.77	0.08	-9.14	0.00	-0.930	-0.60
Offers In-Center PD	0.21	0.04	5.95	0.00	0.144	0.29
Offers Home HD Training	0.11	0.04	2.77	0.01	0.032	0.19
Network						
2	0.62	0.13	4.89	0.00	0.369	0.86
3	0.21	0.13	1.53	0.13	-0.058	0.47
4	0.46	0.12	3.81	0.00	0.226	0.70
5	0.40	0.12	3.40	0.00	0.171	0.64
6	0.21	0.12	1.86	0.06	-0.012	0.44
7	0.87	0.12	7.34	0.00	0.639	1.10
8	0.28	0.12	2.36	0.02	0.048	0.52
9	0.48	0.11	4.26	0.00	0.259	0.70
10	0.37	0.12	2.99	0.00	0.128	0.61
11	0.23	0.12	1.94	0.05	-0.002	0.45
12	0.12	0.12	0.93	0.35	-0.128	0.36
13	0.37	0.12	2.96	0.00	0.123	0.61
14	0.41	0.12	3.43	0.00	0.176	0.65
15	-0.19	0.13	-1.44	0.15	-0.445	0.07
16	-0.34	0.15	-2.26	0.02	-0.626	-0.04
17	-0.05	0.14	-0.37	0.71	-0.323	0.22
18	0.34	0.13	2.70	0.01	0.092	0.58
Total Population	0.00	0.00	-3.58	0.00	0.000	0.00
Population Density	0.00	0.00	4.36	0.00	0.000	0.00
Area	0.00	0.00	-2.62	0.01	-0.002	0.00
Age 65 and Over	-0.56	0.24	-2.35	0.02	-1.023	-0.09
White	0.13	0.25	0.51	0.61	-0.360	0.61
African American	0.89	0.25	3.59	0.00	0.405	1.38
Asian	-0.09	0.33	-0.28	0.78	-0.728	0.55
American Indian	-0.02	0.41	-0.06	0.95	-0.818	0.77
Native Hawaiian	-6.58	2.43	-2.71	0.01	-11.337	-1.82
No High School Diploma	-0.69	0.25	-2.70	0.01	-1.182	-0.19
Unemployed	0.29	0.40	0.73	0.47	-0.491	1.07
Median Household Income	0.00	0.00	-0.01	0.99	0.000	0.00
Income below FPL	0.36	0.21	1.67	0.09	-0.062	0.78
Uninsured	0.29	0.32	0.88	0.38	-0.351	0.92

Model 2 contains an interaction term between *African American* and *Income below the FPL*.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.73	0.05	-15.38	0.00	-0.83	-0.64
Late Shift	0.00	0.04	0.05	0.96	-0.08	0.08
Profit	0.01	0.06	0.20	0.84	-0.10	0.12
Dialysis Stations	0.01	0.00	6.99	0.00	0.01	0.02
Offers Home HD Training	0.11	0.04	2.76	0.01	0.03	0.19
Offers In-Center HD	-0.77	0.08	-9.14	0.00	-0.93	-0.60
Offers In-Center PD	0.21	0.04	5.96	0.00	0.14	0.29
Network						
2	0.61	0.13	4.86	0.00	0.36	0.86
3	0.18	0.13	1.37	0.17	-0.08	0.45
4	0.47	0.12	3.83	0.00	0.23	0.70
5	0.38	0.12	3.18	0.00	0.15	0.61
6	0.21	0.12	1.83	0.07	-0.01	0.44
7	0.87	0.12	7.36	0.00	0.64	1.11
8	0.29	0.12	2.38	0.02	0.05	0.52
9	0.48	0.11	4.30	0.00	0.26	0.70
10	0.37	0.12	3.00	0.00	0.13	0.61
11	0.23	0.12	2.02	0.04	0.01	0.46
12	0.12	0.12	0.97	0.33	-0.12	0.36
13	0.37	0.12	3.00	0.00	0.13	0.62
14	0.41	0.12	3.40	0.00	0.17	0.64
15	-0.18	0.13	-1.40	0.16	-0.44	0.07
16	-0.33	0.15	-2.22	0.03	-0.62	-0.04
17	-0.05	0.14	-0.36	0.72	-0.32	0.22
18	0.34	0.13	2.73	0.01	0.10	0.59
Age 65 and Over	-0.49	0.24	-2.04	0.04	-0.96	-0.02
African American	1.24	0.29	4.34	0.00	0.68	1.80
Income below FPL	0.74	0.26	2.80	0.01	0.22	1.25
African American#Income below FPL	-1.16	0.47	-2.47	0.01	-2.08	-0.24
Total Population	0.00	0.00	-3.67	0.00	0.00	0.00
Population Density	0.00	0.00	4.30	0.00	0.00	0.00
Area	0.00	0.00	-2.56	0.01	0.00	0.00
White	0.19	0.25	0.77	0.44	-0.30	0.68
Asian	-0.03	0.33	-0.08	0.93	-0.67	0.61
American Indian	-0.05	0.40	-0.11	0.91	-0.84	0.75
Native Hawaiian	-6.45	2.43	-2.66	0.01	-11.22	-1.69
No High School Diploma	-0.66	0.25	-2.59	0.01	-1.15	-0.16
Unemployed	0.37	0.40	0.91	0.36	-0.42	1.15
Median Household Income	0.00	0.00	0.56	0.58	0.00	0.00
Uninsured	0.26	0.32	0.80	0.43	-0.38	0.90

Model 3 removes *profit* and *late shift*. Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression

Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.73	0.04	-18.50	0.00	-0.805	-0.65
Dialysis Stations	0.01	0.00	7.13	0.00	0.010	0.02
Offers Home HD Training	0.11	0.04	2.79	0.01	0.033	0.19
Offers In-Center HD	-0.77	0.08	-9.16	0.00	-0.931	-0.60
Offers In-Center PD	0.21	0.04	5.96	0.00	0.144	0.29
Network						
2	0.61	0.13	4.86	0.00	0.365	0.86
3	0.18	0.13	1.37	0.17	-0.079	0.45
4	0.47	0.12	3.84	0.00	0.228	0.70
5	0.38	0.12	3.18	0.00	0.146	0.61
6	0.21	0.11	1.84	0.07	-0.014	0.44
7	0.87	0.12	7.39	0.00	0.643	1.11
8	0.29	0.12	2.39	0.02	0.052	0.52
9	0.48	0.11	4.31	0.00	0.264	0.70
10	0.37	0.12	3.01	0.00	0.130	0.61
11	0.23	0.12	2.01	0.04	0.006	0.46
12	0.12	0.12	0.96	0.34	-0.124	0.36
13	0.37	0.12	3.02	0.00	0.131	0.62
14	0.41	0.12	3.42	0.00	0.174	0.64
15	-0.18	0.13	-1.40	0.16	-0.439	0.07
16	-0.33	0.15	-2.22	0.03	-0.619	-0.04
17	-0.05	0.14	-0.37	0.71	-0.322	0.22
18	0.34	0.12	2.75	0.01	0.098	0.59
Age 65 and Over	-0.49	0.24	-2.04	0.04	-0.954	-0.02
African American	1.24	0.29	4.34	0.00	0.682	1.80
Income below FPL	0.74	0.26	2.80	0.01	0.221	1.25
African American#Income below FPL	-1.16	0.47	-2.47	0.01	-2.079	-0.24
Total Population	0.00	0.00	-3.66	0.00	0.000	0.00
Population Density	0.00	0.00	4.31	0.00	0.000	0.00
Area	0.00	0.00	-2.57	0.01	-0.002	0.00
White	0.19	0.25	0.76	0.45	-0.299	0.68
Asian	-0.03	0.33	-0.09	0.93	-0.667	0.61
American Indian	-0.05	0.40	-0.12	0.91	-0.842	0.74
Native Hawaiian	-6.45	2.43	-2.65	0.01	-11.208	-1.68
No High School Diploma	-0.66	0.25	-2.59	0.01	-1.152	-0.16
Unemployed	0.37	0.40	0.92	0.36	-0.417	1.15
Median Household Income	0.00	0.00	0.57	0.57	0.000	0.00
Uninsured	0.26	0.32	0.80	0.42	-0.377	0.90

Obs	**ll(model)**	**df**	**AIC**	**BIC**
54,105	-34301.56	42	68687.11	69060.86

Model 4 removes the variable *offers home HD training*. Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.04	-18.39	0.000	-0.80	-0.65
Dialysis Stations	0.01	0.00	7.36	0.000	0.01	0.02
Offers In-Center HD	-0.78	0.08	-9.37	0.000	-0.95	-0.62
Offers In-Center PD	0.26	0.03	8.24	0.000	0.20	0.32
Network						
2	0.60	0.13	4.74	0.000	0.35	0.84
3	0.16	0.13	1.18	0.237	-0.10	0.42
4	0.45	0.12	3.72	0.000	0.21	0.69
5	0.36	0.12	3.00	0.003	0.12	0.59
6	0.20	0.11	1.74	0.083	-0.03	0.42
7	0.85	0.12	7.22	0.000	0.62	1.08
8	0.27	0.12	2.29	0.022	0.04	0.51
9	0.47	0.11	4.19	0.000	0.25	0.69
10	0.36	0.12	2.89	0.004	0.12	0.60
11	0.22	0.12	1.86	0.063	-0.01	0.44
12	0.10	0.12	0.84	0.401	-0.14	0.35
13	0.36	0.12	2.88	0.004	0.11	0.60
14	0.38	0.12	3.18	0.001	0.14	0.61
15	-0.20	0.13	-1.55	0.120	-0.46	0.05
16	-0.33	0.15	-2.26	0.024	-0.62	-0.04
17	-0.08	0.14	-0.55	0.584	-0.35	0.20
18	0.31	0.12	2.51	0.012	0.07	0.56
Age 65 and Over	-0.50	0.24	-2.10	0.036	-0.97	-0.03
African American	1.25	0.29	4.35	0.000	0.68	1.81
Income below FPL	0.74	0.26	2.80	0.005	0.22	1.25
African American#Income below FPL	-1.16	0.47	-2.48	0.013	-2.08	-0.24
Total Population	0.00	0.00	-3.64	0.000	0.00	0.00
Population Density	0.00	0.00	4.27	0.000	0.00	0.00
Area	0.00	0.00	-2.65	0.008	0.00	0.00
White	0.20	0.25	0.80	0.425	-0.29	0.69
Asian	-0.01	0.33	-0.03	0.978	-0.65	0.63
American Indian	-0.04	0.40	-0.10	0.920	-0.83	0.75
Native Hawaiian	-6.49	2.44	-2.67	0.008	-11.27	-1.72
No High School Diploma	-0.68	0.25	-2.68	0.007	-1.18	-0.18
Unemployed	0.36	0.40	0.91	0.364	-0.42	1.15
Median Household Income	0.00	0.00	0.54	0.587	0.00	0.00
Uninsured	0.26	0.32	0.81	0.420	-0.37	0.90

Obs	**ll(model)**	**df**	**AIC**	**BIC**
54,105	-34305.44	41	68692.87	69057.72

Model 5 removes the variables *total population, population density* and *area.* Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.73	0.04	-18.53	0.000	-0.81	-0.65
Dialysis Stations	0.02	0.00	7.95	0.000	0.01	0.02
Offers In-Center HD	-0.81	0.08	-9.67	0.000	-0.97	-0.64
Offers In-Center PD	0.26	0.03	8.16	0.000	0.20	0.32
Network						
2	0.73	0.12	5.96	0.000	0.49	0.96
3	0.15	0.13	1.10	0.273	-0.12	0.41
4	0.46	0.12	3.76	0.000	0.22	0.70
5	0.33	0.12	2.78	0.005	0.10	0.57
6	0.11	0.11	0.98	0.330	-0.11	0.33
7	0.79	0.12	6.74	0.000	0.56	1.03
8	0.21	0.12	1.74	0.083	-0.03	0.44
9	0.45	0.11	3.97	0.000	0.23	0.67
10	0.35	0.12	2.81	0.005	0.11	0.59
11	0.20	0.12	1.72	0.085	-0.03	0.43
12	0.07	0.12	0.60	0.547	-0.17	0.32
13	0.31	0.12	2.51	0.012	0.07	0.55
14	0.30	0.12	2.53	0.012	0.07	0.53
15	-0.26	0.13	-1.97	0.049	-0.51	0.00
16	-0.37	0.15	-2.49	0.013	-0.66	-0.08
17	-0.11	0.14	-0.79	0.432	-0.38	0.16
18	0.29	0.12	2.30	0.021	0.04	0.53
Age 65 and Over	-0.39	0.24	-1.66	0.097	-0.85	0.07
African American	1.11	0.29	3.89	0.000	0.55	1.67
Income below FPL	0.92	0.26	3.51	0.000	0.41	1.43
African American#Income below FPL	-1.19	0.47	-2.53	0.012	-2.11	-0.27
White	0.00	0.25	-0.02	0.987	-0.49	0.48
Asian	-0.06	0.33	-0.18	0.858	-0.70	0.58
American Indian	-0.60	0.38	-1.58	0.115	-1.35	0.15
Native Hawaiian	-6.97	2.42	-2.88	0.004	-11.73	-2.22
No High School Diploma	-0.79	0.25	-3.11	0.002	-1.28	-0.29
Unemployed	0.29	0.40	0.72	0.472	-0.50	1.08
Median Household Income	0.00	0.00	0.55	0.585	0.00	0.00
Uninsured	0.44	0.32	1.37	0.171	-0.19	1.08

