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Association of Freestanding Dialysis Facility Size, Quality Incentive Program Scores and Patient Survival

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DEDICATION

To my parents,

Raja Shamrez Affendi and Sultana Shamrez for their prayers and unconditional love through my personal and professional endeavors

To my husband,

Agha Ajmal for his unwavering support, friendship and encouragement in the brightest and murkiest times of our lives

To my children,

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ABSTRACT

Background

In 2011, The Centers for Medicare and Medicaid Services (CMS) has introduced a bundled payment reform along with a Quality Incentive Program (QIP) to bring efficiency in End stage renal disease (ESRD) care. The QIP rates facilities using clinical and reporting criteria, but misses out on patient outcomes. It penalizes facilities not achieving a target score by 0-2% of payments. The small facilities are expected to be impacted more by a reduction in payments. We determined the association between ESRD facility size and QIP scores and the association between QIP scores and patient survival.

Methods

We used the Medicare dialysis facility compare, facility level impact and QIP files; United State Renal Data System (USRDS) facility and patient data and Area health resource (AHRF) file. We restricted the data to 2013, the most recent year for which all data were available.

For the first objective, we aggregated the USRDS patient data by facility. Merging the above data yielded 5,193 facility records. We measured facility size by number dialysis stations. Given a non-linear relationship between QIP sores and dialysis stations, we categorized stations into three categories including small (≤10), medium (11-25) and large

(>25). We used a multivariable generalized linear model to determine the association between QIP scores and facility size.

In the objective 2, we included 96,102 incident ESRD patients from January 2013- December 2013, using USRDS patient files. We determined 1-year patient survival among incident patients who survived the first 90 days. A multivariable Cox proportional hazard model was run to estimate the association between QIP scores and patient.

Result

The medium and large size facilities scored higher on QIP than small facilities. Facilities in South, offering peritoneal dialysis, having higher number of Hispanics patient and county populations scored higher on QIP. However, the facilities with a higher average distance between patients and facility, a higher proportion of black population in a facility or county scored lower. Further, patients in facilities scoring < 60 showed a higher mortality than patients in facilities scoring ≥ 95.

Conclusion

We found small facilities scored lower by the QIP than medium and large facilities. Further, facilities performing lower on the QIP criteria demonstrated lower patient survival. Our finding that a higher black population in a facility or in the county is associated with lower QIP scores warrants more research

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ACE	Angiotensin-converting enzyme
AVF	Arteriovenous fistula
AVG	Arteriovenous graft
BSI	Blood stream infections
BMI	Body mass index
CY	Calendar year
CVC	Cardiovascular catheter
CVD	Cardiovascular disease
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CKD	Chronic Kidney Disease
CPM	Clinical Performance Measures
CRP	C-reactive protein
DFC	Dialysis facility compare
DOPPS	Dialysis outcomes and practice pattern study
ESRD	End-stage renal disease
ESA	Erythropoietin stimulating agent
FFS	Fee-for-service
FDA	Food and Drug Administration

FMC ....Fresenius Medical Care

GFR .... Glomerular filtration rate

GDP ....Gross Domestic Produce

HCT ....Hematocrit

Hgb ....Hemoglobin

IRFCRD .... Independent Renal Facility Cost Report Data file

IOM .... Institute of Medicine

IL .... Interleukin

IV ....Intravenous

MIPPA .... Medicare Improvements for Patients and Providers Act

NHSN .... National Healthcare, Safety Network

NIDDK........................... National Institute of Diabetes and Digestive and Kidney Disease

NIUDIC...................National Kidney and Urological Diseases Information Clearinghouse

NCC .... Network Coordinating Councils

OR ....Odds ratio

OECD ....Organization for Economic Cooperation and Development

PY .... Payment year

PNV .... Pre-nephrology visit

PPS ....Prospective payment system

RBC .... Red blood cell

SES .... Socioeconomic status

SMR .... Standardized mortality ratios

TNF .... Tumor necrosis factor

USRDS..United States Renal Disease System

URR .... Urea reduction ratio

VAT .... Vascular access treatment

CHAPTER I: INTRODUCTION

1.1 THE U.S. HEALTHCARE SYSTEM AND ESRD CARE

The U.S. spends more on healthcare than any other country (Health at a Glance 2011: OECD Indicators, 2011; Woolf & Aron, 2013). However, it lags behind many wealthier nations, both in life expectancy and quality of care (The Commonwealth Fund, 2015; Woolf & Aron, 2013). The US spent $3.2 trillion on health care in 2015, 17.8% of gross domestic product (GDP) (Martin, Hartman, Washington, Catlin, & Team, 2016). Trends show a continuing rise in cost of care, more so, during the past two decades (Dieleman et al., 2016). The rising health care costs have affected both private and public health insurance programs. Medicare, being the largest public insurer, is expected to utilize 8% of the GDP in 2020, an unprecedented consumption of a single program (Thorpe, Ogden, & Galactionova, 2010). Therefore, the Centers for Medicare and Medicaid Programs (CMS) is focused on bringing healthcare delivery reforms.

Some diseases are more costly to treat than the others. An example of such disease is end-stage renal disease (ESRD). Given its high cost, Centers for Medicare and Medicaid Services (CMS) included ESRD as a first disease based eligibility in 1972. In other words, ESRD patients are enrolled in Medicare, irrespective of their age. When the ESRD legislation was being debated in 1972, the estimated cost was $22-25K per patient per treatment year in the most expensive setting (hospital) (Richard A. Rettig, 1991).

ESRD patients require kidney transplantation or frequent dialysis to survive (Levey & Coresh, 2012). Kidney transplantation is a more permanent and cost effective treatment than dialysis, however, a majority of patients remain on dialysis due to the unavailability of kidneys or mismatch in kidney tissues (Garcia, Harden, & Chapman, 2012). Dialysis entails a long treatment with a high recurring cost (National Kidney and Urologic Diseases Information Clearinghouse, 2013). In 2011, total Medicare expenditure by modality included, $24.3 billion for hemodialysis; $1.5 billion for peritoneal dialysis and $2.9 billion for kidney transplants (United States Renal Data System, 2013). The majority of the End-stage renal disease (ESRD) patients are covered by Medicare or jointly by Medicare and Medicaid programs (Wetmore, Rigler, Mahnken, Mukhopadhyay, & Shireman, 2009).

Initially, Medicare reimbursed the cost of ESRD treatment, laboratory services and drugs, using fee-for-service (FFS) methods (Watnick et al., 2012). The fee-for-service (FFS) payment mechanism and growth in the eligible population increased the total ESRD care cost to Medicare. Further, the lifespans of ESRD patients have also increased due to the discovery and use of new treatment modalities (A. W. Williams, 2015). Currently, ESRD patients account for a disproportionate share of Medicare expenditures – ESRD patients comprise about 1% Medicare patient population, however, consume 7% of the program expenditures (Ojo, 2014; The American Society of Nephrology, 2014). The rise in overall healthcare cost and, more specifically, the ESRD care cost, resulted in Medicare seeking more efficient payment models.

1.2 INITIAL COST CONTAINMENT: NARROW BUNDLE PROGRAM

In 1983, the program promulgated the ESRD bundled payment model – also called narrow bundle payments (Chambers, Weiner, Bliss, & Neumann, 2013). Medicare paid $130 per dialysis treatment, however, kept reimbursing facilities for the provider's fee, laboratory tests and medications by FFS method (Watnick, et al., 2012). Consequently, the providers started prescribing more medications to ESRD patients. The higher erythropoiesis stimulating agent (ESA) was one such example. This drug improves hemoglobin levels among anemic ESRD patients. In 2005, 40% of facility payment were mainly driven by ESA — a separately billable drug (Weiner & Watnick, 2010). Epoetin and darbepoetin are the two approved ESAs. Epoetin had become a revenue generator, consuming $2 billion in Medicare costs in the same year (Steinbrook, 2007).

1.3 MODIFICATION: EXPANDED BUNDLE PAYMENT

Realizing the ever increasing cost of the program, Medicare implemented a prospective payment system with an expanded bundle payment in 2011 (Iglehart, 2011; Medicare & Medicaid Services 2010). Using new PPS, CMS pays a predetermined Medicare payment to cove items and services in a dialysis care episode . The composite rate covers routine laboratory The services included intravenous drugs, laboratory services, supplies and capital-related costs related to providing maintenance dialysis (Iglehart, 2011). The expanded bundle makes an average payment of $230 per dialysis episode, This cost was calculated after adjusting for patient characteristics, including, age, body size and acute/chronic health conditions (Medicare & Medicaid Services 2010; Swaminathan, Mor, Mehrotra, & Trivedi, 2012). However, physicians were still reimbursed by FFS method. At the end of 2011, the majority of the dialysis facilities were paid through PPS (Iglehart, 2011).

1.4 POTENTIAL RISKS OF THE EXPANDED BUNDLE PROGRAM

The expanded bundle was designed to bring down cost, however, experts raised concerns about the negative effects of fixed payment (Kristensen & Wish, 2010; Weiner & Watnick, 2010). For instance, to mitigate financial risks, dialysis facilities can undertreat, cherry pick, stint services and increase referrals to ensure financial solvency (Chambers, et al., 2013; Iglehart, 2011; Kristensen & Wish, 2010; Swaminathan, et al., 2012). Such reactions to cost saving can result in higher patient complications, hospitalization, readmissions and mortality due to poor quality of health care (Iglehart, 2011).

The agency theory attempts to explicate the relationship between principal and agent in a marketplace. The bundled payment is likely to affect the relationship between principal and agent. A provider (dialysis facilities) acts as an agent, while a patient acts as a principal (Eisenhardt, 1989; Lee & Zenios, 2012). Under financial constraints, the agent tries to save cost (Eisenhardt 1989). The principal remains unable to assess agent's performance and has no control over the quality of service rendered by an agent. Therefore, cost savings reforms that are not coupled with quality assessment can result in lower quantity and quality of service (Landon et al., 2007; Sekhri, 2000).

1.5 ESRD QUALITY PROGRAM

Researchers raised concerns about the possibility of service quality and quantity decline after the expanded bundle (Chambers, et al., 2013; Kristensen & Wish, 2010). Considering the concerns and taking lessons from the past, Medicare included the Quality Incentive Program (QIP) as part of the Medicare ESRD Program in Medicare Improvement for Patient and Provider Act, 2008 (Medicare & Medicaid Services 2011). In 2011, the program was formally implemented after the initiation of expanded bundled payment. Initially, the QIP tracked the facility performance using indicators: proportion of patients with hemoglobin (Hgb) levels <10 g/dl, Hgb ≥ 12 g/dl and urea reduction ratio of $\geq 65\%$ average over a year (Fishbane & Hazzan, 2012). Over years, the program added more indicators including, clinical measures (proportion of patients with arteriovenous fistula (AVF) and the proportion of patients with catheter for more than 90 days of dialysis initiation) and reporting factors (Table 2.1). The presence of mature AVF decreases the risk of infections associated with dialysis.

CMS penalizes facilities scoring lower than the target score on QIP by 0-2% of the payments (Center for Medicare and Medicaid Services, 2012b). Table 2.1 presents the summary of the clinical measures, reporting measures and scoring criteria. Chapter II includes more details on indicators and performance calculation and criteria.

Generally, the experience with pay for performance is mixed (James, 2012). Researchers have also questioned whether the QIP will improve the patient outcomes (Watnick, et al., 2012; A. W. Williams, 2015). The program was implemented as an uncontrolled pilot – using a “one size fit all” strategy without an initial pilot or effectiveness study (A. W. Williams, 2015). Moss and Davison criticized the program’s narrow clinical focus, rather than a focus on achieving overall health of the patient (Moss & Davison, 2015). QIP includes easy to measure laboratory indicators (Moss & Davison, 2015; Nissenson, 2013). However, both Moss et al. and Nissenson et al. reviewed studies based on specific measures included in the QIP criteria rather than the studies that the QIP criteria. The QIP criteria include a collection of clinical and reporting measures. Therefore, a key unanswered question is the relationship between QIP scores and actual patient outcomes including patient survival.

1.6 FACTORS ASSOCIATED WITH ESRD QUALITY PERFORMANCE

In addition to Medicare quality incentives, facility factors such as chain affiliation, for-profit status, number of dialysis stations and patient to staff ratio influence facility performance and health outcomes (Straube, 2014; Yan, Norris, Xin, et al., 2013; Yue Zhang, 2015). Zhang et al. reported for-profit and chain affiliated facilities rendering better service quality (Yue Zhang, 2015).

QIP is more likely to increase financial constraints of small dialysis facilities (A. W. Williams, 2015). QIP can limit the ability of smaller facilities to receive medication discounts, establish their own pharmacy and laboratory services and administer electronic health records (Slinin & Ishani, 2013)**.** The few studies that have addressed the association between size and quality have reported mixed results. For instance, while Eisenstein et al. and Yan et al. reported that smaller facilities are associated with a higher patient mortality (Eisenstein et al., 2008; Yan, Norris, Xin, et al., 2013,) Zhang et al. reported such facilities perform better (Yue Zhang, 2015). Zhang and associates surmised that a higher focus on producing results in larger facilities losing their sight on performance. Notably, the definition of size also varies in the literature. Yan et al. and Zhang et al. used number of stations, while Eisenstein et al. used number of treatments to measure facility size.

CMS payment reforms are expected to impact small size facilities adversely (Chambers, et al., 2013; A. W. Williams, 2015). Rural dialysis facilities are more likely smaller in size (Medicare Payment Advisory Commission (US), 2015); treat a low patient volume; render fewer treatments; operate on fewer dialysis stations and generate lower profit margin, compared with urban facilities (Eisenstein et al., 2008; Medicare Payment Advisory Commission (US), 2015; O'hare, Johansen, & Rodriguez, 2006; Yan, Norris, Xin, et al., 2013).

In 2012, CMS rebased the bundle payments, further reducing per treatment payment by $30 (Wish, Johnson, & Wish, 2014). Rebasing was expected to further aggravate financial constraints of rural facilities. CMS proposed Low Volume Payment Adjustments (LVPA) for rural and low volume facilities. However, recent reports indicate discrepancies in financial adjustments, causing under adjustment or no adjustment (United States Government Accountability Office, 2013). Low operating margins are associated with poor quality of care (Ly, Jha, & Epstein, 2011). Therefore, we hypothesize that small size dialysis facilities are more likely to render a poor quality of dialysis services.

1.7 RATIONALE

Performance scores were designed by CMS to improve the quality of the program in the face of increased risk of compromised quality. Facility, patient and ecological characteristics work in tandem to influence quality of care (Donabedian, 1988). The literature contains mixed results relating facility size with care quality. Large facilities receive higher patient volume and therefore are expected to perform better on QIP criteria. High volume brings down treatment cost. Large organizations receive higher patient volume which in turn enables them to make more revenues and negotiate on lower prices. However, Zhang et al.'s study found that the larger facilities performed worse (Yue Zhang, 2015). QIP may impact small size dialysis facilities adversely (A. W. Williams, 2015). To the best of our knowledge, no study has determined the association between number of dialysis stations (facility size) and facility QIP performance scores, controlling for patient, facility and ecological factors and demand side factor (patient volume and number of treatments). Small facilities are expected to perform poorly and become liable to QIP penalties, closure and consolidation after the bundled payment. However, empirical evidence of association between facility size and QIP scores are missing. Further, QIP criteria are generally critiqued for their narrow clinical focus, however, no study has yet determined the association between facility QIP score and patient survival. Therefore, the proposed research addresses two main questions, as follows.

1.8 RESEARCH QUESTIONS

1) Is facility size associated with the performance of the freestanding dialysis facilities as measured by QIP scores?

   Hypothesis: Net of other factors, larger facilities have better performance scores than smaller facilities

2) Is freestanding dialysis facility performance as measured by QIP scores associated with the survival of the ESRD patients on dialysis?

Hypothesis: Net of other factors, patient survival are positively associated with QIP performance scores.

CHAPTER II: BACKGROUND

2.1 ESRD: A COSTLY AND FATAL DISEASE

ESRD is the principal sequel of chronic kidney disease (CKD) (Couser, Remuzzi, Mendis, & Tonelli, 2011). CKD results in the inability of kidneys to fully excrete the body waste. Kidneys are made up of millions of nephrons – filtering units that excrete body waste and play a role in mineral and water homeostasis (J. E. Hall, 2015). A normal kidney has a GFR of 125 ml/min/1.73 m^2 (Levey et al., 2011). In CKD nephrons die, reducing the kidney filtration rate, also called the glomerular filtration rate (GFR). As it progresses, more nephrons die causing further reduction in filtration rate. ESRD ensues when GFR is reduced to 15 ml/min/1.73 m^2 (Levey, et al., 2011).

Reduced GFR results in waste build up inside the body causes uremia – a syndrome is characterized by a buildup of nitrogenous end products of protein and amino acids (J. E. Hall, 2015). The nitrogenous end products include urea (measures as Blood Urea Nitrogen) and creatinine. CKD leads to complications including, hypertension; weak bones; anemia; infections; pericarditis; pulmonary edema; damaged nerves; poor nutritional status; and cardiac arrest (Centers for Disease Control and Prevention, 2014; Taal, 2015). Advanced CKD heralds end stage renal disease (ESRD), a chronic and debilitating condition. The kidneys completely stop excreting waste (Couser, et al., 2011).

Currently, about 10% of the U.S. adult population i.e., about 20 million, suffers from CKD. The country reported 778,810 ESRD cases in 2013 (Centers for Disease Control and Prevention, 2014; United States Renal Data System, 2015). The reported rates of ESRD are three times in the U.S. than other Organization for Economic Cooperation and Development (OECD) countries (Levey & Coresh, 2012; McCullough et al., 2011). Indeed, the US ranks third after Taiwan and Japan in ESRD prevalence (Jha et al., 2013; Levey & Coresh, 2012).

The numbers of ESRD patients are expected to grow with an aging population. Since 2012, ESRD has risen at a rate of 3.5 % annually, adding 21,000 patients per year (United States Renal Data System, 2015). Medicare expects its enrollees to increase from 50 million currently to nearly 70 million in 2023 (Blumenthal, Stremikis, & Cutler, 2013). The quality and cost of the ESRD Medicare program will face more brunt of increasing ESRD aging and frail population with the passing time.

ESRD patients have a higher all-cause mortality rate compared to the other Medicare patient populations, including cancer (United States Renal Data System, 2015). In 2015, Jiaquan Xu and colleagues reported kidney diseases among the ten most common causes of mortality in the US (Jiaquan Xu, 2016). The mortality among ESRD patients show a rising trend - age adjusted death rate increased by 1.5% between 2014 and 2015 (Jiaquan Xu, 2016). About 20% ESRD patients die within a year of dialysis and 35% die within three years of diagnosis (de Jager et al., 2009; Nissenson, 2013).

2.2 HISTORY OF THE MEDICARE ESRD COST SYSTEM

In 1972, ESRD patients became eligible to enroll in the Medicare program, irrespective of age (Watnick, et al., 2012; A. W. Williams, 2015). The increasing ESRD enrollees and cost of the program has resulted in CMS introducing payment reforms in 1980s and onwards (Watnick, et al., 2012).

2.2.1 Narrow bundled payment

Before 1983, Medicare reimbursed ESRD facilities using a retrospective FFS payment model, without any payment cap (Chambers, et al., 2013). In 1983, the Social Security amendment introduced a composite dialysis payment rate of $130 (Iglehart, 2011). The amendment, however, allowed for some items, including drugs, to be billable outside the bundle. As a result, the providers prescribed costly medications at a higher rate (Watnick, et al., 2012). ESA is an example of one such costly drug, the use of which increased exponentially after the QIP.

In 1989, Medicare approved the use of ESA, that is, Epoetin, as a separately billable drug (Watnick, et al., 2012). Epoetin maintains blood hemoglobin in normal limits among anemic ESRD patients. Medicare applied a rate of $40 for initial 10,000 units, and the $30 for the units in excess to 10,000 (Watnick, et al., 2012). However, in 1991, Medicare revised the rate to $10 per 1,000 units.

Providers used Epoetin to maximize profits, making it a major revenue source. Consequently, in 2006, Epoetin constituted a 70% of the total ESRD drug cost, a $2 billion (Watnick, et al., 2012). The overall cost of the program increased tremendously. In addition to the possible overuse of ESA, the other factors increasing cost included increasing ESRD prevalence, the number and severity of comorbidities, and changing technology and treatment modalities (A. W. Williams, 2015).

2.2.2 Expanded Bundle Payment System

To rein in the escalating cost, Medicare introduced the ESRD Prospective payment system (PPS) as a part Medicare Improvements for Patients and Providers Act (MIPPA) in 2011 (Weiner & Watnick, 2010). As an expansion of narrow bundle, the new PPS system included the separately billable drugs, laboratory tests and other related services in a fixed payment bundle of $230 per episode of care. CMS adjusted the bundle for patient age, body size and morbidities (Medicare & Medicaid Services 2010; Swaminathan, et al., 2012). The majority of the facilities shifted to the new system within a year of its implementation.

2.3 ADDRESSING QUALITY OF CARE UNDER BUNDLED PAYMENT

The term quality used here and hereafter relates to the QIP scores assigned by Medicare ESRD QIP. The bundled payment increases the financial risks of the providers. The providers had to render services within an allocated amount. Research has indicated potential negative effects of bundled payment including lower service quantity (stinting) quality (Kristensen & Wish, 2010; Winkelmayer & Chertow, 2011). Providers can cherry pick healthier patients and refer patients with complications (Chambers, et al., 2013; Desai, Bolus, et al., 2009).

Stinting results in higher hospitalizations and readmission and thereby a higher cost (Iglehart, 2011). Due to the inclusion of ESA in the bundle payment, providers could also turn to blood transfusions to treat anemia among ESRD patients (Iglehart, 2011; A. W. Williams, 2015). The cost of blood transfusion and hospitalization are paid outside the bundle. An unnecessary blood transfusion compromises the immune system and increases the risk of infections (Winkelmayer & Chertow, 2011).

2.4 QUALITY AND EVOLUTION OF QIP

CMS formally addressed quality in ESRD through the Balanced Budget Act for the first time in 1997 (Frederick, Maxey, Clauser, & Sugarman, 2002; Watnick, et al., 2012). The Act mandated facilities to report on quality. However, the assessment prompted no monetary penalty or incentives (Ramanarayanan & Snyder, 2012). In early 2000, the severe quality deficiency was identified in the US healthcare system by the Institute of Medicine (IOM) (Berwick, 2002). In 2001, the CMS launched a dialysis facility compare data public reporting system. The system tracked the facility performance and allowed CMS to incentivize conforming facilities (Ramanarayanan and Snyder 2012). The broad category of quality criteria included anemia control, dialysis adequacy and survival.

Realizing the compromised quality as a potential risk, Medicare introduced QIP, a pay-for-performance system, a few months after the PPS (Center for Medicare and Medicaid Services, 2016b); (Berenson, Pronovost, & Krumholz, 2013). The term "Pay-for-performance" embodies quality, efficiency and value based purchasing (Eijkenaar, 2013). It creates rewards for providers who meet or exceed quality criteria (James, 2012). It also penalizes the noncompliance to quality measures (Berenson, et al., 2013). Medicare ESRD QIP is such an example. Facility quality measures and benchmarks were developed and publicly reported with a penalty of 0-2% on non-compliance (Berenson, et al., 2013; Center for Medicare and Medicaid Services, 2016b; Iglehart, 2011).

2.4.1 QIP performance indicators

Prior research has shown the association of clinical benchmark such as attainment of target Hgb, hematocrit, URR, albumin, etc. with health outcomes including improved survival and lesser hospitalization. (Lacson, Wang, Lazarus, & Hakim, 2009; Plantinga et al., 2007). Among large nonprofit chains, Tentori et al. found achieving clinical goals (Urea levels, hemodialysis treatments, hemoglobin level, bicarbonate level, albumin level, phosphorus level, fistulae, and catheters) in the large nonprofit chain was associated with better patient survival (Tentori et al., 2007).

Since its inception, QIP criteria varied over the years. The following section presents clinical and reporting measures and target scores used by QIP over the years (Table 2.1).

Medicare publishes facility quality reports two years after the actual service year (Center for Medicare and Medicaid Services, 2016b). Thus, services rendered in calendar year 2010 are reported in 2012. In the current study we used the calendar (service) year as a reference to payment year. In the calendar year 2010, the three performance indicators were included; 1) the proportion of patients with hemoglobin (Hgb) >12 mg/dl, 2) Hgb < 10 mg/dl and 3)urea reduction ratio (URR) of ≥ 65% (Centers for Medicare & Medicaid Services (CMS), 2013). Hgb >10 and Hgb > 12 determine appropriateness of anemia management, while URR measures dialysis adequacy (Swaminathan, et al., 2012). All clinical measures are discussed in more detail at the end of this section.

For the calendar year 2011, CMS revised the QIP criteria. It removed the proportion of patients with Hgb < 10 mg/dl, keeping the other two aforesaid criteria (Centers for Medicare & Medicaid Services, 2013a). Medicare decided to remove Hgb < 10 mg/dl after the Food and Drug Administration (FDA) added a label on ESA indicating a need for cautious use of the drug (Food and Drugs Administration (FDA), 2011). The FDA added the label based on clinical trials reporting cardiovascular events, including stroke and mortality, associated with the drug (Food and Drugs Administration (FDA), 2011; Manns & Tonelli, 2012). Since the overuse of ESA has serious side effects, therefore, Medicare decided to exclude Hgb < 10 mg/dl as a QIP criterion.

In the calendar year 2012, CMS again revised the criteria. This time, it included three clinical measures to determine total performance scores. The clinical indicators included, the proportion of patients with Hgb > 12 mg/dl and URR ≥ 65% and vascular access treatment (VAT) (Centers for Medicare & Medicaid Services, 2013b; Fishbane & Hazzan, 2012). VAT is associated with lower rates of localized infections, thrombosis and better patient survival (Chand, Teo, Fatica, & Brier, 2008). Further, lower rates of Hgb > 12 and higher rates of URR > 65% marks better quality (Fishbane & Hazzan, 2012). In 2012, QIP expanded its base by including pediatric, home dialysis and peritoneal dialysis facilities.

In calendar year 2013, CMS further included six clinical and four reporting indicators to examine the quality of dialysis facilities. Additionally, in lieu of URR, CMS introduced three dialysis adequacy measures – percent adult hemodialysis patients with Kt/V >1.2, percent pediatric hemodialysis patients with Kt/V >1.2 and peritoneal dialysis patients with Kt/V >1.7 (Centers for Medicare & Medicaid Services 2013). However, reporting on anemia management was added as a facility reporting measure (Centers for Medicare & Medicaid Services 2013).

It also enforced a 2% penalty on a non-conformance (Chambers, et al., 2013; CMS.gov Centers for Medicare & Medicaid Services ; Iglehart, 2011).

2.4.2 Calculation and use of performance scores

In the calendar year 2010, Medicare compared facility performance in 2010 against its performance in 2007 or national average in 2008, whichever standard yielded a better score. Medicare assigned a score of 10 on each measure, if a facility met or exceeded the given standard. However, it deducted 2 points per percentage if facility fell short of the standard. Given three measures, Hgb < 10g/dL, Hgb > 12 and URR, a facility could attain a maximum score of 30. While, Medicare assigned a higher weight of 50% to Hgb < 10g/dL, the other two were given a weight of 25%. In 2010, Medicare required a facility to score at least 26 to avoid a penalty, a payment reduction of 0.5-2%.

In the calendar year 2011, Medicare compared facility performance in 2011 against its performance in 2007 or the national average in 2009, whichever yielded a better result. An equal weight was used for both standards, Hgb > 12 and URR. The calculated scores were multiplied by 1.5 to get performance scores ranging from 0-30. Facilities were required to score 30 to avoid payment reductions of 0-2%.

In the calendar year 2012, Medicare compared facility performance in 2012 against its national performance rate of mid 2010-2011 (Centers for Medicare & Medicaid Services, 2012). A performance score was assigned to facilities based on two clinical criteria (Hgb >12 and URR) and one reporting criteria vascular access type (fistula versus catheter). The scores ranged from 0-100. Penalties of 0-2% were applied on a sliding scale for the scores below 53.