Obs	ll(model)	df	AIC	BIC
54,105	-34326.46	38	68728.92	69067.07

Model 6 returns *population density* back in the model. Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.73	0.04	-18.44	0.000	-0.80	-0.65
Dialysis Stations	0.01	0.00	7.67	0.000	0.01	0.02
Offers In-Center HD	-0.80	0.08	-9.56	0.000	-0.96	-0.64
Offers In-Center PD	0.27	0.03	8.34	0.000	0.20	0.33
Network						
2	0.59	0.13	4.65	0.000	0.34	0.83
3	0.15	0.13	1.14	0.254	-0.11	0.42
4	0.45	0.12	3.70	0.000	0.21	0.69
5	0.35	0.12	2.91	0.004	0.11	0.58
6	0.15	0.11	1.28	0.200	-0.08	0.37
7	0.80	0.12	6.82	0.000	0.57	1.03
8	0.24	0.12	1.97	0.049	0.00	0.47
9	0.46	0.11	4.09	0.000	0.24	0.68
10	0.35	0.12	2.84	0.005	0.11	0.59
11	0.21	0.12	1.81	0.070	-0.02	0.44
12	0.09	0.12	0.72	0.470	-0.15	0.33
13	0.34	0.12	2.73	0.006	0.10	0.58
14	0.33	0.12	2.77	0.006	0.10	0.56
15	-0.24	0.13	-1.85	0.064	-0.50	0.01
16	-0.36	0.15	-2.42	0.015	-0.65	-0.07
17	-0.09	0.14	-0.66	0.511	-0.36	0.18
18	0.30	0.12	2.38	0.017	0.05	0.54
Age 65 and Over	-0.35	0.24	-1.47	0.140	-0.81	0.11
African American	1.22	0.29	4.27	0.000	0.66	1.78
Income below FPL	0.85	0.26	3.25	0.001	0.34	1.37
African American#Income below FPL	-1.13	0.47	-2.41	0.016	-2.05	-0.21
Population Density	0.00	0.00	4.35	0.000	0.00	0.00
White	0.16	0.25	0.63	0.530	-0.33	0.64
Asian	-0.04	0.33	-0.12	0.902	-0.68	0.60
American Indian	-0.40	0.38	-1.05	0.293	-1.15	0.35
Native Hawaiian	-6.60	2.43	-2.72	0.007	-11.36	-1.85
No High School Diploma	-0.78	0.25	-3.09	0.002	-1.28	-0.28
Unemployed	0.35	0.40	0.86	0.388	-0.44	1.13
Median Household Income	0.00	0.00	0.32	0.748	0.00	0.00
Uninsured	0.37	0.32	1.14	0.254	-0.27	1.01

Obs	**ll(model)**	**df**	**AIC**	**BIC**
54,105	-34317.13	39	68712.26	69059.31

Model 7 removes the variables *Asian, American Indian,* and *White.* Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf. Interval]**	
Chain	-0.72	0.04	-18.36	0.000	-0.80	-0.64
Dialysis Stations	0.01	0.00	7.63	0.000	0.01	0.02
Offers In-Center HD	-0.79	0.08	-9.52	0.000	-0.96	-0.63
Offers In-Center PD	0.27	0.03	8.40	0.000	0.20	0.33
Network						
2	0.58	0.13	4.62	0.000	0.33	0.83
3	0.15	0.13	1.14	0.253	-0.11	0.42
4	0.45	0.12	3.74	0.000	0.22	0.69
5	0.35	0.12	2.94	0.003	0.12	0.58
6	0.16	0.11	1.37	0.172	-0.07	0.38
7	0.82	0.12	6.94	0.000	0.59	1.05
8	0.25	0.12	2.09	0.036	0.02	0.48
9	0.47	0.11	4.19	0.000	0.25	0.69
10	0.35	0.12	2.85	0.004	0.11	0.59
11	0.20	0.12	1.76	0.078	-0.02	0.43
12	0.10	0.12	0.79	0.431	-0.15	0.34
13	0.34	0.12	2.72	0.006	0.09	0.58
14	0.34	0.12	2.90	0.004	0.11	0.57
15	-0.27	0.13	-2.06	0.039	-0.52	-0.01
16	-0.37	0.15	-2.49	0.013	-0.66	-0.08
17	-0.12	0.14	-0.91	0.365	-0.39	0.14
18	0.27	0.12	2.24	0.025	0.03	0.51
Age 65 and Over	-0.31	0.23	-1.35	0.177	-0.76	0.14
African American	1.07	0.14	7.59	0.000	0.79	1.35
Income below FPL	0.78	0.26	3.01	0.003	0.27	1.29
African American#Income below FPL	-1.02	0.46	-2.19	0.029	-1.93	-0.11
Population Density	0.00	0.00	4.31	0.000	0.00	0.00
Native Hawaiian	-7.08	2.38	-2.97	0.003	-11.75	-2.42
No High School Diploma	-0.78	0.24	-3.24	0.001	-1.25	-0.31
Unemployed	0.26	0.40	0.66	0.506	-0.51	1.04
Median Household Income	0.00	0.00	0.07	0.948	0.00	0.00
Uninsured	0.26	0.32	0.80	0.423	-0.37	0.88

Obs	**ll(model)**	**df**	**AIC**	**BIC**
54,105	-34319.27	36	68710.53	69030.88

Model 8 removes the variable *median household income*. Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.04	-18.390	0.00	-0.80	-0.64
Dialysis Stations	0.01	0.00	7.640	0.00	0.01	0.02
Offers In-Center HD	-0.79	0.08	-9.480	0.00	-0.95	-0.63
Offers In-Center PD	0.27	0.03	8.430	0.00	0.21	0.33
Network						
2	0.58	0.13	4.600	0.00	0.33	0.82
3	0.16	0.13	1.230	0.22	-0.10	0.43
4	0.46	0.12	3.790	0.00	0.22	0.70
5	0.35	0.12	2.980	0.00	0.12	0.59
6	0.16	0.11	1.430	0.15	-0.06	0.39
7	0.82	0.12	7.000	0.00	0.59	1.05
8	0.26	0.12	2.150	0.03	0.02	0.49
9	0.48	0.11	4.270	0.00	0.26	0.70
10	0.36	0.12	2.920	0.00	0.12	0.60
11	0.21	0.12	1.790	0.07	-0.02	0.43
12	0.10	0.12	0.830	0.41	-0.14	0.34
13	0.34	0.12	2.770	0.01	0.10	0.58
14	0.35	0.12	2.970	0.00	0.12	0.58
15	-0.26	0.13	-2.000	0.05	-0.51	-0.01
16	-0.36	0.15	-2.430	0.02	-0.65	-0.07
17	-0.11	0.13	-0.820	0.41	-0.37	0.15
18	0.28	0.12	2.330	0.02	0.04	0.52
Age 65 and Over	-0.31	0.22	-1.410	0.16	-0.74	0.12
African American	1.06	0.14	7.720	0.00	0.79	1.33
Income below FPL	0.75	0.22	3.490	0.00	0.33	1.18
African American#Income below FPL	-0.94	0.45	-2.080	0.04	-1.82	-0.05
Population Density	0.00	0.00	4.410	0.00	0.00	0.00
Native Hawaiian	-7.29	2.33	-3.130	0.00	-11.86	-2.72
No High School Diploma	-0.77	0.24	-3.270	0.00	-1.23	-0.31
Unemployed	0.15	0.39	0.390	0.70	-0.61	0.91
Uninsured	0.24	0.31	0.780	0.44	-0.37	0.85

Obs	**ll(model)**	**df**	**AIC**	**BIC**
54,164	-34348.43	35	68766.86	69078.35

Model 9 removes the variable *unemployed.* Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.04	-18.38	0.000	-0.80	-0.64
Dialysis Stations	0.01	0.00	7.64	0.000	0.01	0.02
Offers In-Center HD	-0.79	0.08	-9.47	0.000	-0.95	-0.63
Offers In-Center PD	0.27	0.03	8.42	0.000	0.21	0.33
Network						
2	0.58	0.13	4.59	0.000	0.33	0.82
3	0.17	0.13	1.25	0.212	-0.09	0.43
4	0.46	0.12	3.78	0.000	0.22	0.70
5	0.35	0.12	2.96	0.003	0.12	0.59
6	0.16	0.11	1.41	0.159	-0.06	0.38
7	0.82	0.12	6.99	0.000	0.59	1.05
8	0.25	0.12	2.14	0.033	0.02	0.49
9	0.47	0.11	4.25	0.000	0.26	0.69
10	0.36	0.12	2.92	0.004	0.12	0.60
11	0.21	0.12	1.79	0.074	-0.02	0.43
12	0.10	0.12	0.80	0.422	-0.14	0.34
13	0.34	0.12	2.75	0.006	0.10	0.58
14	0.35	0.12	2.95	0.003	0.12	0.58
15	-0.26	0.13	-2.01	0.045	-0.51	-0.01
16	-0.36	0.15	-2.43	0.015	-0.65	-0.07
17	-0.11	0.13	-0.81	0.416	-0.37	0.15
18	0.28	0.12	2.33	0.020	0.05	0.52
Age 65 and Over	-0.31	0.22	-1.39	0.165	-0.74	0.13
African American	1.07	0.14	7.84	0.000	0.80	1.33
Income below FPL	0.78	0.21	3.80	0.000	0.38	1.18
African American#Income below FPL	-0.93	0.45	-2.07	0.039	-1.81	-0.05
Population Density	0.00	0.00	4.40	0.000	0.00	0.00
Native Hawaiian	-7.29	2.33	-3.13	0.002	-11.86	-2.72
No High School Diploma	-0.76	0.23	-3.26	0.001	-1.22	-0.30
Uninsured	0.25	0.31	0.79	0.427	-0.36	0.86

Obs	ll(model)	df	AIC	BIC
54,164	-34348.5	34	68765.01	69067.6

Model 10 removes the variable *uninsured*. Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.04	-18.38	0.000	-0.80	-0.64
Dialysis Stations	0.01	0.00	7.65	0.000	0.01	0.02
Offers In-Center HD	-0.79	0.08	-9.47	0.000	-0.95	-0.63
Offers In-Center PD	0.27	0.03	8.44	0.000	0.21	0.33
Network						
2	0.58	0.13	4.60	0.000	0.33	0.82
3	0.17	0.13	1.28	0.200	-0.09	0.43
4	0.46	0.12	3.81	0.000	0.22	0.70
5	0.36	0.12	3.03	0.002	0.13	0.59
6	0.18	0.11	1.58	0.113	-0.04	0.39
7	0.84	0.11	7.39	0.000	0.62	1.06
8	0.27	0.12	2.27	0.023	0.04	0.50
9	0.48	0.11	4.32	0.000	0.26	0.70
10	0.36	0.12	2.96	0.003	0.12	0.61
11	0.21	0.12	1.83	0.067	-0.02	0.44
12	0.11	0.12	0.89	0.373	-0.13	0.35
13	0.35	0.12	2.90	0.004	0.11	0.59
14	0.37	0.11	3.29	0.001	0.15	0.59
15	-0.24	0.13	-1.91	0.056	-0.50	0.01
16	-0.35	0.15	-2.38	0.018	-0.64	-0.06
17	-0.11	0.13	-0.81	0.419	-0.37	0.15
18	0.29	0.12	2.37	0.018	0.05	0.52
Age 65 and Over	-0.34	0.22	-1.59	0.112	-0.76	0.08
African American	1.08	0.14	7.95	0.000	0.81	1.34
Income below FPL	0.80	0.20	3.90	0.000	0.40	1.20
African American#Income below FPL	-0.97	0.45	-2.16	0.031	-1.84	-0.09
Population Density	0.00	0.00	4.43	0.000	0.00	0.00
Native Hawaiian	-7.30	2.33	-3.13	0.002	-11.87	-2.73
No High School Diploma	-0.68	0.21	-3.27	0.001	-1.08	-0.27

Obs	ll(model)	df	AIC	BIC
54,171	-34352.61	33	68771.22	69064.92

Model 11 removes the variable *Age 65 and over*. Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.04	-18.25	0.00	-0.79	-0.64
Dialysis Stations	0.02	0.00	8.28	0.00	0.01	0.02
Offers In-Center HD	-0.81	0.08	-9.67	0.00	-0.97	-0.64
Offers In-Center PD	0.26	0.03	8.18	0.00	0.20	0.32
African American#Income Below FPL	2.20	0.20	10.83	0.00	1.80	2.60
Population Density	0.00	0.00	5.32	0.00	0.00	0.00
Native_Hawaiian	-7.20	2.32	-3.10	0.00	-11.74	-2.65
No HS Diploma	-0.41	0.18	-2.26	0.02	-0.77	-0.05
Network						
2	0.58	0.13	4.61	0.00	0.33	0.83
3	0.22	0.13	1.65	0.10	-0.04	0.48
4	0.48	0.12	3.97	0.00	0.24	0.72
5	0.50	0.12	4.27	0.00	0.27	0.73
6	0.28	0.11	2.55	0.01	0.07	0.50
7	0.87	0.11	7.61	0.00	0.64	1.09
8	0.34	0.12	2.90	0.00	0.11	0.57
9	0.51	0.11	4.52	0.00	0.29	0.72
10	0.40	0.12	3.23	0.00	0.16	0.64
11	0.23	0.12	1.98	0.05	0.00	0.46
12	0.13	0.12	1.09	0.28	-0.11	0.38
13	0.43	0.12	3.51	0.00	0.19	0.67
14	0.41	0.11	3.66	0.00	0.19	0.64
15	-0.25	0.13	-1.92	0.06	-0.50	0.00
16	-0.35	0.15	-2.37	0.02	-0.64	-0.06
17	-0.13	0.13	-0.97	0.33	-0.39	0.13
18	0.27	0.12	2.25	0.03	0.03	0.51