Table 2.1: ESRD quality incentive program (QIP) performance measures summary 2012-15

	PY [a] 2012	PY 2013	PY 2014	PY 2015
Clinical indicators	Hgb [e] > 12 g/dL Hgb < 10 g/dL URR [f] > 65%	Hgb > 12 g/dL, URR > 65%	• Hgb > 12 g/dL • URR • VAT [g]	Hgb > 12 g/dL VAT Measure Topic (fistula, catheter) Kt/V Dialysis Adequacy Measure Topic (hemodialysis, peritoneal dialysis, pediatric hemodialysis)
Reporting indicators	None	None	• NHSN [c] • ICH CAHPS [d] • Mineral Metabolism	• NHSN c ICH CAHPS • Mineral Metabolism • Anemia Management
Performance period	CY[b] 2010	CY 2011	CY 2012	CY 2013
Performance standards	Lesser of the performance rate in CY 2007 OR the national performance rate in CY 2008	Lesser of the performance rate in CY 2007 OR the national performance rate in CY 2009	National Performance Rate (July 1, 2010 – June 30, 2011)	National Performance Rate (CY 2011)
Weights	50% Hgb < 10 g/dL 25% Hgb > 12 g/dL 25% URR > 65%	50% Hgb > 12 g/dL 50% URR > 65%	Clinical: 90%, Reporting: 10% If the facility has only one type of measure, that type is weighted at 100% of the score.	Clinical: 75%, Reporting: 25%

	PY [a] 2012	PY 2013	PY 2014	PY 2015
Total score (min requirement)	30 (26)	30(30)	100 (53)	100 (60)
Minimum Data Requirements	11 cases for each measure	11 cases for each measure	Facility needs either (i) 11 cases for at least one clinical measure or (ii) to qualify for at least one reporting measure.	Facility needs both (i) 11 cases for at least one clinical measure and (ii) to qualify for at least one reporting measure. Note: The 11-case minimum now also applies to reporting measures.
Low volume adjustment	None	None	None	Applied to clinical measures with 11 – 25 cases

Source: Centers for Medicare and Medicaid Services, ESRD QIP Summary: Payment years 2012-2016

Notes:
[a] PY Payment year;
[b] CY Calendar year
[c] NHSN National Healthcare, Safety Network
[d] ICH-CAHPS In-Center Hemodialysis Survey Consumer Assessment of Healthcare Providers and Systems
[e] Hgb Hemoglobin
[f] URR Urea reduction ratio
[g] VAT Vascular Access Treatment

In the calendar year 2013, CMS compared facility performance in 2013 against its performance National performance rate of CY 2011 (Centers for Medicare & Medicaid Services 2013). A performance score was estimated based on six clinical measures and four reporting measures (Table 2.1). A 75% weight was assigned to clinical and 25% to reporting measures (Center for Medicare and Medicaid Services, 2012b). The scale of 0-100 was devised. Medicare required the facility to score at least 60 to avoid penalties.

In addition to the standards and calculation details, Medicare also defined the facility eligibility for score reporting. Before 2012, the eligible facilities included those for which each performance measure was reported for at least 11 patients (Centers for Medicare & Medicaid Services, 2012). In 2012, the eligibility included reporting on 11 patients for at least one clinical indicator and informing on the reporting indicator. In 2013, the total performance scores were reported for facilities that received scores on at least one clinical and one reporting measure (Centers for Medicare & Medicaid Services 2013).

The section below includes the description and clinical significance of the recent measures. For the calendar year, 2013 QIP scores are calculated using both clinical and reporting measures. The clinical measures include, Hgb of >12 mg/dl, Kt/V for adult hemodialysis, adult peritoneal dialysis patients and pediatric hemodialysis patients, VAT-Catheter and VAT-AVF (Centers for Medicare & Medicaid Services 2013). While, reporting measures incorporate, reporting infections to the Centers for Disease Control and Prevention's (CDC) National Healthcare, Safety Network (NHSN); conducting patient surveys on care experience and monitoring patient calcium and phosphorus levels

(Center for Medicare and Medicaid Services, 2016b). In the calendar year 2013, Medicare included anemia management as an additional reporting measure.

2.4.3 QIP: The ESRD Clinical Performance Measures (CPM) for calendar year 2013

The clinical rationales behind the current QIP measures are discussed here. This includes a discussion for the inclusion, and subsequent exclusion, of low hemoglobin values as a measuring point.

Hemoglobin levels

Anemia, or low hemoglobin levels, is the most common complication kidney failure (Kazmi et al., 2001). The lack of erythropoietin, a renal hormone that stimulates bone marrow for RBC production, results in anemia (Bunn, 2013). Uremia, an abnormal urea level in blood, also contributes towards RBC destruction, production of defective RBCs and inability of platelets to create clots at bleeding points (Bunn, 2013). These mechanisms result in either lower RBC count and reduced hematocrit (amount of hemoglobin in the RBC). Hgb less than 9.0-10 g/dl or hematocrit less than 33% are associated with higher mortality among ESRD patients (Hanafusa, Nomura, Hasegawa, & Nangaku, 2014; Hörl, 2013). Treating anemia reduces risk of stroke, cardiovascular diseases and improve outcomes among patients (Groenveld et al., 2008; Saeed, Kousar, Qureshi, & Laurence, 2012).

Before the introduction of bundled payment and FDA label, providers treated anemic patients with Hgb < 10mg/dl with ESA (National Institute of Diabetes and Digestive and Kidney Disease, 2014a). Although, ESA effectively increases the Hgb levels, however, the increase in Hgb $\geq$ 12g/dl is also associated with risk uncontrolled hypertension; vascular thrombosis (blood clots); heart attacks; stroke and higher mortality (Lankhorst & Wish, 2010). The risk of complications increases with the variation in level of Hgb. Specifically, an increase of 1 g/dl in standard deviation of Hgb among ESRD patient population is associated with a 33% increase in mortality rates (Yang et al., 2007). Therefore, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) disapproves the use of ESA among patients with Hgb > 11.5 mg/dl (National Institute of Diabetes and Digestive and Kidney Disease, 2014a). The inclusion of the drug in the PPS bundle and the relabeling by FDA about its use with caution label further restricted the use of epoetin (Manns & Tonelli, 2012). Consequently, the Medicare excluded Hgb < 10 mg/dl from the QIP list. The clinical measures Hgb >12g/dl and URR were included in the QIP criteria in the calendar year 2011.

<u>Dialysis Adequacy Measures</u>

QIP used two measures of URR ≥65% and Kt/V ≥1.2 (National Institute of Diabetes and Digestive and Kidney Disease, 2014b). URR measures a percentage reduction in blood urea during a single dialysis treatment. URR is measured after every 12-14 dialyses or once a month (National Institute of Diabetes and Digestive and Kidney Disease, 2014b). A higher URR demonstrate better dialysis effectiveness. Although, research does not indicate a definitive level of adequate URR, however, URR ≥ 65% implicates in better survival (Port, Ashby, Dhingra, Roys, & Wolfe, 2002).

In 2013, Medicare replaced URR with Kt/V, which denotes dialyzer clearance of urea (Centers for Medicare & Medicaid Services 2013). In Kt/V, ‘Kt’ represents dialysis time and ‘V’ indicates the volume of urea distribution (National Institute of Diabetes and Digestive and Kidney Disease, 2014b). Kt/V estimates both the urea generated by the body during dialysis and extra urea removed during dialysis along with excess fluid (National Institute of Diabetes and Digestive and Kidney Disease, 2014b). The recommended Kt/V normal values for adult and pediatric patient population is ≥ 1.2 and peritoneal dialysis value of ≥ 1.7 (Centers for Medicare & Medicaid Services 2013). A Kt/V of ≥ 1.2 corresponds with the URR of about 63% (National Institute of Diabetes and Digestive and Kidney Disease, 2014b).

Research showed Kt/V ≥ 1.2 relates to lesser dialysis complications and mortality among ESRD patients (Chandrashekar, Ramakrishnan, & Rangarajan, 2014; Greene et al., 2005; Maduell et al., 2016). However, a systematic review of 128 articles that included 44 laboratory outcomes yielded significant but modest effect of dialysis adequacy on mortality compared to the other laboratory markers such as tumor necrosis factor (TNF), pre-albumin, and C-reactive protein (CRP) (Desai, Nissenson, et al., 2009).

Vascular access treatment

Vascular access treatment (VAT) implies the site on the body that is used to remove and return blood during dialysis (National Institute of Diabetes and Digestive and Kidney Disease, 2014c). A perfectly functioning vascular access plays a critical role in efficient dialysis (Pantelias, 2012). The term VAT embodies three types of vascular access, arteriovenous fistula (AVF), an arteriovenous graft (AVG) and central venous catheter (CVC) (Santoro et al., 2014). Compared to the others, AVF is the safest due to lesser infections and thrombosis rates (Chand, et al., 2008; Ng et al., 2011; Pisoni et al., 2009; Ravani et al., 2013). Most providers use a catheter at the onset of dialysis and thereon shift to AVF (Centers for Medicare & Medicaid Services 2013). In calendar year

2013, Medicare included both the percentage of patients with catheter use for more than 90 days and AVF as QIP indicators.

2.4.4 QIP: The ESRD reporting measures for the calendar year 2013

Blood stream infections (BSI)

Hemodialysis increases the risk of localized infection at the vascular access site or widespread BSIs (Patel, Kallen, & Arduino, 2010). NHSN defines BSI as “a positive blood culture collected from a hemodialysis patient as an outpatient or within 1 calendar day after a hospital admission”(Centers for Disease Control and Prevention, 2015). In 2014, CMS introduced BSI as a reporting indicator. Facilities reported infection events on a given protocol to the NHSN, which established an infection surveillance system (National Healthcare Safety Network, 2015) (Center for Disease Control and Prevention, 2015b; Medicare & Medicaid Services 2012).

The order of access type from lowest to highest risk of infections includes, arteriovenous fistula (AVF), an arteriovenous graft (AVG) and Cardiovascular catheter (CVC) (Fysaraki et al., 2013; Patel, et al., 2010). Incidence rates vary from 0.5-27.1/100 patients/month given the type of access used (Klevens et al., 2007). In 2008, CDC reported 37,000 cases of BSI among hemodialysis patients with CVC access. (National Healthcare Safety Network, 2015). BSIs result in substantial complications, hospitalizations and deaths (Li et al., 2009; National Healthcare Safety Network, 2015; Patel, et al., 2010; United States Renal Data System, 2013)

In-Center Hemodialysis- Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) survey

CMS designed ICH-CAHPS in support with the AHRQ to capture patient care experiences (Cavanaugh, 2016; Darby, Crofton, & Clancy, 2006). The survey captures a patient perspective about nephrologist communication and caring; staff communication and caring; operations of the dialysis facility; patient knowledge of treatment options; provider and staff handling of patient problems; and global ratings (Center for Medicare and Medicaid Services, 2016c). In 2011, the facilities started conducting the surveys, however, CMS included ICH-CAHPS as a reporting indicator in 2012 (Centers for Medicare & Medicaid Services, 2013b). CMS publicly reports the survey results and mandates facilities to conduct patient surveys twice a year. (Center for Medicare and Medicaid Services, 2012b).

The psychometric studies on ICH-CAHPS have demonstrated excellent reliability and validity of the survey tool to capture variation in care quality (Weidmer et al., 2014). Further, better patient care experiences translate into higher treatment adherence, lesser use of unnecessary care and lower cost of care (Price et al., 2014).

Mineral Metabolism

In ESRD, damage incapacitate kidneys to maintain blood phosphorus and calcium balance, resulting in deformed bones, vascular problems and seizures (Blaine, Chonchol, & Levi, 2014; Hruska, Mathew, Lund, Qiu, & Pratt, 2008). In the absence of kidney functions, dialysis maintains the mineral balance. Therefore, QIP requires facilities to measure patient serum calcium and phosphorus levels at least once a month (Center for Medicare and Medicaid Services, 2012b).

Anemia Management

To further improve the quality of care and containing the cost, CMS included the anemia management at the facility reporting measure in 2013 (Centers for Medicare & Medicaid Services 2013).

2.5 CONCERNS ABOUT QIP

Researchers raised concerns about QIP's lack of focus on patient outcomes such as patient quality of life and survival (Chambers, et al., 2013; Swaminathan, et al., 2012; Watnick, et al., 2012) (Kliger, 2015). The program has been criticized for its narrow focus on easy to capture clinical and reporting criteria (Moss & Davison, 2015; Nissenson, 2013; Smith & Hayward, 2011). Further, concerns were also raised that completing and reporting QIP data will come at the expense of provider loss of focus on patient care (Watnick, et al., 2012). Research indicated the potential of QIP reports to increase the disparities among ESRD patients, due to not adjusting the scores for patient demographics and socioeconomic conditions (Casalino et al., 2007; A. W. Williams, 2015).

Despite the concerns, the data indicate QIP succeeded in improving the clinical benchmarks (Berenson, et al., 2013). Proportion of patients having target Hgb increased (Fuller, Pisoni, Bieber, Port, & Robinson, 2013; Molony et al., 2016). Data also show a slight increase in use of peritoneal and home dialysis (Rivara & Mehrotra, 2014). QIP also marked an increase in AVF use, after its inclusion as a clinical indicator in 2014. The AVF use increased from 63% in 2010 to 68% in 2013, whereas, catheter use decreased (Pisoni, Zepel, Port, & Robinson, 2015). However, most patients (80%) still undergo catheterization at the onset of hemodialysis (Pisoni, et al., 2015). The main reason for the increase use of the catheter at the initiation of hemodialysis are financial and regulatory barrier to the initial placement and revision of AVF fistula (Allon et al., 2011).

In their review of existing literature, Nissenson et al. found specific clinical measures being weakly correlated with the patient survival (Nissenson, 2013). Conversely, literature showed improvement in survival and reduction in hospitalization rate in 2013 (Medicare Payment Advisory Commission (US), 2015; United States Renal Data System, 2015). Literature also reported the decline in adverse cardiovascular outcomes, including stroke and acute myocardial infarction in ESRD patients in 2013 (Medicare Payment Advisory Commission (US), 2015). However, a limited research exists on association between facility QIP scores and patient outcomes.

This shows that individual clinical measure in the absence of pay-for-performance initiative such as QIP influence care outcome differently.

Another concern regarding QIP implementation was an increased risk of consolidation or closure among smaller and low volume facilities (Slinin & Ishani, 2013; A. W. Williams, 2015). Initial research after the bundled payment initiative indicated merging of smaller facilities with the larger chains (Chambers, et al., 2013). Smaller facilities are more likely to be involved in cherry picking and stinting of required services due to inability to offset financial risk compared to large dialysis organizations (Chambers, et al., 2013; Medicare Payment Advisory Commission (US), 2015). This may impact the quality of care and health outcomes among rural and isolated patients since most rural facilities are smaller in size compared to urban counterparts (Eisenstein, et al., 2008; Medicare Payment Advisory Commission (US), 2015; Yan, Norris, Xin, et al., 2013).

2.6 THEORETICAL FRAMEWORK FOR ADDRESSING QUALITY

The Donabedian model provides a theoretical foundation for our work (Donabedian, 1988). The model has been used in prior researches on ESRD care quality (Argentero, Dell'Olivo, Santa Ferretti, & on Burnout, 2008; Y. N. Hall, Xu, Chertow, & Himmelfarb, 2014; Himmelfarb, Pereira, Wesson, Smedberg, & Henrich, 2004; Lawson & Yazdany, 2012). Donabedian linked structures, processes and outcomes in a continuum to evaluate quality of care (Donabedian, 1988). His model shows structures and processes are associated patient outcomes and quality of care.

In our research, structures include, organizational, patient and population factors (see figure 2.1 below). The processes are the activities that help achieve clinical targets and reporting measure ensured by CMS QIP. The outcomes are further classified into intermediate and final outcomes. The example of intermediate outcomes includes hospitalization ratio and transfusion ratio and of the final outcomes includes, survival rates of patients.

2.6.1 The structure, process and outcome measures

Understanding quality requires a multidimensional paradigm. Here, quality of care refers to QIP scores. The structures, processes and outcomes work closely in tandem to affect quality. The section below presents the structure, process and outcome measures pertinent to our study.

Structures

The structure refers to the characteristics of the setting where the healthcare is provided (Donabedian, 1988). They include administrative processes and physical characteristics, which support the provision of care (Donabedian, 1988). A few examples include human resources (the number of qualified health care personnel, and other health care supporting staff); material resources (money invested and equipment used) and organizational factors (medical staff and method of reimbursement) (Donabedian, 1988).

Structural characteristics are not necessary, but when present, increase the likelihood of better outcomes (Hearld, Alexander, Fraser, & Jiang, 2008). These characteristics impact care processes, which in turn influence healthcare quality. Better health care quality improves health outcomes. The structural variables in our research include dialysis facility resources (chain status, ownership, profit /nonprofit, total stations, night shifts offered); dialysis types offered (in-facility vs home dialysis) and ecological factors (percent population living below the poverty line; percent uninsured; the education rate in the county).

Further, our study also classifies some of the patient characteristics affecting process and outcomes. These characteristics include age; sex; race; comorbidities; the primary cause of renal failure; insurance; location (rural/urban); distance between patient residence and facility ZIP codes (Figure 2.1).

Process

Process refers to activities directly related to the provision of health care (Donabedian, 1988). Healthcare processes involve healthcare providers and support staff. The activities include patient examination, laboratory and radiological testing and disease diagnosis and treatment (Donabedian, 1966). Quality in healthcare process entails meeting required professional standards.

Process measures have a fundamental role in understanding the variation in the performance of the organization and health care outcomes. However, a major limitation in examining the process is that not all processes in an organization can be captured (Donabedian, 1966). Further, a process measure must also be related to the outcome under study. Process measures do not ensure the outcomes, but rather increase the likelihood of them (Donabedian, 1988). Our study includes total performance scores for the QIP six clinical and four reporting measures as a process indicator and its relationship with patient survival.

Outcomes

The outcome measures generally include, patient survival or mortality, morbidities, satisfaction with care, quality of life, the cure of disease (Donabedian, 1966). The organizational structures and processes influence patient outcomes. Further, patient factors also underlie in the relationship between healthcare and health outcomes (Donabedian, 1966). For instance, age, gender, race neighborhood and economic opportunities can confound the relationship between the healthcare and cancer survival. Further, outcomes mostly occur late in the continuum of care, making it difficult to link the processes to the outcome, e.g. survival of cancer patients (Powell, Davies, & Thomson, 2003). Also, multiple factors contribute towards outcomes, making it difficult to attribute factors to an outcome (Steinwachs & Hughes, 2008).

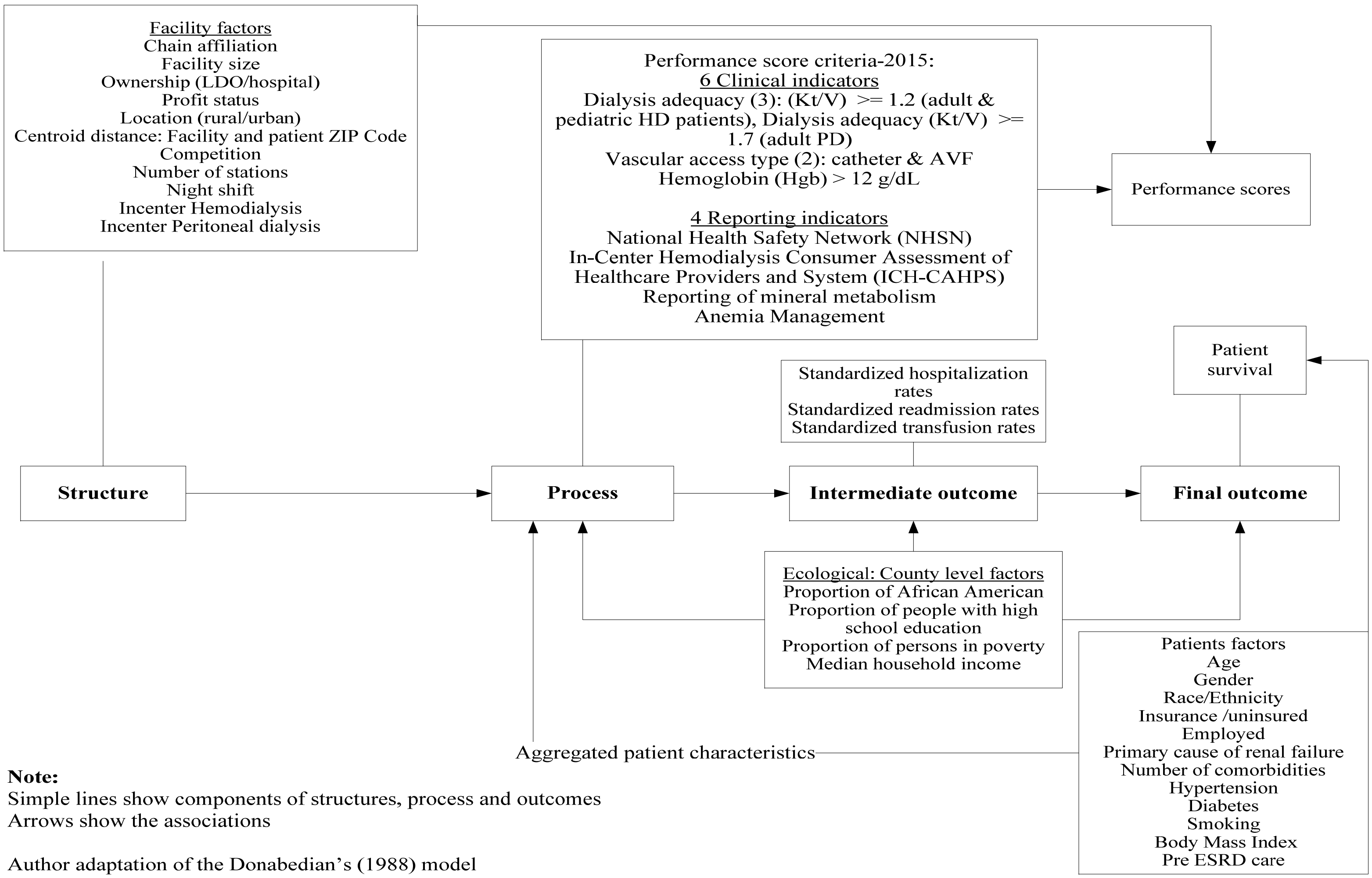

Figure 2.1: Structures, Processes, Outcomes of our study, using the Donabedian framework

The literature emphasizes on using measurable structure, process and outcome indicators (Donabedian, 1966; Steinwachs & Hughes, 2008). For instance, choosing survival as an outcome of a disease that is not acutely fatal could make the study unnecessarily long. However, using death as an outcome of fatal diseases is associated with less bias (Kobewka et al., 2016). Therefore, researchers have assessed the quality of ESRD care using mortality as an outcome indicator (Kobewka, et al., 2016).

ESRD patients have exceptionally high mortality rates. About 20% die annually with a median survival rate of 38 months and five-year survival rate of 33-35% (Kalantar-Zadeh, Kovesdy, & Norris, 2012). This makes mortality a useful indicator of the quality of care of ESRD care.

The section below presents the ESRD literature in relation to the patient, facility and ecological factors associated with the quality of ESRD care and patient outcomes. In summary, a majority included facility and ecological factors or facility and patient factors. However, research generally lacks in accounting for all three types of factors, including, patient, facility and ecological, and even more so after the QIP implementation. Appendix A shows the summary table of the cited articles.

2.7 FACTORS ASSOCIATED WITH ESRD CARE QUALITY

Freestanding facilities constitute 91% ESRD facilities (Medicare Payment Advisory Commission (US), 2015). The facility factors that have been studied for associations with quality of ESRD care include, size, ownership (profit vs. nonprofit) and chain status (chain vs. independent) (William M McClellan, Soucie, & Flanders, 1998; William M. McClellan et al., 2009; Yue Zhang, 2015; Yi Zhang, Cotter, & Thamer, 2011). Mostly, the researchers assessed quality using laboratory indicators, such as URR, Hgb and AVF and albumin levels. However, we found limited data on the association between facility factors and QIP performance scores.

2.7.1 Relationship of facility factors to QIP performance measures/scores

Recently, Zhang et al. reported a variation in QIP performance scores associated with facility and ecological factors (Yue Zhang, 2015). However, the author mentioned not adjusting for the patient factors as the major limitation. Almachraki and colleagues found QIP penalties associated with the facility location. For instance, QIP penalized 6.2% facilities in rural and 4.6% in urban areas (Almachraki et al., 2016). Similarly, facilities in lower socioeconomic areas received more penalties (Almachraki, et al., 2016).

Adjusting for facility, ecological and patient factors, Tangri and colleagues reported that facility factors explain 11.5% variation in URR (Tangri, Tighiouart, Meyer, & Miskulin, 2011). The variation, however, dropped to 6.7% when adjusted for patient case-mix. The study also found patient gender, body surface area, dialysis access type and compliance to the treatment associated with variation in URR. In another study, Fink et al. found that URR varied more by facility factors than individual characteristics, 23.6% vs. 11.3% (Fink, Blahut, Briglia, Gardner, & Light, 2001).

In another study, Tangri et al. reported an association between facility factors and AVF use (Tangri, Moorthi, Tighiouhart, Meyer, & Miskulin, 2010). The variation in AVF due to facility factors persisted even after adjusting for the patient demographics and comorbidities. The authors identified lack of data on surgeon's availability and expertise as a major limitation of their study (Tangri, et al., 2010). Patient gender, age, comorbidities and place of residence did not play a significant role in the AVF use. Further, other researchers also indicated a significant role of facility factors in catheter use, dialysis adequacy and anemia management (Fink, et al., 2001; Fink et al., 2007; Pisoni, et al., 2009).

For-profit status

For-profit organizations own about 85 % renal dialysis facilities (Medicare Payment Advisory Commission (US), 2015). The data show a rising trends in for-profit freestanding dialysis facilities for the past two decades (USRDS 2015). The property rights theory explains the divergence in behavior between profit and nonprofit organizations (Valentinov, 2007). For-profit organizations pursuit for more services to maximize profits to pay dividends to the shareholders (Valentinov, 2007). Compared with non-profit, for-profit ESRD facilities have fewer personnel per dialysis run and lower skilled staff (Meyer and Kassirer 2002; (Held, Garcia, Pauly, & Cahn, 1990; Yoder, Xin, Norris, & Yan, 2013). While for-profit are able to achieve better Hgb and URR targets than non-profit, however, no significant difference is found in patient survival in the two types of facilities. In the case of ESRD care, most facilities are for-profit. Further, market pressure on nonprofits, cause them to become efficient as well (Ozgen 2002).

Studies report a higher proportion of for-profit dialysis facilities achieve clinical benchmarks, after adjusting for the patient factors or facility and ecological factors compared to nonprofit facilities (Griffiths et al., 1994; Hirth, Turenne, Wheeler, Ma, & Messana, 2010; M. R. Saunders & Chin, 2013; Szczech et al., 2006; Yue Zhang, 2015). For instance, Hirth et al. adjusted the patient case-mix to determine the aforesaid association, however, Saunders and colleagues and Zhang et al. adjusted for both the facility and ecological factors, while Szczech et al. adjusted for patient and facility factors. Saunders and colleagues reported URR associated with the status, but not the hemoglobin levels (M. R. Saunders & Chin, 2013; Yue Zhang, 2015). Further, adjusting for patient and facility factors, Foley et al. indicated that for-profit status implicated in better URR, hemoglobin levels and lower use of ESA, intravenous iron, and blood transfusions (Foley et al., 2008).

Chain status

The USRDS defines chain as "…a group of 20 or more freestanding facilities that have been owned or operated by a corporation for one year or longer and that are located in more than one state" (United States Renal Data System, 2014). A remarkable growth has been seen in the chain affiliated freestanding dialysis facilities from 1988 (14%) to 2011 (91%) (United States Renal Data System, 2015).

Two large dialysis organizations account for 70% of all facilities and 75% of treatment of Medicare patients (Medicare Payment Advisory Commission (US), 2015). CMS defines the large dialysis organizations (LDOs) as the ones that own 200 or more facilities. The data show a trend in the consolidation of LDOs. Between 2004-2008, six LDOs merged into two. Further, research also showed that smaller organizations also merged with LDOs at a higher rate after the bundle payment and QIP (Medicare Payment Advisory Commission (US), 2015; The American Society of Nephrology, 2014).