Obs	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
54,171	.	-34388.99	30	68837.98	69104.98

Model 12 puts the variable *uninsured* put back in the model Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.04	-18.24	0.000	-0.79	-0.64
Dialysis Stations	0.02	0.00	8.25	0.000	0.01	0.02
Offers In-Center HD	-0.81	0.08	-9.67	0.000	-0.97	-0.65
Offers In-Center PD	0.26	0.03	8.14	0.000	0.20	0.32
Uninsured	0.68	0.30	2.25	0.024	0.09	1.27
African American#Income Below FPL	2.20	0.20	10.81	0.000	1.80	2.59
Population Density	0.00	0.00	5.13	0.000	0.00	0.00
Native Hawaiian	-7.21	2.32	-3.10	0.002	-11.75	-2.66
No HS Diploma	-0.68	0.22	-3.12	0.002	-1.11	-0.25
Network						
2	0.58	0.13	4.63	0.000	0.34	0.83
3	0.21	0.13	1.55	0.122	-0.06	0.47
4	0.47	0.12	3.88	0.000	0.23	0.71
5	0.48	0.12	4.06	0.000	0.25	0.71
6	0.23	0.11	2.07	0.039	0.01	0.46
7	0.81	0.12	6.93	0.000	0.58	1.04
8	0.30	0.12	2.55	0.011	0.07	0.54
9	0.49	0.11	4.34	0.000	0.27	0.71
10	0.39	0.12	3.12	0.002	0.14	0.63
11	0.21	0.12	1.85	0.064	-0.01	0.44
12	0.10	0.12	0.84	0.402	-0.14	0.35
13	0.38	0.12	3.12	0.002	0.14	0.63
14	0.34	0.12	2.88	0.004	0.11	0.57
15	-0.29	0.13	-2.23	0.026	-0.55	-0.04
16	-0.38	0.15	-2.57	0.010	-0.67	-0.09
17	-0.13	0.13	-0.99	0.324	-0.40	0.13
18	0.26	0.12	2.15	0.031	0.02	0.50

Obs	ll(null)	ll(model)	df	AIC	BIC
54,164	.	-34382.64	31	68827.28	69103.18

Model 13 places the variable *unemployed* back into the model Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression						
Penalty	**Coef.**	**Std. Err.**	**z**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.04	-18.25	0.000	-0.79	-0.64
Dialysis Stations	0.02	0.00	8.24	0.000	0.01	0.02
Offers In-Center HD	-0.81	0.08	-9.70	0.000	-0.98	-0.65
Offers In-Center PD	0.26	0.03	8.16	0.000	0.20	0.32
Uninsured	0.65	0.30	2.14	0.032	0.06	1.24
African American#Income Below FPL	2.03	0.23	8.87	0.000	1.58	2.48
Population Density	0.00	0.00	5.19	0.000	0.00	0.00
Native Hawaiian	-7.21	2.32	-3.10	0.002	-11.76	-2.65
No HS Diploma	-0.74	0.22	-3.36	0.001	-1.18	-0.31
Network						
2	0.59	0.13	4.65	0.000	0.34	0.83
3	0.20	0.13	1.46	0.145	-0.07	0.46
4	0.48	0.12	3.92	0.000	0.24	0.72
5	0.49	0.12	4.14	0.000	0.26	0.72
6	0.24	0.11	2.15	0.031	0.02	0.47
7	0.82	0.12	6.99	0.000	0.59	1.05
8	0.31	0.12	2.62	0.009	0.08	0.55
9	0.49	0.11	4.38	0.000	0.27	0.71
10	0.39	0.12	3.11	0.002	0.14	0.63
11	0.22	0.12	1.87	0.061	-0.01	0.44
12	0.12	0.12	0.94	0.347	-0.13	0.36
13	0.40	0.12	3.23	0.001	0.16	0.64
14	0.36	0.12	3.00	0.003	0.12	0.59
15	-0.29	0.13	-2.22	0.026	-0.54	-0.03
16	-0.38	0.15	-2.56	0.010	-0.67	-0.09
17	-0.13	0.13	-0.99	0.323	-0.40	0.13
18	0.26	0.12	2.16	0.031	0.02	0.50
Unemployed	0.60	0.37	1.61	0.108	-0.13	1.32

Obs	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
54,164	.	-34381.36	32	68826.71	69111.51

Model 14 removes the variable *unemployed* from the model. Akaike's information criterion and Bayesian information criterion, which are post estimation reports and statistics, are followed by the model output. These reports compare the current model to the previous model and are based on the log-likelihood function.

Random-Effects Ordered Logistic Regression

Penalty	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Chain	-0.72	0.04	-18.24	0.00	-0.79	-0.64
Dialysis Stations	0.02	0.00	8.25	0.00	0.01	0.02
Offers In-Center HD	-0.81	0.08	-9.67	0.00	-0.97	-0.65
Offers In-Center PD	0.26	0.03	8.14	0.00	0.20	0.32
Uninsured	0.68	0.30	2.25	0.02	0.09	1.27
African American#Income below FPL	2.20	0.20	10.81	0.00	1.80	2.59
Population Density	0.00	0.00	5.13	0.00	0.00	0.00
Native Hawaiian	-7.21	2.32	-3.10	0.00	-11.75	-2.66
No HS Diploma	-0.68	0.22	-3.12	0.00	-1.11	-0.25
Network						
2	0.58	0.13	4.63	0.00	0.34	0.83
3	0.21	0.13	1.55	0.12	-0.06	0.47
4	0.47	0.12	3.88	0.00	0.23	0.71
5	0.48	0.12	4.06	0.00	0.25	0.71
6	0.23	0.11	2.07	0.04	0.01	0.46
7	0.81	0.12	6.93	0.00	0.58	1.04
8	0.30	0.12	2.55	0.01	0.07	0.54
9	0.49	0.11	4.34	0.00	0.27	0.71
10	0.39	0.12	3.12	0.00	0.14	0.63
11	0.21	0.12	1.85	0.06	-0.01	0.44
12	0.10	0.12	0.84	0.40	-0.14	0.35
13	0.38	0.12	3.12	0.00	0.14	0.63
14	0.34	0.12	2.88	0.00	0.11	0.57
15	-0.29	0.13	-2.23	0.03	-0.55	-0.04
16	-0.38	0.15	-2.57	0.01	-0.67	-0.09
17	-0.13	0.13	-0.99	0.32	-0.40	0.13
18	0.26	0.12	2.15	0.03	0.02	0.50

Obs	ll(null)	ll(model)	df	AIC	BIC
54,164	.	-34382.64	31	68827.28	69103.18

Final Model

Random-Effects Ordered Logistic Regression		Number of obs	=	54,164
Group Variable: providernumber		Number of groups	=	8,090
Random effects u_i ~ Gaussian		Obs per group:		
		Min	=	1
		Avg	=	6.7
		Max	=	9
Integration Method: mvaghermite		Integration pts.	=	12
		Wald chi2(25)	=	1118.85
Log Likelihood = -34388.66		Prob > chi2	=	0

Penalty	**Coef.**	**P>|z|**	**[95% Conf.**	**Interval]**
Chain	-0.72	0.001	-0.80	-0.64
Dialysis Station	0.02	0.001	0.01	0.02
Offers In-Center HD	-0.81	0.001	-0.97	-0.64
Offers In-Center PD	0.26	0.001	0.20	0.32
Uninsured	0.68	0.02	0.09	1.27
African American*Income Below FPL	2.20	0.001	1.80	2.60
Population Density	9.12E-06	0.001	5.62E-06	1.26E-05
No High School	-0.67	0.002	-1.10	-0.24
Network				
2	0.58	0.001	0.34	0.83
3	0.21	0.12	-0.05	0.47
4	0.47	0.001	0.24	0.71
5	0.48	0.001	0.25	0.71
6	0.23	0.04	0.01	0.46
7	0.81	0.001	0.58	1.04
8	0.30	0.01	0.07	0.54
9	0.49	0.001	0.27	0.71
10	0.39	0.002	0.14	0.63
11	0.21	0.06	-0.01	0.44
12	0.10	0.42	-0.14	0.34
13	0.38	0.002	0.14	0.63
14	0.34	0.004	0.11	0.57
15	-0.31	0.02	-0.56	-0.05
16	-0.43	0.004	-0.72	-0.14
17	-0.22	0.10	-0.48	0.04
18	0.24	0.05	0.00	0.48
/cut1	1.16		0.90	1.42
/cut2	2.30		2.03	2.56
/cut3	3.23		2.97	3.50
/cut4	4.46		4.18	4.74
/sigma2_u	0.71		0.64	0.78
LR test vs. ologit model: chibar2(01) = 933.13	Prob >= chibar2 = 0.0000			

Pairwise Correlation

	African American	Native Hawaiian	No HS Diploma	Unemployed	Income below FPL	Uninsured	Median Household Income
African American	1						
Native Hawaiian	-0.06	1					
No HS Diploma	0.22	0.00	1				
Unemployed	0.43	-0.02	0.39	1			
Income below FPL	0.41	-0.03	0.57	0.59	1		
Uninsured	0.21	-0.03	0.60	0.25	0.41	1	
Median Household Income	-0.33	0.03	-0.53	-0.45	-0.72	-0.45	1

Variance Inflation Factor

Variable	**VIF**	**1/VIF**
Income below FPL	2.06	0.49
No HS Diploma	1.98	0.51
Unemployed	1.69	0.59
Uninsured	1.66	0.60
African American	1.32	0.76
65 and over	1.14	0.88
Native Hawaiian	1.01	0.99
Mean VIF	1.55	

APPENDIX B

Chapter 5 Missing Data Regression Model

The logistic regression models to examine the missing data patterns. The below tables assess whether any of the variables predict missingness. Variables associated with missingness and are statistically significant are identified as missing at random instead of missing completely at random.

Missing Penalty	**Coef.**	**P>z**	**[95% Conf.Interval]**	
Year	-0.11	0.59	-0.49	0.28
Sex	-0.11	0.84	-1.17	0.95
Race	0.14	0.82	-1.09	1.37
Hispanic	-1.79	0.00	-2.90	-0.69
Access Type	-0.71	0.16	-1.69	0.27
Patient Informed	1.37	0.03	0.14	2.59
Transplant	1.22	0.08	-0.12	2.57
Number of Diagnoses	-0.01	0.86	-0.10	0.09
Age Categories	0.45	0.33	-0.45	1.34
Place of Death	-0.01	0.98	-0.53	0.52
RRT Discontinued	0.97	0.22	-0.58	2.52

Missing RRT Discontinued	**Coef.**	**P>z**	**[95% Conf.Interval]**	
Sex	-0.59	0.10	-1.30	0.12
Race	-0.04	0.88	-0.49	0.42
Penalty	-0.30	0.54	-1.28	0.67
Access Type	-0.47	0.04	-0.91	-0.02
Number of Diagnoses	-0.09	0.003	-0.16	-0.03

Missing Age Categories	**Coef.**	**P>z**	**[95% Conf.Interval]**	
Sex	-0.42	0.18	-1.04	0.20
Race	0.40	0.07	-0.03	0.82
Access Type	0.55	0.05	-0.01	1.10

Missing Employment Status	**Coef.**	**P>z**	**[95% Conf.Interval]**	
Sex	-1.27	0.09	-2.75	0.21
Race	-0.77	0.26	-2.10	0.56
HD Hours	-0.62	0.34	-1.89	0.65
Number of Diagnoses	0.07	0.27	-0.06	0.20
Hospice	2.38	0.03	0.27	4.49
Place of Death	0.35	0.31	-0.32	1.02
Penalty	-3.12	0.14	-7.27	1.03
Hispanic	0.02	0.98	-1.54	1.58

Missing Race	**Coef.**	**P>z**	**[95% Conf.Interval]**	
Sex	-0.14	0.001	-0.15	-0.12
Age Categories	-0.69	0.001	-0.70	-0.68

Missing Year	**Coef.**	**P>z**	**[95% Conf.Interval]**	
Sex	-0.24	0.74	-1.67	1.19
Race	0.75	0.10	-0.16	1.66
Modality Type	1.09	0.003	0.36	1.82

Chapter 5 Descriptive Statistics

Age Category	Race: White	AA	Other	Total
1 (0-44)	82,957	51,928	10,421	145,306
2 (45-64)	260,137	114,190	25,001	399,328
3 (65-74)	145,492	42,897	11,959	200,348
4 (75+)	103,616	24,555	8,522	136,693
Total	592,202	233,570	55,903	881,675
Pearson chi2(6) = 1.6e+04 Pr = 0.000				

Age Category	Transplant: 0	1	Total
1	126	31,055	31,181
2	51	48,002	48,053
3	16	8,997	9,013
4	4	4,985	4,989
Total	197	93,039	93,236
Pearson chi2(3) = 84.7302 Pr = 0.000			

Age Category	Place of Death: Hospital	Dialysis Unit	Home	Nursing Home	Total
1 (0-44)	1,929	6	942	184	3,061
2 (45-64)	1,000	3	458	140	1,601
3 (65-74)	64	0	25	9	98
4 (75+)	248	0	115	9	372
Total	3,241	9	1,540	342	5,132
Pearson chi2(9) = 27.5978 Pr = 0.001					

Age Category	HD Sessions per Week: 0	1	2	3	4	5	6	7	Total
1	1	241	863	106,326	530	623	154	15	108,753
2	0	681	2,670	309,514	1,224	1,635	187	21	315,932
3	0	386	2,071	164,566	616	833	68	7	168,547
4	0	250	2,304	113,610	412	517	30	5	117,128
Total	1	1,558	7,908	694,016	2,782	3,608	439	48	710,360
Pearson chi2(21) = 1.3e+03 Pr = 0.000									

hispanic	RECODE of age 1	2	3	4	Total
0	2,223	902	52	278	3,455
1	1,634	4,842	1,687	980	9,143
2	5,199	23,413	9,986	4,800	43,398
9	537	4,490	2,767	2,339	10,133
Total	9,593	33,647	14,492	8,397	66,129

Pearson chi2(9) = 9.3e+03 Pr = 0.000

Chapter 5 Binary Logistic Regression Models and Goodness of Fit Tests

Binary logistic regression output for the dependent variable hospice.

Logistic Regression		Number of obs	=	3952
		LR chi2(14)	=	521.94
		Prob > chi2	=	0.00
Log Likelihood = -1859.3656		Pseudo R2	=	0.12

Hospice	**Odds Ratio**	**P>z**	**[95% Conf.**	**Interval]**
Age Categories				
2	1.67	0.001	1.40	1.98
3	1.70	0.08	0.95	3.06
4	0.72	0.07	0.51	1.02
Year				
2013	1.02	0.86	0.81	1.29
2014	0.97	0.81	0.76	1.24
2015	1.03	0.82	0.80	1.33
2016	1.12	0.44	0.84	1.48
2017	1.19	0.34	0.83	1.72
2018	1.59	0.33	0.63	4.06
Sex	1.19	0.04	1.01	1.40
Race				
2	0.57	0.001	0.47	0.70
3	0.67	0.06	0.45	1.01
Patient Informed	0.73	0.04	0.54	0.99
Place of Death	5.22	0.001	4.44	6.14
_cons	0.14	0.001	0.09	0.20

Goodness of Fit Test for Hospice Binary Logistic Regression

	TRUE		
Classified	D	~D	Total
+	**171**	**144**	**315**
-	**729**	**2908**	**3637**
Total	**900**	**3052**	**3952**

Classified + if predicted Pr(D)>= .5

True D defined as Hospice != 0

Sensitivity	Pr(+ D)	**19.00%**
Specificity	Pr(-~D)	**95.28%**
Positive predictive value	Pr(D +)	**54.29%**
Negative predictive value	Pr(~D -)	**79.96%**
False + rate for true ~D	Pr(+~D)	**4.72%**
False - rate for true D	Pr(- D)	**81.00%**
False + rate for classified +	Pr(~D +)	**45.71%**
False - rate for classified -	Pr(D -)	**20.04%**
Correctly classified		**77.91%**

Binary logistic regression output for the dependent variable hospice.

Logistic Regression	Number of obs	=	1,197		
	LR chi2(22)	=	42.62		
	Prob > chi2	=	0.005		
Log Likelihood = -631.01	Pseudo R2	=	0.032		
Hospice	**Odds Ratio**	**P>z**	**[95% Conf. Interval]**		
Year					
2013	0.81	0.28	0.54	1.19	
2014	0.95	0.80	0.63	1.43	
2015	0.92	0.72	0.60	1.43	
2016	0.74	0.22	0.46	1.19	
Sex	1.41	0.02	1.06	1.86	
Race					
2	0.63	0.01	0.45	0.89	
3	0.48	0.07	0.22	1.07	
Hispanic	0.72	0.14	0.46	1.12	
Employment Status	1.07	0.42	0.90	1.28	
hemosessions	1.49	0.18	0.83	2.66	
hemohours	0.89	0.42	0.66	1.18	
Access Type	1.00	0.98	0.85	1.18	
Hemoglobin	0.97	0.44	0.89	1.05	
Patient Informed	0.94	0.80	0.59	1.50	
Transplant	0.77	0.28	0.47	1.24	
Modality Type	0.82	0.49	0.46	1.45	
Number of Diagnoses	1.03	0.06	1.00	1.05	
Number of Surgeries	1.04	0.13	0.99	1.09	
ICU Days	0.96	0.03	0.93	1.00	
Age Categories					
2	1.47	0.01	1.09	2.00	
3	0.89	0.86	0.24	3.25	
4	0.73	0.35	0.37	1.41	

Goodness of Fit Test for Hospice Binary Logistic Regression

	TRUE		
Classified	D	~D	Total
+	**3**	**1**	**4**
-	**278**	**916**	**1194**
Total	**281**	**917**	**1198**

Classified + if predicted Pr(D) >= .5

True D defined as Hospice != 0

Sensitivity	Pr(+ D)	**1.07%**
Specificity	Pr(-~D)	**99.89%**
Positive predictive value	Pr(D +)	**75.00%**
Negative predictive value	Pr(~D -)	**76.72%**
False + rate for true ~D	Pr(+~D)	**0.11%**
False - rate for true D	Pr(- D)	**98.93%**
False + rate for classified +	Pr(~D +)	**25.00%**
False - rate for classified -	Pr(D -)	**23.28%**
Correctly classified		**76.71%**

Binary logistic regression output for the dependent variable hospice

Logistic Regression		Number of obs	=	1,281	
		LR chi2(18)	=	43.51	
		Prob > chi2	=	0.0007	
Log Likelihood = -675.48		Pseudo R2	=	0.031	
Hospice		**Odds Ratio**	**P>z**	**[95% Conf. Interval]**	
Year					
	2013	0.94	0.76	0.65	1.38
	2014	0.96	0.84	0.64	1.43
	2015	0.96	0.84	0.63	1.46
	2016	0.82	0.41	0.52	1.31
Sex		1.37	0.02	1.05	1.79
Race					
	2	0.61	0.00	0.44	0.86
	3	0.46	0.06	0.21	1.02
Hispanic		0.72	0.12	0.47	1.09
Employment Status		1.09	0.32	0.92	1.29
Hemoglobin		0.99	0.75	0.91	1.07
Transplant		0.75	0.24	0.47	1.20
Modality Type		0.92	0.57	0.70	1.21
Number of Diagnoses		1.03	0.05	1.00	1.05
Number of Surgeries		1.03	0.30	0.98	1.08
ICU Days		0.96	0.03	0.93	1.00
Age Categories					
	2	1.54	0.00	1.15	2.06
	3	0.78	0.70	0.22	2.77
	4	0.68	0.24	0.35	1.30

Goodness of Fit Test for Hospice Binary Logistic Regression

	TRUE		
Classified	D	~D	Total
+	**2**	**1**	**3**
-	**298**	**980**	**1278**
Total	**300**	**981**	**1281**

Classified + if predicted Pr(D) >= .5
True D defined as Hospice != 0

Sensitivity	Pr(+ D)	**0.67%**
Specificity	Pr(-~D)	**99.90%**
Positive predictive value	Pr(D +)	**66.67%**
Negative predictive value	Pr(~D -)	**76.68%**
False + rate for true ~D	Pr(+~D)	**0.10%**
False - rate for true D	Pr(- D)	**99.33%**
False + rate for classified +	Pr(~D +)	**33.33%**
False - rate for classified -	Pr(D -)	**23.32%**
Correctly classified		**76.66%**

Binary Logistic Regression Output for the Dependent Variable RRTdcd

Logistic Regression	Number of obs	=	1,992	
	LR chi2(19)	=	967.79	
	Prob > chi2	=	0	
Log Likelihood = -686.96	Pseudo R2	=	0.41	
RRT Discontinued Prior to Death	**Odds Ratio**	**P>z**	**[95% Conf. Interval]**	
Employment Status	1.11	0.25	0.93	1.32
Access Type	0.88	0.12	0.75	1.04
Modality Type	1.43	0.17	0.86	2.35
ICU Days	0.99	0.73	0.97	1.03
Hospice	45.70	0.00	32.91	63.47
Year				
2013	1.42	0.09	0.95	2.11
2014	1.18	0.45	0.77	1.79
2015	1.37	0.16	0.88	2.13
2016	1.18	0.52	0.71	1.94
Sex	1.29	0.09	0.96	1.71
Race				
2	0.53	0.00	0.37	0.75
3	0.86	0.67	0.43	1.71
Hispanic	0.71	0.12	0.46	1.10
Age Categories				
2	1.00	0.98	0.72	1.37
3	1.88	0.26	0.63	5.59
4	1.11	0.72	0.63	1.97
Patient Informed	0.83	0.47	0.50	1.37
Place of Death	1.04	0.57	0.91	1.19
Number of Diagnoses	0.99	0.30	0.96	1.01

Goodness of Fit Test for RRTdcd Binary Logistic Regression

	TRUE		
Classified	D	~D	Total
+	**397**	**78**	**475**
-	**150**	**1367**	**1517**
Total	**547**	**1445**	**1992**

Classified + if predicted Pr(D) >= .5

True D defined as RRT Discontinued Prior to Death != 0

Sensitivity	Pr(+ D)	**72.58%**
Specificity	Pr(-~D)	**94.60%**
Positive predictive value	Pr(D +)	**83.58%**
Negative predictive value	Pr(~D -)	**90.11%**
False + rate for true ~D	Pr(+~D)	**5.40%**
False - rate for true D	Pr(- D)	**27.42%**
False + rate for classified +	Pr(~D +)	**16.42%**
False - rate for classified -	Pr(D -)	**9.89%**
Correctly classified		**88.55%**

Binary Logistic Regression Output for the Dependent Variable RRTdcd

Logistic Regression	Number of obs	=	3,721			
	LR chi2(13)	=	117.6			
	Prob > chi2	=	0			
Log Likelihood = -2043.21	Pseudo R2	=	0.03			
RRTdcd	**Odds Ratio**	**Std. Err.**	**z**	**P>z**	**[95% Conf. Interval]**	
Year						
2013	0.93	0.10	-0.61	0.54	0.75	1.16
2014	0.98	0.11	-0.15	0.88	0.78	1.24
2015	1.11	0.14	0.83	0.41	0.87	1.41
2016	0.93	0.13	-0.5	0.62	0.71	1.23
2017	1.28	0.22	1.44	0.15	0.92	1.78
2018	1.53	0.62	1.06	0.29	0.69	3.37
Sex	1.33	0.10	3.73	0	1.15	1.55
Race						
2	0.45	0.05	-7.78	0	0.36	0.55
3	0.56	0.11	-2.97	0.003	0.38	0.82
Hispanic	0.59	0.07	-4.2	0	0.46	0.75
Age Categories						
2	1.44	0.13	4.13	0	1.21	1.72
3	1.07	0.34	0.22	0.83	0.58	1.99
4	0.81	0.12	-1.45	0.15	0.61	1.08

Goodness of Fit Test for RRTdcd Binary Logistic Regression

	TRUE		
Classified	D	~D	Total
+	**2**	**0**	**2**
-	**937**	**2782**	**3719**
Total	**939**	**2782**	**3721**

Classified + if predicted Pr(D) >= .5
True D defined as RRTdcd != 0

Sensitivity	Pr(+ D)	**0.21%**
Specificity	Pr(-~D)	**100.00%**
Positive predictive value	Pr(D +)	**100.00%**
Negative predictive value	Pr(~D -)	**74.81%**
False + rate for true ~D	Pr(+~D)	**0.00%**
False - rate for true D	Pr(- D)	**99.79%**
False + rate for classified +	Pr(~D +)	**0.00%**
False - rate for classified -	Pr(D -)	**25.19%**
Correctly classified		**74.82%**

Negative Binomial Regression for ICU Days

Negative Binomial Regression		Number of obs	=	1197.00
		LR chi2(18)	=	160.42
Dispersion = Mean		Prob > chi2	=	0.001
Log likelihood = -1895.19		Pseudo R2	=	0.041

ICU Days	Coef.	P>z	[95% Conf.	Interval]
Year	-0.04	0.38	-0.14	0.05
Sex	0.07	0.62	-0.20	0.34
Race	0.16	0.20	-0.08	0.40
Hispanic	0.46	0.02	0.08	0.84
Employment Status	-0.01	0.87	-0.16	0.14
HD Sessions	0.01	0.99	-0.54	0.55
HD Hours	-0.02	0.88	-0.28	0.24
Access Type	0.13	0.11	-0.03	0.30
Hemoglobin	0.04	0.35	-0.04	0.12
Patient Informed	-0.25	0.28	-0.69	0.20
Transplant	-0.33	0.17	-0.79	0.14
Modality Type	0.22	0.35	-0.24	0.68
Number of Diagnoses	0.06	0.00	0.04	0.09
Number of Surgeries	0.20	0.00	0.15	0.25
Age Categories	-0.01	0.90	-0.17	0.15
Hospice	-0.35	0.09	-0.77	0.06
Place of Death	0.08	0.21	-0.04	0.21
RRT Discontinued prior to Death	-0.10	0.60	-0.48	0.28
LR test of alpha=0: chibar2(01) = 3300.35		Prob >= chibar2 = 0.000		

Model Selection Criterion for Negative Binomial Regression for ICU Days

Akaike's Information Criterion and Bayesian Information Criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
	1,197	-1975.40	-1895.20	20	3830.39	3932.14

Negative Binomial Regression for ICU Days

Negative Binomial Regression		Number of obs	=	1198.00
		LR chi2(16)	=	159.80
Dispersion = Mean		Prob > chi2	=	0.001
Log likelihood = -1895.97		Pseudo R2	=	0.040
ICU Days	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
Year	-0.04	0.38	-0.14	0.05
Sex	0.07	0.61	-0.20	0.34
Race	0.16	0.20	-0.08	0.40
Hispanic	0.45	0.02	0.07	0.84
Employment Status	-0.01	0.86	-0.16	0.14
Access Type	0.13	0.11	-0.03	0.30
Hemoglobin	0.04	0.34	-0.04	0.12
Patient Informed	-0.25	0.27	-0.69	0.20
Transplant	-0.33	0.17	-0.79	0.14
Modality Type	0.21	0.36	-0.24	0.67
Number of Diagnoses	0.06	0.00	0.04	0.09
Number of Surgeries	0.20	0.00	0.15	0.25
Age Categories	-0.01	0.89	-0.17	0.15
Hospice	-0.35	0.09	-0.76	0.06
Place of Death	0.08	0.21	-0.04	0.21
RRT Discontinued prior to Death	-0.10	0.61	-0.48	0.28
LR test of alpha=0: chibar2(01) = 3316.59 Prob >= chibar2 = 0.000				