Trend in chain affiliation has increased due to increase in number of dialysis facilities providing outpatient dialysis as a single product (Pozniak, Hirth, Banaszak-Holl, & Wheeler, 2010). Although, financial insolvency is associated with consolidation, however, it is not the only major reason for dialysis facility chain affiliation (Erickson et al., 2016). ESRD facilities with above average profits and quality also merged with chains (Pozniak, et al., 2010). Consolidation appears to be influenced by the presence of other ESRD facilities in close proximity (Erickson, et al., 2016; Pozniak, et al., 2010).

In a recent study, Zhang reported chain affiliated facilities demonstrated better QIP performance scores (Yue Zhang, 2015). While, the literature reports on the association between chain affiliation and specific clinic measures, however, it remains scarce in reporting on the association between QIP scores and chain affiliation. For instance, comparing quality across the large chains vs. independent facilities, Hirth et al. found that large chains achieved URR targets better than independent facilities (Hirth, et al., 2010). The same study found no association between chain affiliation and hematocrit levels. Saunders reported that both URR and hematocrit varied by chain status (M. R. Saunders & Chin, 2013).

Ozgen et al argued that consolidation of the market has an effect on dialysis facility care quality (Ozgen & A Ozcan, 2002). They allude that monopolistic behavior of organization holding a large share of the market impact quality negatively. The authors utilized Hirschman-Herfindahl index (HHI) to determine market competitiveness (Ozgen 2002; (Erickson, et al., 2016)). The risk of consolidation has further increased for small facilities since the QIP implementation (Erickson, et al., 2016; Iglehart, 2011).

2.8 FACILITY FACTORS AND PATIENT SURVIVAL

Facility size

While limited research exists on facility size and survival, although research indicates facility size influences patient outcomes in other settings (Fareed, 2012).

Review of prior research is complicated by the fact that studies measure size in different ways. The literature indicates use of the number of stations (Yan, Norris, Xin, et al., 2013), number of patients treated (Eisenstein, et al., 2008) and number of treatments rendered (Pozniak, et al., 2010) as measures of facility size. Therefore, reports on the association between facility size and patient survival has remained vague.

Further, facility size has also shown a recent increase. A Medicare report of 2015 reported a 4% increase in dialysis stations and 2% increase in the number of treatments between 2013-2014. Similarly, the number of patients treated have shown an annual increase of 2% since 2009 (Medicare Payment Advisory Commission (US), 2015).

Larger facilities of both profit and nonprofit ownership may be operationally efficient- a concept of economies of scale (Nissenson & Rettig, 1999; Richards, Shultz, & Singh, 2009). Yan reported a higher mortality among patients in facilities with 15 dialysis stations or less. Their analysis adjusted for patients, facility and ecological factors (Yan, Norris, Xin, et al., 2013). The study also reported that, compared with whites, blacks and Hispanics demonstrated a higher mortality in the facilities with less than 15 stations (Yan, Norris, Xin, et al., 2013). The authors asserted that financial constraints cause smaller facilities to lack the resources needed to treat complicated patients.

Lee and associates classified facility size using number of patients (Lee, Chertow, & Zenios, 2010). The facilities with 75 or more patients demonstrated 14% higher hospital length of stay than those with 35 or less patients (Lee, et al., 2010). Further, patients being treated in facilities with more than 100 patients demonstrated less compliance or receive shorter treatment than those who visited small size facilities (C. Obialo, Zager, Myers, & Hunt, 2014). Low compliance and shorter treatments are associated with higher mortality (C. I. Obialo, Hunt, Bashir, & Zager, 2012). Einstein also determined facility size using number of patients (small ≤60, medium 61–120, and large ≥120). Smaller size facilities were associated with higher long term mortality among diabetic and non -diabetic patients receiving in-center hemodialysis patients (Eisenstein, et al., 2008).

Chain affiliation

Comparing data from two large chains, Saunders showed no effect of chain type on patient mortality (M. R. Saunders & Chin, 2013). Saunders used ESRD facility reported mortality aggregates. Conversely, comparing chain versus non-chain facilities, USRDS reported lower mortality among patients treated at a chain affiliated facility, using 2012-13 data (United States Renal Data System, 2015). The analysis adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and population death rates. However, it did not account for the ecological and facility factors.

Size of the chain and length of ownership

The chain size, in addition to facility size, shows an association with mortality (Yi Zhang, et al., 2011). Zhang et al. reported that patients at nonprofit small chain affiliated facilities demonstrate lesser mortality than the for-profit large chain organization. The facilities associated with for-profit large chains tend to use higher intravenous drugs, however, do not show improved survival (Yi Zhang, Thamer, Kshirsagar, & Cotter, 2013). Similarly, Van Wyck et al. reported the length of chain ownership among large chain facilities was associated with improved patient (Van Wyck, Robertson, Nissenson, Provenzano, & Kogod, 2010). The study, however, did not compare the large versus small chains or independent facilities. Further, the study adjusted for the patient factors only.

For-profit dialysis facility

Dalrymple et al. reported higher overall hospitalizations due to cardiac failure and vascular access complications among dialysis patients at the for-profit facilities (Dalrymple et al., 2013). The majority of for-profit dialysis facilities achieved better clinical benchmark (URR>65%, hematocrit level and albumin level). However, the studies relating for-profit status with mortality found mixed results. While, most studies demonstrated higher mortality among for-profits (Devereaux et al., 2002; Garg, Frick, Diener-West, & Powe, 1999; M. R. Saunders & Chin, 2013; Straube, 2014; Yi Zhang, et al., 2011), some others found equivocal results (Brooks et al., 2006; Foley, et al., 2008). Brooks and colleagues demonstrated no association between profit status and patient survival using instrumental variable analysis, a pseudo-randomized observational study participants to control for unmeasured bias (Brooks, et al., 2006). Though Foley found a relationship between for-profit status and the attainment of Hgb, URR>65%, but did not find with the survival (Foley, et al., 2008). Foley included hospital patients, in addition to the patients visiting freestanding facilities.

The mixed results of studies examining the survival by profit status facilities suggest the need for further research. Earlier, research indicates that nonprofits try to improve their efficiency in the face of market pressure due to the presence of for-profits. (Garg, et al., 1999; Hirth, 1997). Conversely, for-profit facilities are under pressure due to competition from non-profit to provide services at a lower cost (Hirth, 1997). For-profit are more likely to use fewer resources compared to non-profit to maximize the profits (Yoder, et al., 2013). Therefore, for-profit facilities have also found to be associated with lower care quality and poor patient outcomes including higher comorbidities and mortality (Devereaux, et al., 2002; M. R. Saunders & Chin, 2013; Yi Zhang, et al., 2011).

2.9 ECOLOGICAL FACTORS AND PATIENT SURVIVAL

Evidence suggests a role of neighborhoods in shaping health care systems and their quality and patient outcomes (Stafford & Marmot, 2003; Yen, Michael, & Perdue, 2009). Variation in morbidity, mortality, health care access, risky behavior, income inequality exists across the US nation (Truman et al., 2011). The ecological factors interacts with facility structural factors to influence performance and health outcomes (William M. McClellan, et al., 2009). Dialysis facilities serving poor neighborhoods having more uninsured, minority, unemployed and less educated population are affected with poor patient survival and health outcomes (Y. N. Hall, et al., 2014; Kimmel, Fwu, & Eggers, 2013; Patzer & McClellan, 2012). Similarly, facilities in rural and remote areas report poor performance/quality of care and health outcomes (Almachraki, et al., 2016; Yue Zhang, 2015).

The sections below review major ecological factors that may be associated with dialysis quality and patient survival.

2.9.1 Socioeconomic status

Link and Phelan identified socioeconomic status (SES) as a major determinant of health disparities (Link & Phelan, 1995). SES has been defined as "a broad concept that refers to the placement of persons, families, households and census tracts or other aggregates with respect to the capacity to create or consume goods that are valued in our society"(Miech & Hauser, 2001). Given a broad definition of SES, prior research has used patient income, education and occupation to create a composite factor of socioeconomic status at the individual level without considering the impact of the socioeconomic status of the neighborhood (Link & Phelan, 1995). However, more recent research has focused on neighborhood racial composition, level of Rurality and regional poverty and education levels to determine the impact of SES in relation to incidence and health outcomes (Y. N. Hall, et al., 2014; Ludwig et al., 2011; Nuru-Jeter & LaVeist, 2011; Plantinga, 2013; Shavers, 2007); (Kimmel, et al., 2013; Patzer & McClellan, 2012; Rodriguez et al., 2007; M. Saunders, Cagney, Ross, & Alexander, 2010). The section below presents SES determinants and their association with health outcomes among dialysis patients.

Regional Poverty

Neighborhood poverty and racial segregation are strong predictors of ESRD incidence and associated health outcomes and disparities (Hu, Gonsahn, & Nerenz, 2014; Ludwig, et al., 2011; Stevens et al., 2014; Volkova et al., 2008). In the U.S., about 20% dialysis facilities are located in poor counties (Almachraki, et al., 2016). ESRD facilities located in poor urban counties also serve minorities (Y. N. Hall, et al., 2014). Dialysis patients in poor areas are younger and African Americans (Almachraki, et al., 2016).

The characterization of poverty varies in ESRD literature. The commonly used criteria include, geospatial concentration of poverty, ZIP code defined areas, and the areas defined by census tract. Facilities located in poor areas show poor health outcomes, including patient survival, in both urban and rural areas (Almachraki, et al., 2016;

Kimmel, et al., 2013; William M McClellan et al., 2010; M. Saunders, et al., 2010). Whites tend to live in areas with a higher median income (black, $26,742 versus White, $41,922) (Kimmel, et al., 2013). Living in a higher income area relates to better survival (M. R. Saunders & Chin, 2013). Further, minority ESRD patients living in segregated areas are more likely to die early (Kimmel, et al., 2013).

Rurality

Facility location has been reported as associated with health outcomes among ESRD patients (Maripuri, Arbogast, Ikizler, & Cavanaugh, 2012; O'hare, et al., 2006). Rural patients face more healthcare access issues than urban. The section below presents the association between facility rurality and its interaction with structural and patient factors and health outcomes among dialysis patients.

Rurality and facility volume

About 20% of ESRD facilities are rural (Medicare Payment Advisory Commission (US), 2015). The low number of rural facilities relates to low rural population density. Rural facilities face low patient volume and low profit margins (Medicare Payment Advisory Commission (US), 2015). Further, compared to urban facilities, rural facilities operate fewer dialysis stations and offer fewer night shifts (O'hare, et al., 2006; Yoder, et al., 2013). Rural facilities are also smaller in size, cater to a smaller number of patients, have fewer nursing staff and provide a lower number of treatments (Medicare Payment Advisory Commission (US), 2015; O'hare, et al., 2006; Yoder, et al., 2013). These facilities also offer less peritoneal dialysis services and home hemodialysis training services (O'hare, et al., 2006).

Due to a low profitability, large chains and for-profit do not prefer to operate in rural areas. Therefore, most rural facilities are owned by small chain, independent and nonprofit organization (O'hare, et al., 2006). Rural facilities also face financial constraints due to low volume of patients and a higher treatment costs (Medicare Payment Advisory Commission (US), 2015). The remote rural facilities remain at even a higher financial risk.

Rurality and patient characteristics

Rural patients face access to care challenges, including availability of only in-center hemodialysis; lack of transportation; longer travel distances and commuting time; geographic isolation; less dietary education, lack of access to a nephrologist and specialized care; delayed initiation of Pre-ESRD care and lower quality of care (Bennett, Probst, Vyavaharkar, & Glover, 2012; L. Chan, Hart, & Goodman, 2006; Maripuri, Ikizler, & Cavanaugh, 2013; Murray, 2008; Nemet & Bailey, 2000; Stephens et al., 2013; Wang, Lee, Patel, Maciejewski, & Ricketts, 2011).

Moreover, referral hospitals may be out of reach for the patients due to large travel distance in the rural areas. Rural patients travel 2.5-4 times farther than the urban patients to access specialized ESRD care (Stephens, et al., 2013). The fewer night shifts, lesser dialysis stations and consolidation also cause rural patients to travel more distances (O'hare, et al., 2006). Higher travel distances are associated with missed appointments and shorter treatment sessions (K. E. Chan, Thadhani, & Maddux, 2014).

These barriers, along with the need for a long-term dialysis, needing about 3-4 sessions of 3-4 hours each per week, hamper rural patients access to care. Frailty among ESRD patients also aggravates the negative effects of these physical barriers (Jhamb, Weisbord, Steel, & Unruh, 2008). Rural residents also tend to be uninsured, live farther from hospitals and lack transportation (L. Chan, et al., 2006). Therefore, lower adherence of dialysis is common among rural patients.

Rurality and health outcomes

Research indicated worse outcomes among rural patients undergoing peritoneal dialysis (Maripuri, et al., 2012). Patients especially, in micropolitan and remote rural areas experience higher mortality than urban patients. Maripuri et al. suggested that rural patients opt for peritoneal dialysis as the modality can be administered at home. (Maripuri, et al., 2012). Maripuri et al adjusted for patients' characteristics.

Contrary to Manipuri et al., other studies did not find an association between rurality and patient survival (Ajmal, Bennett, & Probst, 2016; Thompson et al., 2012). The authors adjusted for patient characteristics including, travel distances. In another study, Mairpuri et al related patient survival with the pre-ESRD care (Maripuri, et al., 2013). They noted that rurality did not influence patient survival, keeping pre-ESRD care and other patient covariates constant. O'Hare and associates explored within rural variation, after adjusting for patient factor only. They reported a better survival among rural blacks than rural whites (O'hare, et al., 2006).

Neighborhood segregation and racial composition

Minority serving facilities are larger in size and mostly located in metropolitan poor counties (Y. N. Hall, et al., 2014). Hall categorized facilities into quintiles with facilities in 5th quintile serving lower socioeconomic areas. They also provide lesser home dialysis to the patients and fewer part time staff member as compared to the facilities providing treatment to the lesser number of minority population (Y. N. Hall, et al., 2014). Facilities serving black populations and poor neighborhood lack specialized care and report lower rates of AVF use (William M McClellan, et al., 2010; Prakash et al., 2010).