Model Selection Criterion for Negative Binomial Regression for ICU Days

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	1,198	-1975.87	-1895.97	18	3827.93	3919.52

Negative Binomial Regression for ICU Days

Negative Binomial Regression		Number of obs	=	1198.00
		LR chi2(14)	=	157.98
Dispersion = Mean		Prob > chi2	=	0.001
Log likelihood = -1896.88		Pseudo R2	=	0.040

ICU Days	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
Year	-0.04	0.40	-0.14	0.06
Sex	0.06	0.68	-0.21	0.33
Race	0.14	0.25	-0.10	0.37
Hispanic	0.45	0.02	0.07	0.83
Employment Status	0.00	0.98	-0.15	0.15
Access Type	0.13	0.12	-0.03	0.29
Hemoglobin	0.04	0.30	-0.04	0.13
Patient Informed	-0.21	0.35	-0.65	0.23
Transplant	-0.34	0.15	-0.80	0.12
Modality Type	0.18	0.44	-0.27	0.63
Number of Diagnoses	0.07	0.00	0.04	0.09
Number of Surgeries	0.20	0.00	0.15	0.25
Age Categories	-0.01	0.88	-0.17	0.15
Hospice	-0.35	0.02	-0.65	-0.05
LR test of alpha=0: chibar2(01) = 3340.66 Prob >= chibar2 = 0.000				

Model Selection Criterion for Negative Binomial Regression for ICU Days

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	1,198	-1975.87	-1896.88	16	3825.76	3907.17

Negative Binomial Regression for ICU Days

Negative Binomial Regression		Number of obs	=	1198.00
		LR chi2(11)	=	156.70
Dispersion = Mean		Prob > chi2	=	0.001
Log likelihood = -1897.52		Pseudo R2	=	0.040

ICU Days	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
Sex	0.06	0.68	-0.21	0.33
Race	0.12	0.30	-0.11	0.36
Hispanic	0.44	0.03	0.06	0.82
Access Type	0.12	0.14	-0.04	0.29
Hemoglobin	0.04	0.29	-0.04	0.13
Patient Informed	-0.22	0.32	-0.66	0.22
Transplant	-0.33	0.16	-0.79	0.13
Number of Diagnoses	0.06	0.00	0.04	0.09
Number of Surgeries	0.20	0.00	0.15	0.25
Age Categories	-0.01	0.87	-0.17	0.15
Hospice	-0.36	0.02	-0.66	-0.06
LR test of alpha=0: chibar2(01) = 3384.20 Prob >= chibar2 = 0.000				

Model Selection Criterion for Negative Binomial Regression for ICU Days

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	1,198	-1975.87	-1897.52	13	3821.03	3887.18

Negative Binomial Regression for ICU Days

Negative Binomial Regression		Number of obs	=	1198.00
		LR chi2(9)	=	155.66
Dispersion = Mean		Prob > chi2	=	0.001
Log likelihood = -1898.03		Pseudo R2	=	0.039
ICU Days	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
Sex	0.07	0.62	-0.20	0.34
Race	0.12	0.32	-0.11	0.35
Hispanic	0.44	0.03	0.06	0.82
Access Type	0.13	0.13	-0.04	0.29
Hemoglobin	0.04	0.28	-0.04	0.13
Transplant	-0.32	0.17	-0.78	0.14
Number of Diagnoses	0.06	0.00	0.04	0.09
Number of Surgeries	0.20	0.00	0.15	0.25
Hospice	-0.37	0.02	-0.67	-0.07
LR test of alpha=0: chibar2(01) = 3423.13 Prob >= chibar2 = 0.000				

Model Selection Criterion for Negative Binomial Regression for ICU Days

Akaike's Information Criterion and Bayesian Information Criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
	1,198	-1975.87	-1898.04	11	3818.07	3874.04

Negative Binomial Regression for ICU Days

Negative Binomial Regression		Number of obs	=	1198.00
		LR chi2(8)	=	155.42
Dispersion = Mean		Prob > chi2	=	0.001
Log likelihood = -1898.16		Pseudo R2	=	0.039
ICU Days	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
Race	0.13	0.29	-0.11	0.36
Hispanic	0.44	0.02	0.06	0.82
Access Type	0.14	0.09	-0.02	0.29
Hemoglobin	0.04	0.30	-0.04	0.12
Transplant	-0.31	0.19	-0.77	0.15
Number of Diagnoses	0.07	0.00	0.04	0.09
Number of Surgeries	0.20	0.00	0.15	0.25
Hospice	-0.36	0.02	-0.66	-0.06
LR test of alpha=0: chibar2(01) = 3440.37		Prob >= chibar2 = 0.000		

Model Selection Criterion for Negative Binomial Regression for ICU Days

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	1,198	-1975.87	-1898.16	10	3816.31	3867.20

Negative Binomial Regression for ICU Days

Negative Binomial Regression		Number of obs	=	12856.00
		LR chi2(10)	=	1514.59
Dispersion = Mean		Prob > chi2	=	0.001
Log likelihood = -20434.68		Pseudo R2	=	0.036
ICU Days	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
Number of Diagnoses	0.04	0.001	0.03	0.05
Number of Surgeries	0.20	0.32	0.18	0.21
Age Category				
2	0.12	0.001	0.05	0.20
3	0.24	0.02	0.04	0.43
4	-0.22	0.01	-0.38	-0.06
Year				
2013	-0.02	0.74	-0.13	0.09
2014	-0.09	0.10	-0.20	0.02
2015	-0.04	0.44	-0.15	0.07
2016	-0.05	0.43	-0.17	0.07
Sex	0.03	0.38	-0.04	0.11
LR test of alpha=0: chibar2(01) = 3.1e+04 Prob >= chibar2 = 0.00				

Model Selection Criterion for Negative Binomial Regression for ICU Days

Akaike's information criterion and Bayesian information criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
.	12,856	-21191.98	-20434.68	12	40893.37	40982.9

Multinomial Logistic Regression for Place of Death

Multinomial Logistic Regression		Number of obs	=	4371
		LR chi2(27)	=	581.61
		Prob > chi2	=	0.00
Log Likelihood = -3412.78		Pseudo R2	=	0.08

Place of Death	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
1		(Base Outcome)		
2				
Year	-0.44	0.19	-1.11	0.22
Sex	-0.07	0.94	-1.81	1.67
Race	0.64	0.28	-0.51	1.79
Employment Status	-0.25	0.58	-1.12	0.63
Access Type	-0.33	0.45	-1.19	0.53
dialysistype	-11.03	1.00	-3773.77	3751.71
Age Categories	-0.58	0.41	-1.96	0.79
Hospice	2.99	0.001	1.25	4.73
RRT Discontinued Prior to Death	-15.29	0.98	-1474.39	1443.81
3				
Year	0.01	0.56	-0.03	0.06
Sex	-0.08	0.30	-0.22	0.07
Race	-0.18	0.01	-0.31	-0.05
Employment Status	-0.01	0.87	-0.09	0.07
Access Type	-0.11	0.01	-0.19	-0.03
dialysistype	-0.20	0.27	-0.56	0.16
Age Categories	-0.06	0.17	-0.14	0.02
Hospice	1.71	0.001	1.49	1.94
RRT Discontinued Prior to Death	-0.04	0.73	-0.26	0.18
4				
Year	0.11	0.003	0.04	0.18
Sex	0.11	0.36	-0.13	0.36
Race	-0.20	0.08	-0.43	0.03
Employment Status	0.33	0.001	0.17	0.49
Access Type	0.07	0.36	-0.08	0.21
dialysistype	-0.38	0.30	-1.10	0.34
Age Categories	-0.05	0.50	-0.20	0.10
Hospice	1.22	0.001	0.86	1.58
RRT Discontinued Prior to Death	0.44	0.01	0.09	0.80

Model Selection Criteria for Place of Death

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	4,371	-3703.58	-3412.775	30	6885.55	7077.032

Multinomial Logistic Regression for Access Type

	Multinomial Logistic Regression		Number of obs	=	2,376
			LR chi2(33)	=	82.32
			Prob > chi2	=	0.00
	Log Likelihood = -1776.21		Pseudo R2	=	0.02

	Access Type	Coef.	P>z	[95% Conf.	Interval]
1	Year	-0.01	0.76	-0.08	0.06
	Sex	-0.60	0.001	-0.81	-0.39
	Race	0.19	0.03	0.02	0.36
	Hispanic	-0.18	0.25	-0.49	0.13
	Employment Status	0.07	0.27	-0.05	0.19
	HD Sessions	-0.32	0.17	-0.77	0.14
	HD Hours	-0.21	0.04	-0.40	-0.01
	ICU Days	-0.05	0.001	-0.07	-0.02
	Age Categories				
	2	0.03	0.81	-0.19	0.25
	3	0.28	0.52	-0.58	1.14
	4	-0.15	0.48	-0.55	0.26
	_cons	23.42	0.75	-119.97	166.81
2	Year	0.03	0.70	-0.11	0.16
	Sex	0.03	0.88	-0.34	0.40
	Race	0.38	0.01	0.08	0.68
	Hispanic	0.11	0.69	-0.44	0.67
	Employment Status	-0.04	0.74	-0.26	0.18
	HD Sessions	-0.30	0.52	-1.20	0.60
	HD Hours	0.18	0.34	-0.18	0.54
	ICU Days	-0.003	0.87	-0.04	0.03
	Age Categories				
	2	0.11	0.57	-0.28	0.51
	3	-0.29	0.78	-2.32	1.75
	4	-1.15	0.06	-2.33	0.02
	_cons	-56.02	0.68	-325.19	213.15
3	(Base Outcome)				
4	Year	-0.05	0.85	-0.54	0.45
	Sex	-0.02	0.97	-1.37	1.32
	Race	-0.27	0.70	-1.67	1.12
	Hispanic	0.60	0.47	-1.02	2.22
	Employment Status	-0.16	0.67	-0.89	0.57
	HD Sessions	-0.24	0.86	-2.88	2.40
	HD Hours	-0.84	0.17	-2.04	0.35
	ICU Days	-0.04	0.66	-0.20	0.13
	Age Categories				
	2	-0.45	0.58	-2.06	1.15
	3	-12.65	0.99	-2726.13	2700.83
	4	-12.69	0.98	-1113.62	1088.24
	_cons	93.43	0.85	-897.33	1084.19

Model Selection Criteria for Access Type

Akaike's Information Criterion and Bayesian Information Criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
	2,376	-1817.368	-1776.208	36	3624.416	3832.25

Multinomial Logistic Regression for Access Type

	Multinomial Logistic Regression		Number of obs	=	2,376
			LR chi2(27)	=	78.49
			Prob > chi2	=	0.00
	Log Likelihood = -1778.12		Pseudo R2	=	0.02
	Access Type	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
1	Year	-0.01	0.73	-0.08	0.06
	Sex	-0.60	0.001	-0.81	-0.40
	Race	0.19	0.03	0.02	0.36
	Hispanic	-0.18	0.25	-0.49	0.13
	HD Hours	-0.19	0.06	-0.39	0.004
	ICU Days	-0.05	0.001	-0.07	-0.02
	Age Categories				
	2	0.06	0.61	-0.16	0.27
	3	0.27	0.54	-0.59	1.13
	4	-0.17	0.41	-0.57	0.23
	_cons	25.38	0.73	-117.94	168.70
2	Year	0.03	0.70	-0.11	0.16
	Sex	0.04	0.84	-0.33	0.41
	Race	0.38	0.01	0.08	0.68
	Hispanic	0.12	0.67	-0.43	0.67
	HD Hours	0.19	0.31	-0.17	0.55
	ICU Days	-0.002	0.89	-0.04	0.03
	Age Categories				
	2	0.11	0.59	-0.28	0.50
	3	-0.28	0.79	-2.31	1.75
	4	-1.13	0.06	-2.30	0.04
	_cons	-56.71	0.68	-325.67	212.26
3	(Base Outcome)				
4	Year	-0.05	0.84	-0.54	0.44
	Sex	0.002	0.997	-1.34	1.34
	Race	-0.27	0.71	-1.66	1.13
	Hispanic	0.62	0.45	-0.99	2.23
	HD Hours	-0.84	0.17	-2.01	0.34
	ICU Days	-0.04	0.67	-0.20	0.13
	Age Categories				
	2	-0.50	0.54	-2.08	1.08
	3	-12.62	0.99	-2747.08	2721.83
	4	-12.62	0.98	-1118.67	1093.43
	_cons	100.51	0.84	-887.35	1088.37

Model Selection Criteria for Access Type

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	2,376	-1817.368	-1778.121	30	3616.243	3789.438

Multinomial Logistic Regression for Access Type

	Multinomial Logistic Regression		Number of obs	=	710,817
			LR chi2(39)	=	7415.88
			Prob > chi2	=	0.00
	Log Likelihood = -428467.65		Pseudo R2	=	0.01