Prior research showed that the racial composition of the neighborhood also influences the occurrence of ESRD, access to pre-ESRD care, rate of transplantation and survival (Evans et al., 2011; Kucirka et al., 2011; Nee et al., 2016; M. Saunders, et al., 2010). Black patients receiving hemodialysis in minority neighborhoods experience more disparities in health, income and employment, compared with whites (Kimmel, et al., 2013). Further, black hemodialysis patients living in segregated areas experience higher mortality (Kimmel, et al., 2013). Facilities serving a predominantly black population score lower on QIP criteria than those serving largely white populations (Yue Zhang, 2015). Facilities serving minorities in the greater number report worse survival (Y. N. Hall, et al., 2014; Kalbfleisch et al., 2015; M. R. Saunders & Chin, 2013). The facilities located in black neighborhoods reported worse survival among black patients, compared with white patients going to the same facilities. The association sustained even after controlling for neighborhood poverty (M. R. Saunders & Chin, 2013).

Converse to the above findings, Rodriguez et al. found a black advantage in survival when race was used to determine at an individual patient level (Rodriguez, et al., 2007). The authors compared black and white survival among patients living in predominantly black ZIP codes. After adjusting for the patient and ZIP code characteristics, they found that blacks were less likely to die, however, the time to transplant did not differ in the two races. However, the facility aggregated data showed worse outcomes in facilities located in predominantly black ZIP codes.

Neighborhood regional education and income level

Research to assess the impact of regional education and income level at the of quality of dialysis facility remains scarce. Educational attainment and income level implicate both in healthcare access and health outcomes (Adler & Newman, 2002; Ross & Mirowsky, 1999). The county morbidities and mortality levels vary by regional income and education (World Health Organization, 2008). Lower county income is associated with higher mortality among both black and white population (Kimmel, et al., 2013). Lower county education and income are also associated with lower rates of pre-ESRD care and delayed nephrologist referral (Patzer & McClellan, 2012).

Regional ESRD networks

After the inclusion of ESRD as a disease based eligibility for the Medicare in 1972, the Congress realized a need to integrate a broad array of ESRD providers. In 1976, CMS proposed 32 ESRD networks in the country (Center for Medicare and Medicaid Services, 2012a). Subsequently, in 1978, Congress created a statutory requirement for the Network Organization Program in consistency with the criteria defined by the secretary of the Department of Health and Human Services (Center for Medicare and Medicaid Services, 2012a). The Network Coordinating Councils (NCC) were formed to coordinate ESRD care. They linked hospital and dialysis facility representatives with patients, physicians, dietitians, social workers and other related healthcare professionals. The focus of ESRD networks was to bring cost effectiveness and accountability; ensure quality of care and promote kidney transplantation and home dialysis (Center for

Medicare and Medicaid Services, 2013). Later in 1987, the 32 networks were condensed into 18 networks. Broadly, the networks were classified by regions - Northeast: 1-5; South: 6-8 and 13-14; Midwest: 9-12 and West: 15-18.

In 1988, CMS awarded contracts to the 18 networks. Quality assurance remained a major focus of the network organizations. Facilities submit data to their respective regional network. The networks conduct quality improvement projects by collecting information on the measures including the Kt/V, urea reduction ratio, serum albumin, and hemoglobin. The reports help determine a regional variation in care quality and facility performance.

Intra and inter network variations exist in AVF use, anemia management and URR targets (United States Renal Data System, 2015). The networks also vary in ESRD incidence rates and health outcomes (M. R. Saunders & Chin, 2013). Analyzing the networks by the regions, South, Midwest, West and Northeast, the same study found South was more likely to report a worse survival and less likely to attain target hemoglobin, compared with the Midwest. Conversely, South demonstrated better dialysis adequacy. Zhang reported worse ESRD care quality in the Northeast (Yue Zhang, 2015). Szcezec et al. reported a confounding effect of case-mix in association between network and mortality (Szczech, et al., 2006).

2.10 PATIENT FACTORS AND SURVIVAL

Health outcomes vary by individual age; race; ethnicity; gender; poverty; health insurance; employment, number and severity of comorbidities (Truman, et al., 2011). Patient factors relate with the incidence and prevalence of CKD and ESRD and associated health outcomes (Centers for Disease Control and Prevention, 2014). In our study, patient factors are adjusted as covariates. The section below reviews evidence about the association between individual factors and health outcomes.

Race

Patient level racial disparities pose a major challenge in providing equitable care in the U.S. Racial disparities are multifaceted. Assari delineated the underlying factors in the association between patient race and mortality(Assari, 2016). He hypothesized that racial difference in mortality is basically the function of the interconnection of multidimensional factors: the proximity factor (behavioral factors), intermediate factor (chronic medical condition) and distal factors (SES) (Assari, 2016). Community level vulnerability (residential segregation, poverty) and individual level vulnerability (individual dialysis dose, treatment frequency, race, income, education) are intertwined to influence health and health outcomes (Nissenson, 2013).

A clear gradient exists between income and education among minorities versus whites, and so in the health outcomes (D. R. Williams, Mohammed, Leavell, & Collins, 2010). Minorities are more likely to have CKD associated risk factors (Centers for Disease Control and Prevention, 2014; Jackson et al., 2013). Minorities experience a higher prevalence of CKD, its complications and rapid progression to ESRD (Derose et al., 2013). Further, Minorities including blacks, Hispanics, Native Americans and Asians develop ESRD at a 1.5-4 times higher rates than whites (Garcia-Garcia & Jha, 2015). SES interacts with relationship of race and CKD/ESRD (Crews, Charles, Evans, Zonderman, & Powe, 2010). ESRD, also shows an increasing trend among older age minority population (United States Renal Data System, 2015).

Despite the higher incidence of CKD, ESRD and associated risk factors among minorities (Kochanek, Arias, & Anderson, 2013);(Volkova, et al., 2008), minority ESRD patients demonstrate better survival than whites (Arce, Goldstein, Mitani, & Winkelmayer, 2013; Derose, et al., 2013; Yan, Norris, Alison, et al., 2013). The survival advantage of blacks is called 'survival paradox' (Kalantar-Zadeh, et al., 2012; United States Renal Data System, 2015). While, the mortality among blacks and whites is comparable at younger at, blacks show better survival than whites at later ages (Kucirka, et al., 2011; United States Renal Data System, 2014).

Krucika et al provides a possible explanation for the aforesaid paradox. (Kucirka, et al., 2011). They found an interaction between age and race. While, younger ESRD black patients had worse survival than the White counterparts, however, the white advantage reversed among patients older than 50 years (Kucirka, et al., 2011). Zadeh et al. asserted that lack of insurance, access to care and access to specialized care among younger black patients result in worse outcomes (Kalantar-Zadeh, et al., 2012). These factors delay access to pre ESRD care resulting in patients seeing providers with more advanced disease and complication. However, older blacks and whites have better parity in health insurance coverage and access to care (Kalantar-Zadeh, et al., 2012). Author asserted in addition to difficulties in access, younger blacks also mistrust the healthcare system.

The other researchers have indicated biological phenomenon underlying survival paradox. Whites possess higher levels of pro inflammatory cytokine interleukin (IL) 6 and C-reactive protein (CRF) (Crews, Sozio, Liu, Coresh, & Powe, 2011; Noori et al., 2011). The IL6 increases the predisposition to inflammation and mortality (Crews, et al., 2011). The survival advantage among older blacks also links with a larger body mass index (BMI) and high energy fat diet, compare with whites(Ricks et al., 2011). Further, a higher parathyroid hormone has also been implicated in the survival advantage among blacks (Noori, et al., 2011). Feroze et al found that family system among blacks relates to the advantage (Feroze, Martin, Reina-Patton, Kalantar-Zadeh, & Kopple, 2010).

Age and gender

Older males are more likely to develop CKD and faster progression to ESRD than women (Centers for Disease Control and Prevention, 2014). Older age among ESRD patients is also associated with higher morbidity. The aging U.S. population, increasing comorbidities, and longevity have resulted in higher ESRD incidence and prevalence (M. E. Williams, Sandeep, & Catic, 2012). Further, the risk of mortality also increases with the comorbidities including, dementia; cancer; congestive heart failure; peripheral vascular disease and low albumin level are individually associated with mortality in the initial six months of maintenance dialysis therapy (Bradbury et al., 2007; Cohen, Ruthazer, Moss, & Germain, 2010).

Villar and colleagues reported age, gender and diabetes associated with the long term health outcomes among patients on hemodialysis (Villar, Remontet, Labeeuw, & Ecochard, 2007). The study reported higher four-year mortality rates among women than men after accounting for patients characteristics and comorbidities (Villar, et al., 2007). The high mortality of women in ESRD is contrary to the female survival advantage in the general population.

Comorbidities/risk factors

Diabetes, cardiovascular disease, obesity and hypertension predispose individual to CKD (United States Renal Data System, 2015). Further, they are also the common comorbidities associated with ESRD. Diabetes and Hypertension attribute to more than two-third ESRD incidence (Centers for Disease Control and Prevention, 2014). Cancers and cardiovascular diseases (CVD) relate to a higher mortality (United States Renal Data System, 2015). USRDS indicated CVD as a main cause of mortality among ESRD patients (United States Renal Data System, 2015).

Mineral metabolism, albumin levels and GFR

In a meta-analysis, Palmer et al found deranged serum phosphate associated with a higher ESRD mortality (Palmer et al., 2011). Conversely, the analysis reported no effect of parathyroid hormone and calcium on mortality. The other study reported a higher mortality among patients with albuminuria and low GFR (Hallan et al., 2012).

Access to pre-ESRD care

Early initiation of Pre-ESRD care is associated with lesser infections, hospitalization, morbidity and mortality, and higher transplantation rates (Chen et al., 2010; Gillespie et al., 2015; Maripuri, et al., 2013; Smart & Titus, 2011). Early pre ESRD care improves patient readiness and smooth transition for dialysis. Receiving ESRD care is associated with decrease rate of all-cause mortality and increase transplant (Hao et al., 2015; Maripuri, et al., 2013; William M. McClellan, et al., 2009; Ravani, et al., 2013). Duration of pre-ESRD care plays an important role in the survival of dialysis patients.

Pre-ESRD care for more than 12 months is more likely to result in better health outcomes (Gillespie, et al., 2015).

A better survival among ESRD patients is associated with timely referral to a nephrologist; initiation of dialysis and dietary education; placement of a permanent vascular access; and referral for pre-emptive kidney transplantation (Saggi et al., 2012). However, data indicate low rates of pre-ESRD care (67%) (Hao, et al., 2015) including, nephrologist care (53.5%), permanent dialysis access at the time of the start of hemodialysis (17.7%) and dietary education (11.9%) (Gillespie, et al., 2015; Maripuri, et al., 2013). Even lower proportion of patients (28%) had consistent access to Nephrology care for 12 months or more (Gillespie, et al., 2015). Further, about 33% of incident cases of CKD did not receive any nephrology care. Rural and micropolitan population receive even less dietary and other care(Maripuri, et al., 2013).

Barriers to optimal pre-ESRD care include, older age; low SES; being a minority, living in black residential, large metropolitan and remote rural areas; lack of education and insurance and comorbidities (Hao, et al., 2015; William M. McClellan, et al., 2009; Navaneethan, Aloudat, & Singh, 2008; Prakash, et al., 2010; Yan, Cheung, et al., 2013). Navaneethan and associates reported lack of communication between primary care physician and nephrologist as a reason for delayed pre-ESRD care. Linking census data to the CMS data, McClellan reported an inverse association between county poverty and AVF use (William M McClellan, et al., 2010).

Among pre-ESRD care factors, only AVF is the part of the QIP criteria. Despite the initiatives such as “fistula first” and AVF inclusion in QIP, the rates of AVF use remain low, especially among incident hemodialysis patients. Linking census data to the

CMS data, McClellan reported an inverse association between county poverty and AVF (William M McClellan, et al., 2010). Research lacks in probing interaction between poverty and minority population in relation to the health outcomes among ESRD patients.

Dialysis modality

ESRD patients on dialysis undergo either peritoneal dialysis or hemodialysis. Most patients undergo hemodialysis, which is mostly administered in facilities (United States Renal Data System, 2015). Conversely, peritoneal dialysis is usually performed at home.

Data show mortality rates dropped by 22% among hemodialysis patients and by 34% among peritoneal dialysis (United States Renal Data System, 2015). In 2013, the adjusted mortality rate among hemodialysis patients was 172/1000 patients/year and among peritoneal dialysis patients was 152/1000 patients/years. The mortality by dialysis modality varies with facility location, severity of comorbidities and age. Peritoneal dialysis is associated with lesser mortality among younger than 65 years nondiabetic patients with no cardiovascular comorbidities (McDonald, Marshall, Johnson, & Polkinghorne, 2009; Weinhandl et al., 2010).

Duration of treatment also affects the association of dialysis modality and outcomes. Mehrotra et al. reported no difference in mortality among patient on hemodialysis and peritoneal dialysis in the initial phase (Mehrotra, Chiu, Kalantar-Zadeh, Bargman, & Vonesh, 2011). Conversely, Sinnakirouchenan et al. reported a better survival among peritoneal than hemodialysis patients, however, the latter survived better after the initial phase of treatment, with an overall survival advantage of 1.5-2 years (Sinnakirouchenan & Holley, 2011). However, younger than 65 years, nondiabetic peritoneal dialysis patients with no comorbidities at the incidence of ESRD demonstrated better survival. Type of vascular access interact with dialysis modality to influence survival. For instance, use of CVC among hemodialysis patients is associated with better survival in the early treatment period than among peritoneal dialysis patients (Perl et al., 2011).

Distance from facilities

Given frequent and long term treatment, travel time and distances are particular issues faced by the ESRD dialysis patients. A typical dialysis patient travels 150-160 times/year to seek treatment. In the U.S., each visit entails an average travel of 7.2 one-way miles (Stephens, et al., 2013). Travel distances vary by region. Rural patients travel 2.5 times farther than urban patients (an average of 15.9 one-way miles versus 6.2 one-way miles) The travel distances are longest in the South central region (9.5 miles one-way) and the shortest in the Northeast region (average of 6.0 miles one-way) in the country(Stephens, et al., 2013). ESRD patients living in remote areas experience most access to care challenges, along with higher likelihood of comorbidities and complications.