	Access Type	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
	Sex	-0.28	0.001	-0.29	-0.27
	Race				
	2	-0.09	0.001	-0.11	-0.08
	3	0.13	0.001	0.10	0.15
	Age Categories				
	2	0.11	0.001	0.09	0.13
	3	0.16	0.001	0.14	0.18
	4	-0.03	0.01	-0.05	-0.01
1	Year				
	2013	0.03	0.01	0.01	0.05
	2014	0.02	0.07	-0.002	0.04
	2015	0.04	0.001	0.02	0.06
	2016	0.01	0.24	-0.01	0.04
	2017	0.02	0.03	0.002	0.05
	2018	0.08	0.001	0.05	0.10
	Modality Type	-0.19	0.01	-0.32	-0.05
	_cons	-1.02	0.001	-1.16	-0.88
	Sex	0.46	0.001	0.43	0.49
	Race				
	2	0.64	0.001	0.61	0.67
	3	0.24	0.001	0.18	0.30
	Age Categories				
	2	0.30	0.001	0.26	0.35
	3	0.51	0.001	0.46	0.56
	4	0.53	0.001	0.48	0.58
2	Year				
	2013	-0.004	0.86	-0.06	0.05
	2014	0.02	0.36	-0.03	0.07
	2015	0.06	0.02	0.01	0.11
	2016	0.07	0.01	0.02	0.12
	2017	0.08	0.001	0.04	0.13
	2018	0.19	0.001	0.13	0.25
	Modality Type	-0.87	0.004	-1.47	-0.28
	_cons	-3.70	0.001	-4.30	-3.10

3	(Base Outcome)				
	Sex	0.05	0.36	-0.06	0.17
	Race				
	2	-0.04	0.52	-0.17	0.09
	3	0.10	0.38	-0.13	0.34
	Age Categories				
	2	-0.15	0.07	-0.31	0.01
	3	-0.11	0.23	-0.29	0.07
	4	-0.06	0.56	-0.25	0.14
4	Year				
	2013	0.03	0.77	-0.17	0.23
	2014	0.07	0.47	-0.12	0.27
	2015	0.03	0.77	-0.17	0.23
	2016	-0.22	0.04	-0.43	-0.01
	2017	-0.11	0.29	-0.32	0.10
	2018	-0.20	0.14	-0.46	0.07
	Modality Type	2.35	0.001	2.23	2.47
	_cons	-8.49	0.001	-8.78	-8.19

Model Selection Criteria for Access Type

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	710,817	-432175.6	-428467.7	42	857019.3	857501.2

Multinomial Logistic Regression for Access Type

	Multinomial Logistic Regression		Number of obs	=	710,964
			LR chi2(36)	=	6743.64
			Prob > chi2	=	0.00
	Log Likelihood = -428905.41		Pseudo R2	=	0.01
	Access Type	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
1	Sex	-0.28	0.001	-0.29	-0.27
	Race				
	2	-0.09	0.001	-0.11	-0.08
	3	0.13	0.001	0.10	0.15
	Age Categories				
	2	0.11	0.001	0.09	0.13
	3	0.16	0.001	0.14	0.18
	4	-0.03	0.01	-0.05	-0.01
	Year				
	2013	0.03	0.01	0.01	0.05
	2014	0.02	0.06	-0.001	0.04
	2015	0.04	0.001	0.02	0.06
	2016	0.01	0.21	-0.01	0.04
	2017	0.03	0.03	0.003	0.05
	2018	0.08	0.001	0.05	0.10
	_cons	-1.21	0.001	-1.24	-1.18
2	Sex	0.46	0.001	0.43	0.49
	Race				
	2	0.64	0.001	0.61	0.67
	3	0.24	0.001	0.18	0.30
	Age Categories				
	2	0.30	0.001	0.26	0.35
	3	0.51	0.001	0.46	0.56
	4	0.53	0.001	0.48	0.58
	Year				
	2013	-0.004	0.89	-0.05	0.05
	2014	0.02	0.34	-0.03	0.07
	2015	0.06	0.02	0.01	0.11
	2016	0.07	0.01	0.02	0.12
	2017	0.09	0.001	0.04	0.14
	2018	0.19	0.001	0.14	0.25
	_cons	-4.58	0.001	-4.65	-4.51

3	(Base Outcome)				
4	Sex	0.05	0.43	-0.07	0.16
	Race				
	2	-0.08	0.22	-0.21	0.05
	3	0.05	0.65	-0.18	0.28
	Age Categories				
	2	-0.23	0.003	-0.39	-0.08
	3	-0.23	0.01	-0.40	-0.05
	4	-0.17	0.08	-0.36	0.02
	Year				
	2013	0.002	0.98	-0.19	0.20
	2014	0.04	0.71	-0.16	0.23
	2015	-0.02	0.85	-0.21	0.18
	2016	-0.26	0.01	-0.47	-0.05
	2017	-0.19	0.07	-0.40	0.01
	2018	-0.27	0.04	-0.53	-0.01
	_cons	-5.91	0.001	-6.16	-5.66

Model Selection Criteria for Access Type

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
.	710,964	-432277.2	-428905.4	39	857888.8	858336.3

Multinomial Logistic Regression for Access Type

	Multinomial Logistic Regression		Number of obs	=	710,113
			LR chi2(39)	=	7781.92
			Prob > chi2	=	0.00
	Log Likelihood = -427327.05		Pseudo R2	=	0.01
	Access Type	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
1	Sex	-0.29	0.001	-0.31	-0.28
	Race				
	2	-0.08	0.001	-0.10	-0.07
	3	0.10	0.001	0.08	0.13
	Age Categories				
	2	0.10	0.001	0.08	0.12
	3	0.15	0.001	0.13	0.17
	4	-0.06	0.001	-0.09	-0.04
	Year				
	2013	0.03	0.003	0.01	0.06
	2014	0.03	0.02	0.004	0.05
	2015	0.04	0.001	0.02	0.07
	2016	0.02	0.05	-0.0003	0.04
	2017	0.03	0.01	0.01	0.05
	2018	0.08	0.001	0.05	0.11
	HD Hours	-0.19	0.001	-0.21	-0.18
	_cons	-0.44	0.001	-0.50	-0.38
2	Sex	0.44	0.001	0.42	0.47
	Race				
	2	0.65	0.001	0.63	0.68
	3	0.21	0.001	0.15	0.26
	Age Categories				
	2	0.30	0.001	0.25	0.34
	3	0.49	0.001	0.45	0.54
	4	0.49	0.001	0.44	0.54
	Year				
	2013	0.001	0.999	-0.05	0.05
	2014	0.03	0.24	-0.02	0.08
	2015	0.07	0.01	0.02	0.11
	2016	0.07	0.003	0.03	0.12
	2017	0.09	0.001	0.04	0.14
	2018	0.19	0.001	0.14	0.25
	HD Hours	-0.22	0.001	-0.25	-0.20
	_cons	-3.69	0.001	-3.82	-3.56

3	(Base Outcome)				
	Sex	0.03	0.68	-0.09	0.14
	Race				
	2	-0.06	0.41	-0.19	0.08
	3	0.09	0.48	-0.15	0.33
	Age Categories				
	2	-0.20	0.02	-0.36	-0.03
	3	-0.17	0.08	-0.35	0.02
	4	-0.14	0.18	-0.34	0.06
4	Year				
	2013	-0.01	0.95	-0.22	0.20
	2014	0.05	0.65	-0.16	0.25
	2015	0.002	0.99	-0.21	0.21
	2016	-0.21	0.06	-0.43	0.01
	2017	-0.11	0.30	-0.33	0.10
	2018	-0.23	0.10	-0.50	0.05
	HD Hours	-0.19	0.002	-0.31	-0.07
	_cons	-5.33	0.001	-5.88	-4.79

Model Selection Criteria for Access Type

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	710,113	-431218	-427327.1	42	854738.1	855220

Multinomial Logistic Regression for Place of Death

Multinomial Logistic Regression		Number of obs	=	4372
		LR chi2(21)	=	564.47
		Prob > chi2	=	0.00
Log Likelihood = -3422.57		Pseudo R2	=	0.08

Place of Death	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
1		(Base Outcome)		
2				
Year	-0.43	0.20	-1.09	0.23
Sex	-0.24	0.79	-1.96	1.49
Race	0.72	0.20	-0.39	1.83
Employment Status	-0.26	0.56	-1.12	0.61
Access Type	-0.30	0.50	-1.15	0.56
Age Categories	-0.49	0.47	-1.81	0.83
Hospice	1.54	0.08	-0.18	3.27
3				
Year	0.01	0.61	-0.03	0.06
Sex	-0.08	0.28	-0.23	0.07
Race	-0.17	0.01	-0.30	-0.04
Employment Status	-0.01	0.85	-0.09	0.07
Access Type	-0.11	0.01	-0.19	-0.03
Age Categories	-0.06	0.19	-0.14	0.03
Hospice	1.68	0.001	1.52	1.85
4				
Year	0.11	0.004	0.04	0.18
Sex	0.12	0.34	-0.12	0.36
Race	-0.22	0.06	-0.45	0.01
Employment Status	0.33	0.001	0.18	0.49
Access Type	0.07	0.38	-0.08	0.21
Age Categories	-0.05	0.50	-0.20	0.10
Hospice	1.55	0.001	1.29	1.80

Model Selection Criteria for Place of Death

Akaike's Information Criterion and Bayesian Information Criterion

Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	4,372	-3704.808	-3422.571	24	6893.142	7046.333

Multinomial Logistic Regression for Place of Death

Multinomial Logistic Regression		Number of obs	=	4372
		LR chi2(54)	=	627.69
		Prob > chi2	=	0.00
Log Likelihood = -3390.96		Pseudo R2	=	0.08

Place of Death	**Coef.**	**P>z**	**[95% Conf.**	**Interval]**
1		(Base Outcome)		
2				
Year				
2013	-14.60	0.99	-1549.08	1519.87
2014	-14.61	0.99	-1788.82	1759.60
2015	-0.21	0.81	-1.92	1.50
2016	-14.58	0.99	-2231.79	2202.63
2017	-14.66	0.99	-3330.97	3301.66
2018	-14.83	0.997	-9174.37	9144.71
Sex	-0.16	0.85	-1.90	1.58
Race				
2	0.59	0.53	-1.23	2.40
3	1.48	0.23	-0.91	3.88
Employment Status				
2	0.65	0.61	-1.85	3.16
3	-0.54	0.56	-2.37	1.29
Access Type				
2	0.68	0.59	-1.78	3.15
3	-0.55	0.55	-2.37	1.27
4	-14.34	0.998	-10355.34	10326.65
Age Categories				
2	-0.12	0.90	-1.91	1.66
3	-13.65	0.995	-4382.73	4355.44
4	-13.20	0.99	-2005.66	1979.26
Hospice	1.51	0.09	-0.24	3.26
3				
Year				
2013	0.06	0.57	-0.15	0.27
2014	0.08	0.47	-0.14	0.30
2015	0.06	0.63	-0.17	0.28
2016	0.16	0.21	-0.09	0.41
2017	0.00	0.98	-0.33	0.32
2018	-0.39	0.37	-1.22	0.45
Sex	-0.06	0.39	-0.21	0.08
Race				
2	-0.13	0.15	-0.29	0.04
3	-0.35	0.06	-0.70	0.01
Employment Status				
2	0.27	0.04	0.01	0.54
3	0.08	0.33	-0.09	0.25
Access Type				
2	-0.16	0.36	-0.49	0.18
3	-0.23	0.01	-0.39	-0.06
4	-0.60	0.34	-1.85	0.64
Age Categories				
2	-0.29	0.001	-0.46	-0.13
3	-0.43	0.16	-1.04	0.17
4	0.06	0.68	-0.21	0.32
Hospice	1.72	0.001	1.56	1.89
4				
Year				
2013	0.15	0.44	-0.23	0.52
2014	0.29	0.13	-0.09	0.67
2015	0.24	0.24	-0.16	0.63
2016	0.26	0.25	-0.18	0.69
2017	0.77	0.001	0.30	1.23
2018	0.67	0.20	-0.37	1.72
Sex	0.10	0.41	-0.14	0.35
Race				
2	-0.38	0.02	-0.69	-0.07
3	-0.25	0.40	-0.83	0.33
Employment Status				
2	-0.40	0.24	-1.07	0.27
3	0.49	0.002	0.18	0.81
Access Type				
2	0.29	0.31	-0.27	0.84
3	0.18	0.23	-0.12	0.48
4	-14.34	0.99	-2495.53	2466.84
Age Categories				
2	0.15	0.25	-0.11	0.41
3	0.60	0.13	-0.17	1.36
4	-0.86	0.02	-1.59	-0.13
Hospice	1.50	0.001	1.24	1.76

Model Selection Criteria for Place of Death

Akaike's Information Criterion and Bayesian Information Criterion

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
	4,372	-3704.808	-3390.962	57	6895.925	7259.754