The distance adds its toll with a need for frequent travel episodes. Age and frailty add to the travel stress. Patients living 50 km (about 31 miles) or more from the facility are assessed less frequently on HbA1c and serum albumin levels and less likely to receive medications including, Angiotensin-converting enzyme (ACE) inhibitors or receptor blocker (Rucker et al., 2011). The distances are also associated with delayed pre-ESRD care-seeking, suboptimal hemoglobin levels, serum calcium and phosphorus level (Chao, Lai, Huang, Chiang, & Huang, 2015; Thompson et al., 2013).

The literature also reports an association between travel distances and mortality (Bello et al., 2012; Rucker, et al., 2011; Thompson, et al., 2012). Using centroid (straight line distances between center of patient ZIP code and facility ZIP code), Thompson and colleagues reported a distance of 100 miles or more from facility increase the risk of mortality among ESRD patients (Thompson, et al., 2012). Conversely shorter travel distances are associated with higher treatment adherence, better quality of care and improved survival (Moist et al., 2008).

2.11 LIMITATION OF PUBLISHED LITERATURE

Given QIP recent promulgation, limited evidence exists in association between facility factors such as facility size and QIP scores and the association between the scores with patient survival. Further, patients, facility and ecological factors work in tandem to influence care quality and patient survival, therefore, they need to be adjusted while determining factors associated with QIP and survival. In a recent study, Zhang et al. determined association between facility and ecological factors with QIP performance, however, non-inclusion of aggregated patient characteristics was their major limitation (Yue Zhang, 2015). Further, Almachraki et al. also did not include aggregated patient data while demonstrating an association between facility location and QIP scores (Almachraki, et al., 2016). Therefore, our study adjusted for aggregated patient, facility and ecological factors to demonstrate the association between facility size and QIP scores. Moreover, association between QIP scores and patient outcomes including survival has yet not been studied.

2.12 HYPOTHESES

1. Net of other factors, free standing dialysis facilities have better performance scores than smaller facilities
2. Net of other factors, patient survival is associated with QIP performance scores.

CHAPTER III- METHODS

3.1 RESEARCH QUESTIONS

1) Is facility size, measured as number of dialysis stations at the facility, associated with the performance of freestanding dialysis facilities as measured by QIP scores?

   Hypothesis: Net of other factors, larger facilities have better performance scores than smaller facilities

2) Is freestanding dialysis facility performance as measured by QIP scores associated with the survival of the ESRD patients on dialysis?

   Hypothesis: Net of other factors, patient survival is positively associated with QIP performance scores

3.2 STUDY METHODS - QUESTION 1

Before we start describing study 1 methods, it is important to clarify that for Medicare data, reporting or payment year (PY) lags by two years from the service or calendar year (CY). For example, services rendered in 2013 are reported in 2015 (Centers for Medicare & Medicaid Services, 2013a). For AHRF, Census and USRDS data, we take the data corresponding to the Medicare CY data.

3.2.1 Study design and unit of analysis

We used a cross-sectional design. All analyses were conducted at the facility level using CY 2013 data files. The performance scores vary by year, therefore we used the latest scores for which we could have complete CMS and USRDS data files. The USRDS individual patient data were aggregated to calculate facility level information for variables not present in the aggregated files including Medicare, Census or AHRF. Our aggregated facility indicators included: proportion of patients of age ≥ 65 years, proportion of African-Americans patients, proportion of patients with two or more comorbidities, proportion of patients with pre-ESRD care and proportion of patients jointly covered by Medicare and Medicaid. The details are included in the section describing variable construction (Section 3.2.5).

3.2.2 Study Sample

We used the most recent Medicare data (CY 2013 or PY 2015) and USRDS 2013 data files. A total of 5517 facilities, yielded from merging the CMS "Quality Incentive Program" (QIP), "Dialysis Facility Compare" (DFC) and "Dialysis Facility Level Impact" data files, were included in the analysis.

3.2.3 Data files

The study utilized Medicare and USRDS data including CMS QIP; CMS dialysis facility compare; CMS facility level impact; United States Renal Data, Core Standard Analytical ((USRDS-SAF); Census data and Area Health Resource Files (AHRF). As indicated earlier, the USRDS patient data were aggregated only for variables not available in facility level Medicare, Census or AHRF files.

The section below describes the data files and variables included in them. Table 3.1 lists the covariates we included from each file in our study.

Medicare facility files

CMS QUALITY INCENTIVE PROGRAM DATA

The QIP file PY 2015 were used to extract facility QIP performance scores (outcome) for CY 2013. The variable served as the outcome for study 1 and the key exposure in the study 2. The QIP file is publicly available at the URL: https://data.medicare.gov/data/archives/dialysis-facility-compare.

CMS DIALYSIS FACILITY COMPARE DATA

The CMS dialysis facility compare data was used in the calendar year 2013. We extracted facility structural factors including ownership (profit/non-profit), chain status and number of stations. The file can be accessed from the URL: https://data.medicare.gov/data/archives/dialysis-facility-compare.

CMS FACILITY LEVEL IMPACT FILE

The CMS level impact file of the calendar year 2013 was used for the analysis. The impact data file reports facility location, type (freestanding/hospital based), number of treatments rendered and volume (low vs. not low). The file is available at the URL: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1614-F.html

UNITED STATES RENAL DATA SYSTEM PATIENT AND FACILITY DATA

United States Renal Data system (USRDS), a national renal data registry, which collects, analyzes and disseminates findings about the ESRD patients in the U.S (United States Renal Data System). Funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), USRDS collects patient sociodemographic, morbidity and mortality; treatments; and dialysis facility level information.

We used the USRDS patient and facility Standard Analytical Files (SAF). The SAF files include both facility and patient data in separate files. The facility file included number of treatments, number of patients, number and type of staff (technician and dietitian) (Table 3.1). The patient file included patient demographics, socioeconomic status, treatment history, insurance and comorbidities (Table 3.1). Patients data were aggregated at facility level using facility USRDS identification (PROVUSRD) to report indicators mentioned in the section 3.2.1 above. We linked USRDS facility and aggregated patient data with the publicly available CMS dialysis facility files including DFC, impact and QIP.

AREA HEALTH RESOURCE FILE

Area Health resource files (AHRF) comprised of information about health care resources and socioeconomic characteristics of the population relevant to health care use. We used 2013 AHRF file. The data are provided of more than 6000 variables across US counties. AHRF data are available at https://ahrf.hrsa.gov/download.html. We included median annual household income, percentage of persons in poverty, proportion of blacks and Hispanic per county and unemployment rate among 16 plus individual, using the county FIPS.

3.2.4 List of variables

<u>Dependent variable</u>

We included QIP performance scores, CY 2013, as the study 1 outcome

<u>Independent variable</u>

Main exposure

The number of dialysis stations per facility was our main exposure.

Covariates

The study adjusted for patient, facility and ecological characteristics at an aggregated level. Please see the table 3.1 for details of source file and variable names and types.

3.2.5 Variable construction

<u>Dependent variables</u>

Of the 5517 facilities included in CMS QIP, DFC and impact files, in CY 2013, we noted missing QIP scores for 305 (5.5%). Among the 5,212 facilities for which the QIP scores were reported, 269 facilities scored less than 60 (failed). CMS did not report QIP scores for facilities rendering less than 11 treatments (Centers for Medicare & Medicaid Services, 2012).

<u>Independent variables</u>

Main exposure

The number of dialysis stations per facility was our main exposure.

Facility level variables

ESRD Network

We consolidated the 18 ESRD networks into four regions including Midwest, Northeast, South and West. Further, prior research has also consolidated networks into regions (M. R. Saunders & Chin, 2013).

Estimation of rurality

The facility level rurality was determined using Urban Influence Codes (UIC). The UIC codes are available at the URL: https://www.ers.usda.gov/data-products/urban-influence-codes.aspx. UIC categorizes 3,143 counties, county equivalent and the independent cities of United States into 12 distinct groups (United States Department of Agriculture Economic Research Service: Economic Research Service, 2013). The division is based on population size and commuting data from population data from the 2010 Census of Population and commuting data from the 2006-2010 American Community Survey (ACS). UICs of 1 and 2 levels of rurality was classified as "Urban" while all other UICs as rural. Analysis across levels of rurality used three groups: "micropolitan rural" (UICs 3 5 and 8) "small adjacent rural" (UICs 4 6 and 7) and "remote rural" (UICs 9 10 11 and 12).

Market competition

Market competition was determined using Hirschman-Herfindahl index (HHI) (Hyman & Kovacic, 2004). The index utilizes market share of each organization in the larger pool of similar organization. The market share of each organization was then squared to determine HHI and summed across the organization in a market, which ranges from 0-1. A higher score demonstrates less competition or monopoly (Hyman & Kovacic, 2004).

We calculated the market share of each dialysis facility using the proportion of total dialysis treatments produced by a facility to the total number of dialysis treatments rendered by all other freestanding, in each county.

USRDS patient data-aggregated at the facility level

Age and gender

Gender and age of patients was aggregated as per facility proportion of male patients and per facility average age of the patients, respectively. We calculated age by using data of birth and date of death and December 31, 2013 for patient who remained alive until the end of December, 2013.

Racial composition

We adjusted for per facility proportions of non-Hispanic black patients and proportion of Hispanic patients.

Average distance covered by the patient at the facility

We also adjusted for the per facility average distance covered by the patients in 2013. We calculated centroid distances between patient and facility ZIP Code using ZIPDIST SAS macro (SAS support, 2014). Further, the average distance of patients from respective facilities was calculated.

Proportion of patients with more than 2 comorbidities and health insurance

We calculated per facility proportion of patients jointly covered by Medicaid, uninsured and with two or more comorbidities as separate variables.

3.2.6 Data Management

3.2.7 Data merging

The data merging was a three-step process. First, we merged the Medicare facility files containing facility level data, including QIP, DFC and facility level impact, using Medicare facility unique identification, called "PROVIDER_ID". Second, USRDS facility and patient aggregated data was merged with the Medicare using USRDS crosswalk file, which provided both USRDS facility identification (PROVUSRD) and Medicare facility identification (PROVHCFA). Finally, AHRF files were merged using the county FIPS as a unique identifier, the final merged file included 5,193 facilities.

3.2.8 Analytical Approach

We used SAS version 9.4 for analysis. We conducted descriptive analysis, calculating frequencies for categorical and mean and standard deviations for continuous variables. Bivariate analysis compared the facility size and QIP score categories on the covariates (table 3.1). We used Chi-square test to determine the association between performance categories and categorical variables and ANOVA for the continuous variables. Generalized linear model was conducted to determine the association between facility size and performance, adjusting other *covariates*.

3.3 STUDY METHODS - QUESTION 2

3.3.1 Study design and unit of analysis

The study utilized a retrospective cohort study. All analyses were conducted at the patient level. The USRDS patient data and facility data were used. Further, facility and ecological correlates were merged to each patient information using Medicare, and AHRF data.

3.3.2 Study population

Our study population included all adult (age ≥18 years) incident patients between January 1, 2013 — December 31, 2013 (n=96,102). We included incident patients from January 1, 2013- December 31, 2013. We followed patients who survived the first 90 days from (April 1, 2013-March 31, 2014) to determine one year survival and its association with QIP scores, adjusting for the covariates. Patients were followed up until death or until the end of follow-up (March 31, 2014) and censored if patients received a kidney transplant after 90 days of dialysis. Research indicates transplant patients having better survival than dialysis patients (Levey & Coresh, 2012). Transplant ends exposure to dialysis.

3.3.3 Data files

Patient data

The USRDS patient data from were used to extract patient information.

Facility data

For facility data, CMS QIP, DFC and facility level impact files were used (see details in the section 3.2.3 above). Further, the USRDS facility level data were used for variables not included in the CMS data.

3.3.4 Variables

Dependent variable

Time to death is our outcome variable.

Most dialysis patients (60%) aged younger than 65 years (K. E. Chan et al., 2011). It takes 90 days for Medicare to enroll younger ESRD patients. Further, dialysis patients demonstrate significantly higher mortality in the first 90 days (Bradbury, et al., 2007; K. E. Chan, et al., 2011). We applied the 90-day rule because USRDS recommends beginning outcome analysis after 90 days of the first ESRD service, partly because of delay in enrollment of new patients with Medicare and partly to stabilize patients on a suitable dialysis modality (United states renal Data System, 2015).

We calculated the one-year mortality from 91-455 days (from April 1, 2013 — March 31, 2014), and its association with QIP scores, adjusting for the covariates. We used the data for the aforesaid years, since the most recent USRDS and CMS data were available for these years at the time of the study.

Independent variables

Main exposure

QIP scores

We used the QIP scores for the year 2013. Further, we excluded the patient records for which the respective facility QIP scores are missing.

As noted above, among 5212 facilities, for which the QIP scores were reported, 269 (4.9%) facilities failed to achieve a target score of 60.

Covariates

The study adjusted for patient, facility and ecological characteristics. Please see the table 3.1 for details of source file and variable names and types.

Variable Construction

Age

Patient age was included using age at incidence.

Race and Ethnicity

The variable race was constructed using two separate variables, race and ethnicity. The new variables included four categories: White non-Hispanic, Black non-Hispanic, Hispanic only and others non-Hispanic.

Patient Insurance

The USRDS captures the public and private insurance status as separate binary variables. We included three distinct categories including Medicaid insured, private insured and uninsured in our analysis.

Estimation of centroid for distance

Straight line distances (centroids) were calculated between facilities zip codes and patients' zip codes. For centroid calculations, we used the "SAS ZIP Code file of January 2015" provided by SAS (SAS support., 2015). The longitude and latitude of each of the respective patient and facility zip codes were extracted and processed using the SAS "ZIPCITYDISTANCE" macro to calculate the centroids. The distances were categorized based on the lower quartile median and upper quartile.

Comorbidities

We de-concatenated the variable "comorbids" in the USRDS patient file to calculate the count of comorbidities as a covariate to adjust for severity of comorbidities.