Multinomial Logistic Regression for Place of Death

	Place of Death		Number of o	=	4843.00		
	Multinomial logistic regression		LR chi2(36)	=	118.36		
			Prob > chi2	=	0.00		
	Log likelihood = -4031.4671		Pseudo R2	=	0.01		
	Place of Death	**Coef.**	**Std. Err.**	**z**	**P>z**	**[95% Conf.**	**Interval]**
1		(base outcome)					
2	Year						
	2013	-15.71	1226.55	-0.01	0.99	-2419.69	2388.28
	2014	-15.75	1407.47	-0.01	0.99	-2774.35	2742.84
	2015	0.02	0.74	0.03	0.98	-1.42	1.46
	2016	-15.73	1768.69	-0.01	0.99	-3482.29	3450.84
	2017	-15.84	2637.25	-0.01	1.00	-5184.75	5153.07
	2018	-17.04	14254.82	0.00	1.00	-27955.98	27921.90
	Sex	-0.68	0.82	-0.83	0.41	-2.29	0.93
	Race						
	2	0.17	0.87	0.20	0.84	-1.53	1.87
	3	1.72	0.89	1.94	0.05	-0.02	3.45
	Age Categories						
	2	0.06	0.74	0.08	0.94	-1.40	1.52
	3	-14.87	4528.63	0.00	1.00	-8890.82	8861.07
	4	-14.56	1881.09	-0.01	0.99	-3701.42	3672.31
	_cons	-4.37	1.21	-3.60	0.00	-6.74	-1.99
3	Year						
	2013	-0.02	0.09	-0.17	0.87	-0.20	0.17
	2014	-0.03	0.10	-0.35	0.73	-0.23	0.16
	2015	0.09	0.10	0.91	0.36	-0.11	0.30
	2016	0.16	0.11	1.36	0.17	-0.07	0.38
	2017	0.04	0.15	0.28	0.78	-0.25	0.33
	2018	-0.21	0.38	-0.55	0.58	-0.95	0.53
	Sex	-0.08	0.07	-1.28	0.20	-0.21	0.04
	Race						
	2	-0.31	0.08	-4.00	0.00	-0.46	-0.16
	3	-0.58	0.17	-3.46	0.00	-0.91	-0.25
	Age Categories						
	2	-0.12	0.07	-1.70	0.09	-0.27	0.02
	3	-0.27	0.27	-0.99	0.32	-0.81	0.26
	4	-0.05	0.12	-0.43	0.67	-0.29	0.19
	_cons	-0.53	0.12	-4.60	0.00	-0.76	-0.30
4	Year						
	2013	0.08	0.18	0.44	0.66	-0.27	0.43
	2014	0.21	0.18	1.13	0.26	-0.15	0.56
	2015	0.32	0.19	1.67	0.09	-0.05	0.69
	2016	0.30	0.21	1.43	0.15	-0.11	0.71
	2017	0.81	0.23	3.57	0.00	0.37	1.26
	2018	0.82	0.51	1.62	0.11	-0.17	1.82
	Sex	0.15	0.12	1.27	0.20	-0.08	0.38
	Race						
	2	-0.56	0.15	-3.68	0.00	-0.85	-0.26
	3	-0.39	0.28	-1.40	0.16	-0.94	0.16
	Age Categories						
	2	0.47	0.12	3.90	0.00	0.23	0.71
	3	0.63	0.37	1.69	0.09	-0.10	1.36
	4	-0.98	0.35	-2.81	0.01	-1.66	-0.30
	_cons	-2.63	0.22	-12.15	0.00	-3.05	-2.21

Chapter 5 Multiple Linear Regression Model and Selection Criteria

Multiple Linear Regression Model for Hemoglobin

Source	SS	df	MS			
				Number of obs	=	7175.00
Source	SS	df	MS	F(17, 7157)	=	10.76
Model	469.28	17.00	27.60	Prob > F	=	0.00
Residual	18359.35	7157.00	2.57	R-squared	=	0.02
Total	18828.64	7174.00	2.62	Adj R-squared	=	0.02
				Root MSE	=	1.60

Hemoglobin	**Coef.**	**P>t**	**[95% Conf.**	**Interval]**
HD Hours	-0.08	0.04	-0.15	0.00
Access Type	-0.10	0.001	-0.15	-0.06
Modality Type	0.04	0.78	-0.22	0.29
HD Sessions	-0.01	0.87	-0.15	0.13
Year				
2013	-0.09	0.32	-0.25	0.08
2014	-0.10	0.28	-0.28	0.08
2015	-0.32	0.001	-0.51	-0.13
2016	-0.23	0.04	-0.44	-0.02
2017	-0.25	0.08	-0.53	0.03
2018	-0.55	0.001	-0.74	-0.36
Sex	-0.14	0.001	-0.22	-0.06
Race				
2	-0.27	0.001	-0.35	-0.18
3	-0.18	0.03	-0.35	-0.02
Hispanic	0.01	0.89	-0.08	0.09
Age Categories				
2	0.22	0.001	0.13	0.32
3	0.41	0.001	0.28	0.54
4	0.18	0.02	0.03	0.34

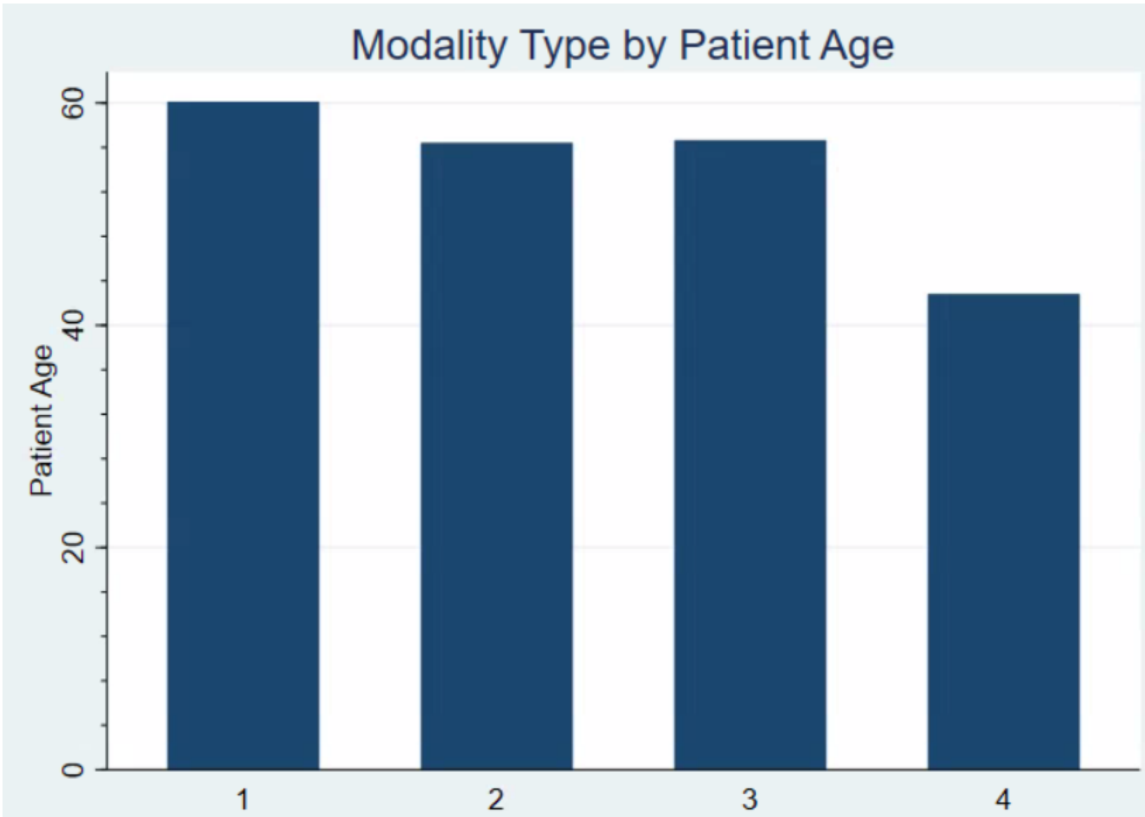
Selection Criteria for Multiple Linear Regression

Akaike's Information Criterion and Bayesian Information Criterion

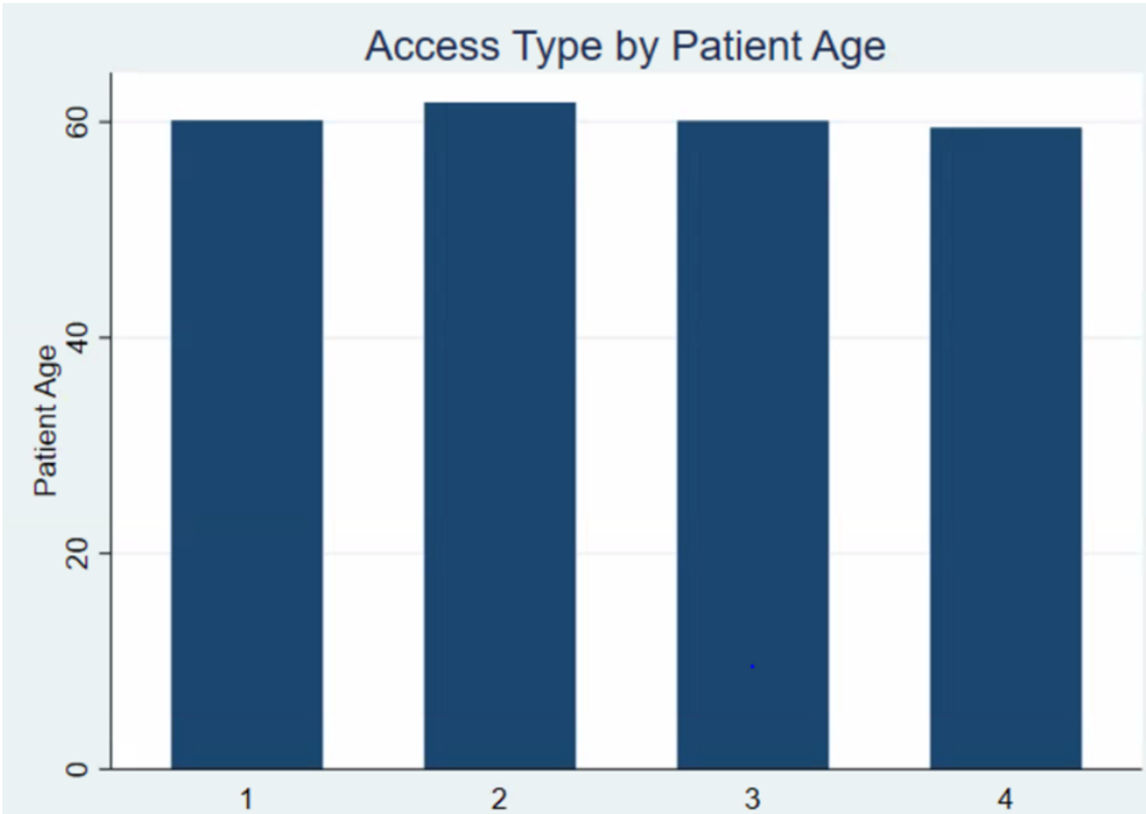
Model	**Obs**	**ll(null)**	**ll(model)**	**df**	**AIC**	**BIC**
	7,175	-13642.02	-13551.48	17	27136.97	27253.9

Chapter 5 Graphical Display of Variables

The bar graph displays the relationship between patient age and modality type (1=in-center HD, 2=home HD, 3=PD, 4=transplant). Younger patients are more likely to have a transplant, while older patients are more like to use in-center HD.

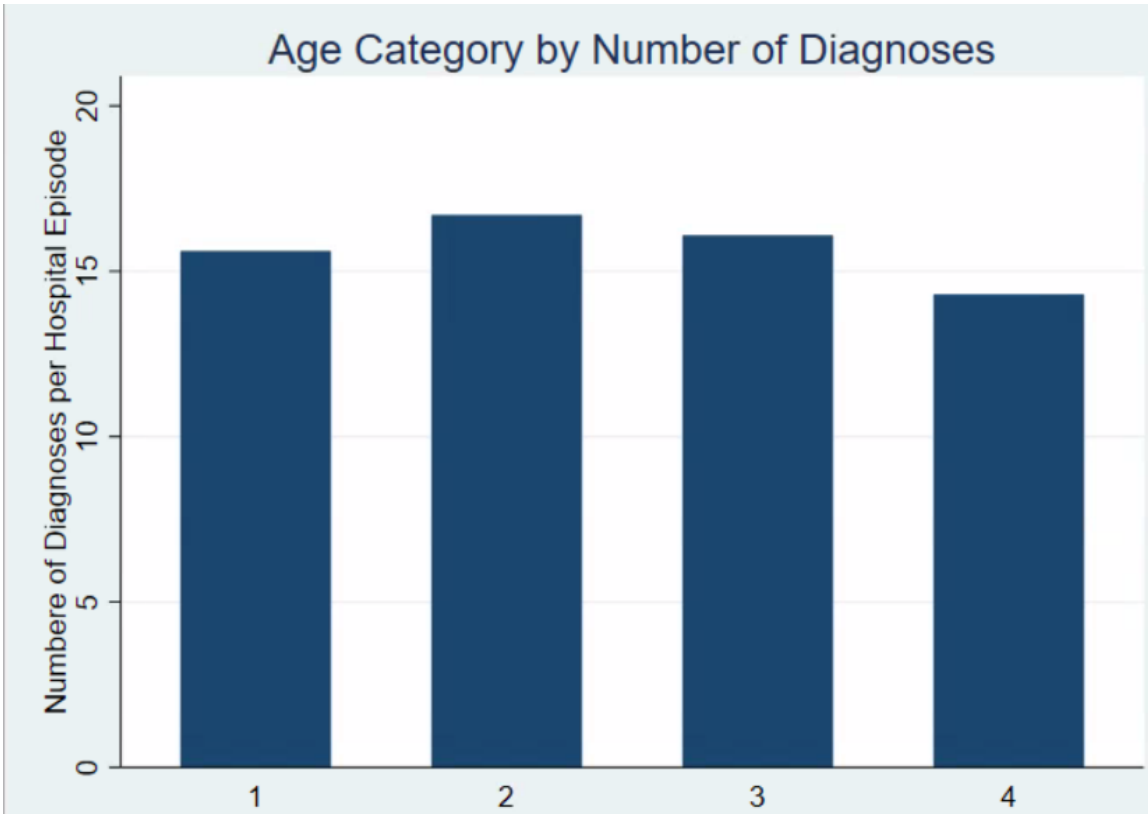


The bar graph displays the relationship between patient age and access type (1=arteriovenous fistula, 2=arteriovenous graft, 3=central venous catheter, 4=other).

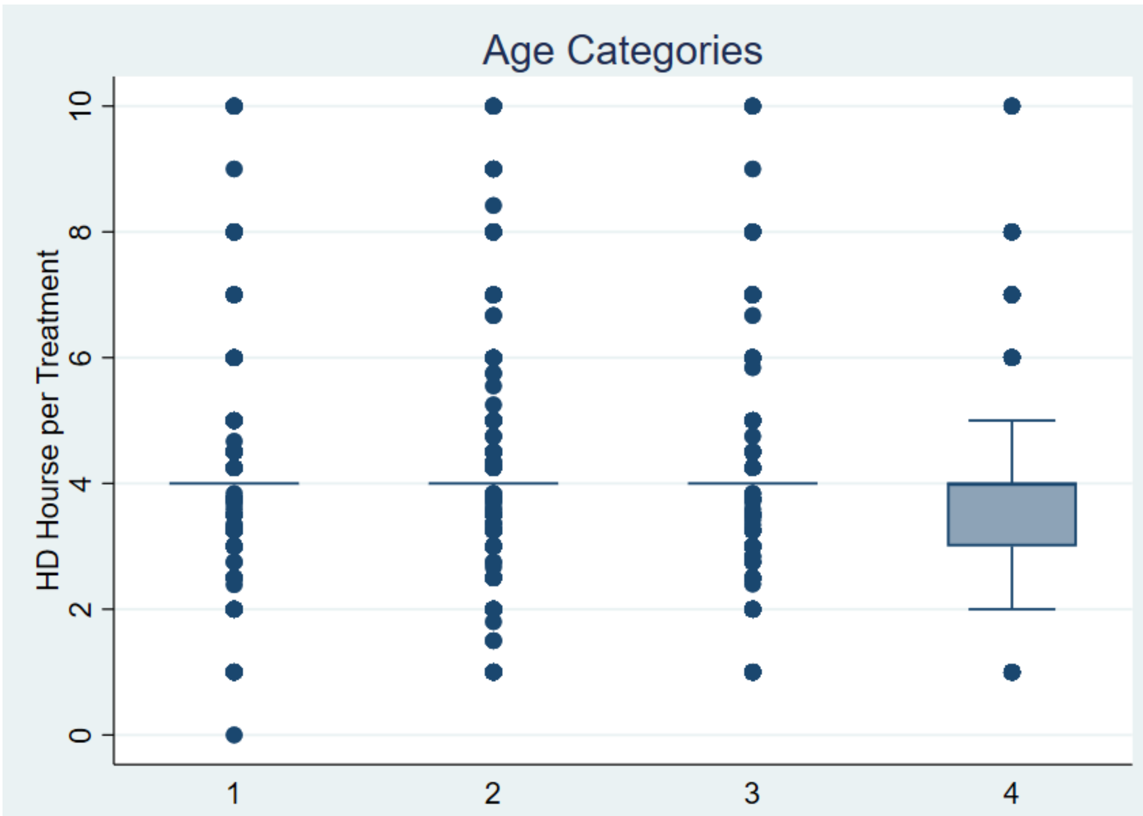


The bar graph displays the relationship between age and employment status (1=unemployed, 2=employed, 3=retired). The three categories are not equal. Most patients are retired, and more patients are unemployed than employed. Older patients are more likely to be retired, and younger patients are more likely to be employed.

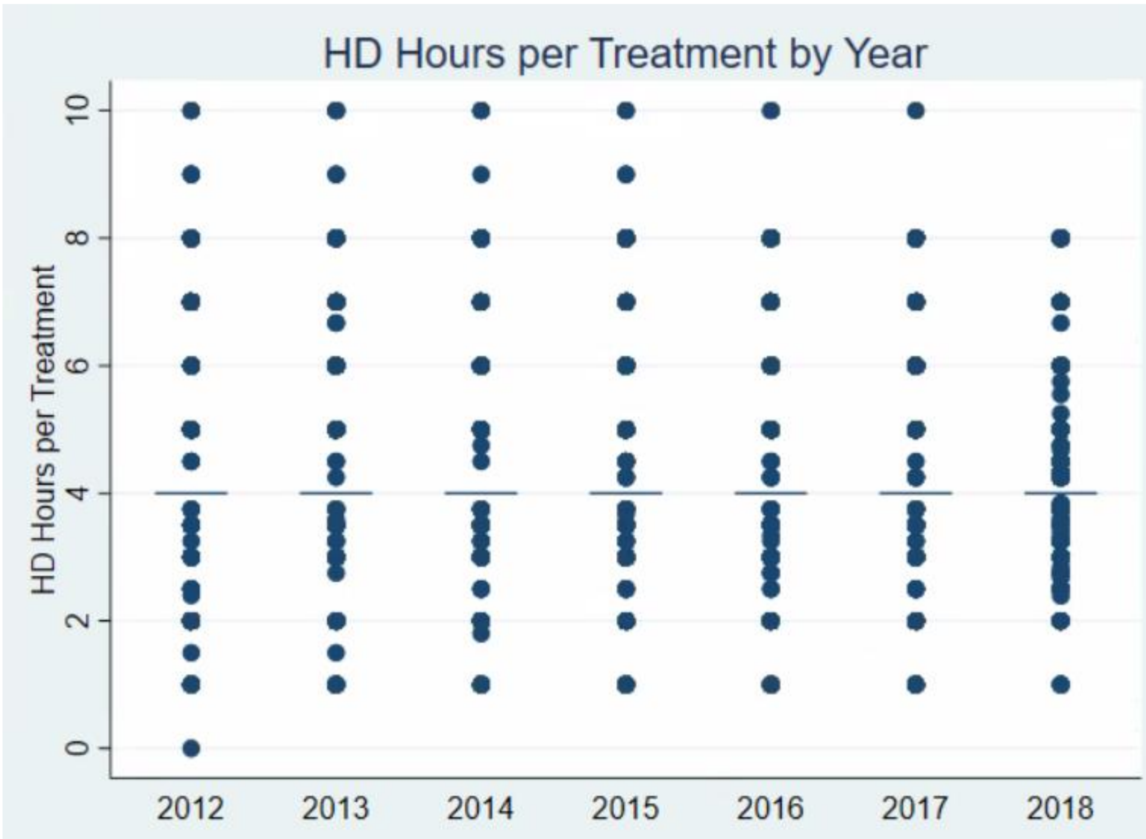
The bar graph displays the number of diagnoses per hospital episode by age category. Older patients have the lease number of diagnoses. Patients in age category 2 (45-64 years old) have the greatest number of diagnoses.



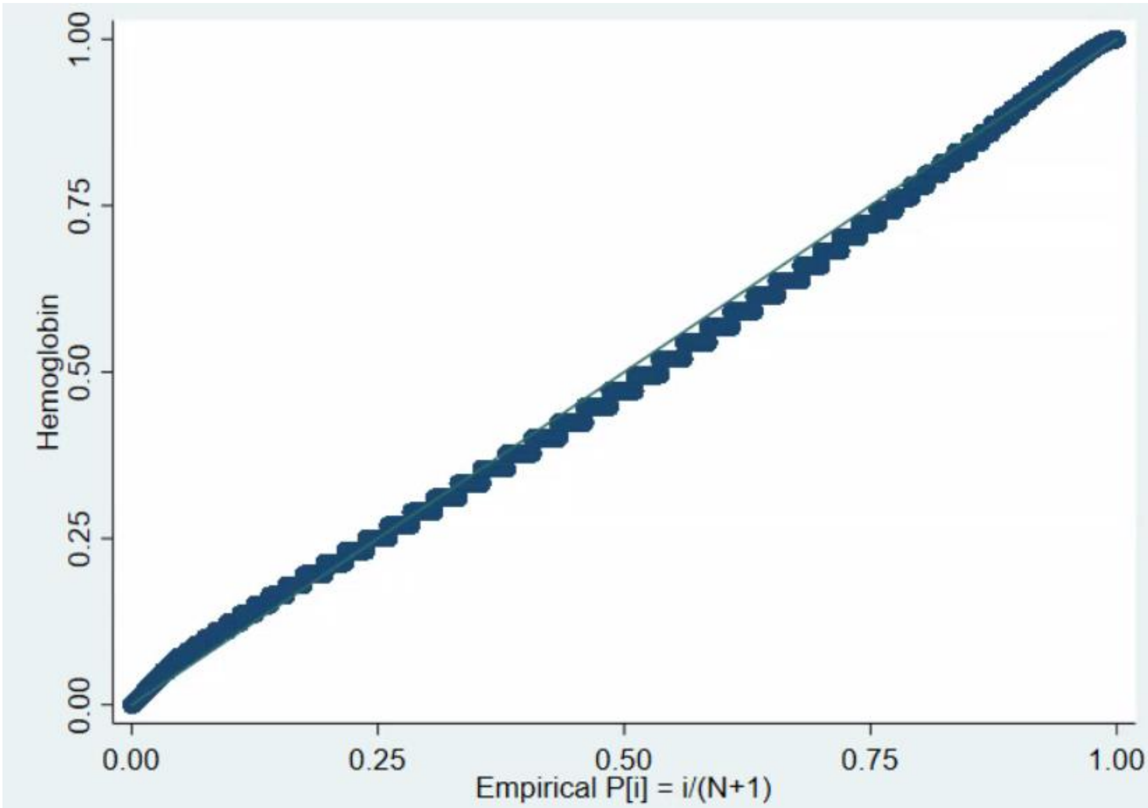
A box and whisker plot demonstrating the shape of the distribution, its central value, and its variability shows the number of hours per treatment that a patient receives dialysis from four age categories (1=0-44, 2=45=64, 3=65-74, 4=75+). The median weights of the four groups of age categories are similar, but the weights of age category 4 are more variable than the others.



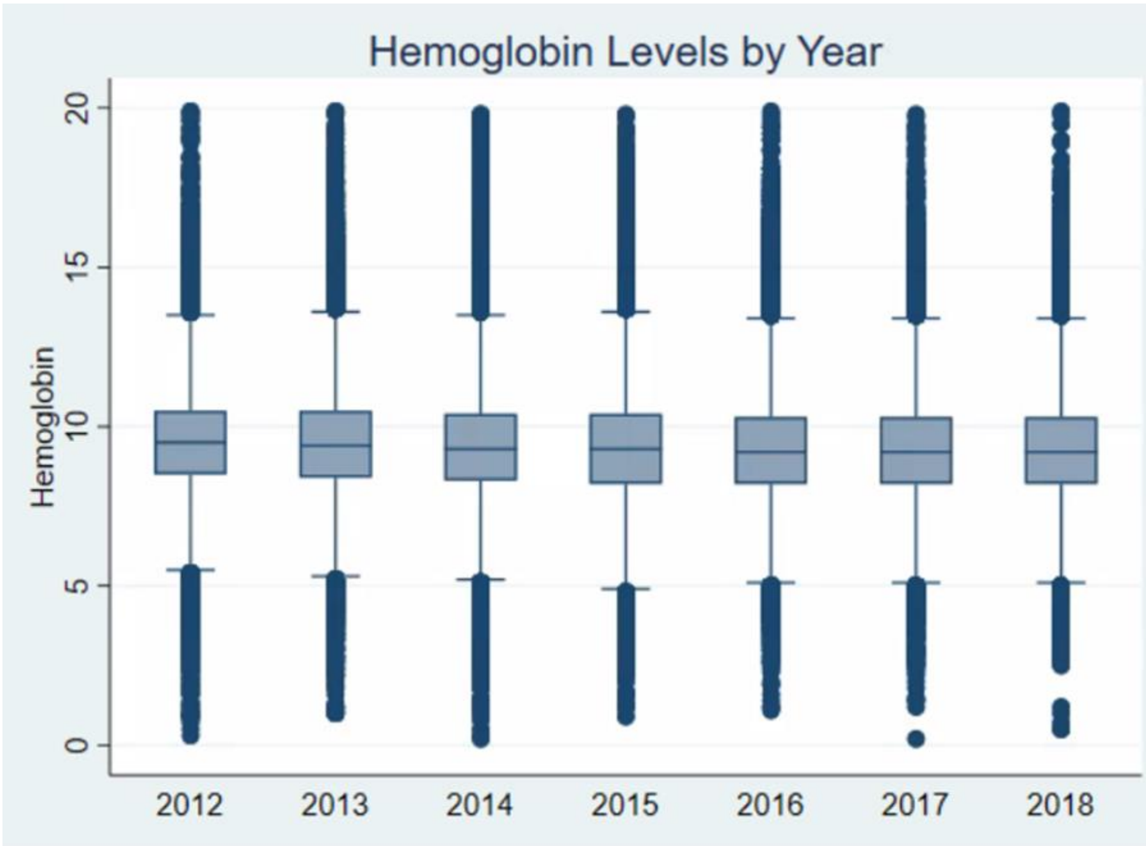
A box and whisker plot demonstrating the shape of the distribution, its central value, and its variability shows HD hours per treatment for years 2012 through 2018. The median weights for each year are similar, and the box plots appear symmetrical with some outliers.



The points on this Standardized Normal Probability Plot for hemoglobin form a nearly linear pattern, which indicates that the normal distribution is a good model for the data set.



A box and whisker plot demonstrating the shape of the distribution, its central value, and its variability shows patient hemoglobin levels from years 2012 through 2018. The median weights for each year are similar, and the box plots are symmetrical. Therefore, the data appears to follow a normal distribution.



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