Primary cause of ESRD

We included most common causes of ESRD namely, diabetes, hypertension, glomerulonephritis as distinct categories. Further, we made separate categories for other causes and unknown cause.

Pre ESRD care

We included four discrete components of pre-ESRD care, including Epoetin use, nephrologist care, the presence of mature AVF/AVG and diet care as distinct variables.

Data merging

We included information on 96,102 incident cases of patients who received care from freestanding dialysis facilities between January 1 and December 31, 2013. We excluded patients who died in the first 90 days (n=5,205); who received transplants in the initiation of treatment (n=36) and who were lost to follow up (n=334) yielded 90,527 records.

We then merged Medicare facility data with USRDS patient data. Then, the Medicare QIP, DFC and impact files were merged (5,212 free standing dialysis facility). Finally, AHRF data were merged with the Medicare facility data, using the county FIPS.

We merged 2013 USRDS "Patient" and "Medical Evidence" files, using USRDS_ID as the unique patient identifier. The USRDS "Treatment History" file contained the unique identification number for both the patient (USRDS_ID) and facility (PROVUSRD). We merged treatment history file in the next step. Finally, the "Facility File" was merged, using the provider identification number, to include the facility ZIP codes. We used the USRDS crosswalk file to merge Medicare data with the USRDS data, using Medicare facility identification as a unique identifier (PROVHCFA). Merging Medicare and USRDS data yielded 85,187 records.

3.3.5 Statistical Analysis

Descriptive analysis was conducted to present the characteristics of the dialysis facility, ecological and patient characteristics. Bivariate analysis was run using time to death as an outcome and binary performance scores variable (achieved and not achieved) as exposure. Kaplan Meier estimates were used to determine the survival probabilities.

The Log Rank test was used to determine the suitability of using the Cox Proportional hazards model.

We used the Cox Proportional hazards model to estimate the association between facility performance scores and with time to death, after adjusting for patient, facility and ecological factors (Table 3.1). Each covariate was assessed using "Assess" function to determine whether the covariate is time dependent. Two sided tests were used at a level of significance of 5%.

We conducted a multilevel modeling to demonstrate distinct effects of the patient, facility and ecological factors. In the model 1, we adjusted for patient factors, including, demographic and socioeconomic characteristics; comorbidities; primary cause of renal disease, severity of comorbidities and pre-ESRD care. In the model 2, we added facility structural factors, including for-profit status, chain ownership, number of treatments and number of stations. Finally, in the model 3, we adjusted additionally for area rurality; ESRD network regions (Northeast, South, Midwest, and West); and socioeconomic and demographic characteristics of the patients' county, including, percentage of black and Hispanic population; median household income, percentage of persons in poverty and unemployment rate in 16 plus.

3.4 INSTITUTIONAL REVIEW BOARD

We sought an exemption from full ethical review from the institutional review board of the University of South Carolina for the use of secondary USRDS and Medicare data for our analysis.

Table 3.1: List of covariates and data sources

File	Variable	Variable name	Variable type
	Facility factors		
CMS QIP data file	QIPs scores	QIP scores	Numeric
Dialysis Facility Compare	Profit/nonprofit *	OWNTYPE	Categorical
Dialysis Facility Compare	Part of chain, chain owned (Y/N) *	CHAINYN	Categorical
Dialysis Facility Compare	Late shift (Y/N) *	SHIFT	Categorical
Dialysis Facility Compare	Total stations # *	TOTSTAS	Numeric
Dialysis Facility Compare	In-center hemodialysis (Y/N) *	HD	Categorical
Dialysis Facility Compare	In-center peritoneal dialysis (Y/N) *	PD	Categorical
Dialysis Facility Compare	Home hemodialysis *	HOMEHD	Categorical
CMS facility level Impact	Size of the facilities (<4000 treatments, 4000-10000, >10,000) ††	Size	Numeric
CMS facility level Impact	Low volume††	Low volume	Categorical

File	Variable	Variable name	Variable type
CMS facility level Impact	Dialysis treatments ††	Dialysis treatments	Numeric
USRDS (facility file)	Total number of patients per facility †	END_TOT	Numeric
USRDS (facility file)	Patient to full time staff ratio†	Estimated using END_TOT and # of full time staff (RN, SW, D, APN)	Numeric
USRDS (facility file)	Number of outpatient treatments†	TRSI_TRT	Numeric
USRDS (facility file)	Number of nurses, technician and dietitians †	HAPNFT, HDIETFT, HLPNFT, HPCTFT, HRNFT, HSWFT	Numeric
	Patient factors		
USRDS (Patient file)	Gender †	SEX	Categorical
USRDS (Patient file)	Race †	RACE, HISPANIC	Categorical
USRDS (Patient file)	Date of Birth (to calculate age) †	BORN	Categorical
USRDS (Patient file)	Age at incidence	Inc_age	Numeric

File	Variable	Variable name	Variable type
USRDS (Patient file)	Date of Death† (to calculate time to death)	DIED	Date
USRDS (Patient data)	Primary Cause of death†	CAUSEPRIM	Categorical
USRDS (Patient data)	Date of first dialysis†	FIRSTDIAL	Date
USRDS (Patient data)	Date of First ESRD Service† (to determine the time to death)	FIRST_SE	Date
USRDS (Patient data)	Proportion of patients with co-morbidities†	COMORBID	Categorical
USRDS (Patient data)	Proportion of patients with primary cause of renal failure†	PDIS	Categorical
USRDS (Patient data)	Proportion of patients who received early nephrology care†	DIETCARERANGE, EPORANGE, NEPHCARERANGE, AVF/AVGMATURING	Categorical
USRDS (Patient data)	Serum Hemoglobin level (g/dl) †	HEGLB	Numeric

File	Variable	Variable name	Variable type
USRDS (Patient data)	Insurance type†	NOCOV, MDCD, MDCR, MEDCOV_GROUP, MEDCOV_Others	Categorical
USRDS (Patient data)	Tobacco use†	SMOKE	Categorical
USRDS (Patient data)	Employed/not employed†	EMPCUR	Categorical
USRDS (Medical evidence file)	Body Mass Index - Calculated†	BMI	Categorical
	Ecological factors		
USRDS - Patient & Facility data	Distance between patient ZIP codes & facility ZIP codes†	Centroid distances were calculated between ZIP codes	Numeric
AHRF	Rurality using UIC of the facility	Estimated using AHRF files	Numeric
AHRF	Minorities living in ZIP code of the facility †††	Hispanic (f1392013, f1392113) Black (f1397913, f1398013)	Numeric
AHRF	Proportion of people in poverty	f1332113	Numeric

File	Variable	Variable name	Variable type
AHRF	Unemployment rate §	f0679513	Numeric
AHRF	Median household income	f1322613	Numeric
DFC	ESRD networks*	Network	Numeric
USRDS (facility data)	Facility state†	PHYSTATE	Nominal
USRDS (facility data)	Facility county†	PHYCOUNTY	Nominal

Data sources

* Dialysis Facility Compare (DFC)

† United States Renal Data Systems (USRDS

†† CMS Facility Level Impact File

§ Areas Health Resource File (AHRF)

CHAPTER IV- MANUSCRIPT ONE: Association of facility size and Medicare ESRD Quality incentives program's performance scores[1]

[1] Ajmal F., Probst J.C., Brooks J.M., Hardin J.W., & Qureshi Z. Association of facility size and Medicare ESRD Quality incentives program's performance scores. To be submitted to *American Journal of Kidney Disease and Kidney International*

4.1 ABSTRACT

Background

End stage renal disease (ESRD) requires long term and costly care. As such, Medicare has worked on strategies to bring efficiency in ESRD care since the inclusion of the disease as the first disease- based eligibility in the program in 1972. In 2011, Medicare launched an expanded bundled payment reform with the Quality Incentive Program (QIP). This reform was devised to control for the possible fall in quality and quantity of care after the bundled payment.

The QIP rates facilities using clinical and reporting indicators, and penalizes underperforming facilities by 0-2% of total payments. Small dialysis facilities are expected to receive such penalties due to poor performance. Further, small facilities are more likely to be rural, low volume and low profit margin and are, therefore, expected to receive more penalties due to poor performance. The current study investigates the association between facility size and QIP scores.

Methods

We used the Medicare dialysis facility compare file; Medicare facility level impact file; Medicare Quality Incentive programs file; United State Renal Data System facility and patient data (aggregated by a facility) and Area health resource (AHRF) file. We restricted data files to service year 2013, the most recent data available. The facility size was classified based on number of dialysis stations into small (≤10), medium (11-25) and large (>25) sizes. A generalized linear model for which inference was based on a

5% level of significance to determine an association between facility size and QIP scores, after adjusting for other potential covariates.

Results

The medium and large sized facilities scored higher compared to small facilities. We found significantly higher QIP scores among facilities not offering peritoneal dialysis, located in the South, affiliated with a chain, except chain 3, reporting higher number of dialysis hours per session and higher number of patients who had access to pre-ESRD care. Further, a higher proportion of Hispanics in the facility and facility neighborhood was associated with higher QIP scores. Conversely, a higher proportion of black population in the facility or neighborhood was associated with lower QIP scores. Finally, facilities where patients travelled longer distances to access care were associated with lower QIP scores.

Conclusions

We found an association between facility size and QIP scores. The QIP scores also varied by characteristics of the patient population and neighborhood population. We recommend more research in the area to advocate for inclusion of the facility size, patient population and neighborhood population characteristics as factors adjusting the QIP scores.

4.2 BACKGROUND

End stage renal disease (ESRD) patients constitute less than 1% Medicare population but consumes 7% of its cost (Ojo, 2014; The American Society of Nephrology, 2014).Medicare ESRD care cost is high as the majority of patients remain on dialysis due to non-availability of kidney donors and renal tissue mismatch (Levey & Coresh, 2012). Patients on dialysis require long term and frequent treatment (National Kidney and Urologic Diseases Information Clearinghouse, 2013). Medicare, being cognizant of the rising cost trend, has proposed payment reforms since 1983. Despite Medicare's continued efforts, ESRD costs have been escalating each year (United States Renal Data System, 2015) .

In 2011, Medicare launched a new payment reform called ESRD expanded bundled payment (Chambers, et al., 2013; Iglehart, 2011).The reform proposed a fixed payment per dialysis of $ 230 including laboratory services and medications, previously paid by fee-for-service methods (Chambers, et al., 2013). Considering a potential drop in quantity and quality of services after the fixed payments, Medicare introduced the quality incentive program (QIP) few months after the reform to monitor service quality (Iglehart, 2011; Watnick, et al., 2012). QIP penalizes facilities for not achieving the target performance scores by 0-2% of the payments. In 2012, Medicare rebased the bundle, reducing per dialysis payment further by $30 (Wish, et al., 2014).

The reduction in payments was expected to adversely affect small facilities (Chambers, et al., 2013; Watnick, et al., 2012). Since such facilities are mostly located in rural and remote areas and run on a low volume and low profit margins (Medicare Payment Advisory Commission (US), 2015; Wish, et al., 2014). Lower facility revenues are associated with poor service quality. Thus, small facilities are more vulnerable to QIP penalties (Chambers, et al., 2013; Slinin & Ishani, 2013; Watnick, et al., 2012) . Research indicates facilities operating on lower profit margins demonstrate poor patient outcomes (Ly, et al., 2011). Prior research indicates facilities located in rural and low socioeconomic areas demonstrating poor facility performance and health outcomes (Almachraki, et al., 2016; Kimmel, et al., 2013; M. R. Saunders & Chin, 2013).

Research remains scarce in studies relating facility size with QIP scores. In a singular study, Zhang reported that a higher number of dialysis stations associated with poor QIP scores (Yue Zhang, 2015). However, the authors noted not including patient factors as their major limitations. Patient demographic and socioeconomic factors and health status are associated with quality of health care (Chao, et al., 2015; Kovesdy et al., 2013; Rucker, et al., 2011; M. R. Saunders & Chin, 2013; Tangri, et al., 2010; Tangri, et al., 2011). Medicare adjusts for patient factors while assigning facility QIP scores. Therefore, adjusting for patient covariates is important while determining the association between facility factors and QIP scores. In the current study, we determined the association between freestanding dialysis facility size and QIP scores after adjusting for facility-level aggregate of patient data and facility and ecological characteristics.

4.3 METHODS

Study population and Data files' sources

We used a cross sectional design, including Medicare facility data, United States Renal Disease Data System (USRDS) facility level and patient data, and Area Health Resource File (AHRF) for the year 2013. Since our unit of analysis was freestanding dialysis facility, we aggregated USRDS patient data by facility. Medicare reports facility dialysis data two years from the service year (Centers for Medicare & Medicaid Services, 2013a). For instance, services rendered in 2013 are reported in 2015(Centers for Medicare & Medicaid Services, 2013a). Medicare calls service year as the calendar year (CY) and reporting year as the payment year (PY) (Centers for Medicare & Medicaid Services, 2013a).

The Medicare datasets included in our study and their respective URL include Quality Incentive Program (QIP), [Available at URL:https://data.medicare.gov/data/archives/dialysis-facility-compare; Dialysis Compare Facility File (DFC) [Available at URL: https://data.medicare.gov/data/archives/dialysis-facility-compare; CMS facility level impact [Available at URL: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1614-F.html]. The AHRF file was available at https://ahrf.hrsa.gov/topics/ahrf.aspx

We extracted QIP performance scores from the Medicare QIP data file CY2013 (corresponding to PY 2015). The Medicare DFC file provided information about chain type, profit status, late shift, offer home hemodialysis, peritoneal dialysis and Hemodialysis. The Medicare impact file included the variables, hospital affiliation, number of dialysis treatment and low volume status.

USRDS facility data included information about number of staff (full time dietitians, technicians, registered nurse, practical nurse and social workers), number of patients and ESRD network. The Centers for Medicare and Medicaid Services consolidated ESRD providers into 18 regional networks including – Northeast 1-5; South

6-8 and 13,14; Midwest 9-12 and West 15-18 (Center for Medicare and Medicaid Services, 2012a). We aggregated patient level USRDS data for each facility. The variables include patient population mean age; proportion of males; proportion of Hispanics; proportion of black patients; proportion of uninsured patients; proportion of patients with Medicaid only; proportion of patients having access to early nephrology care and proportion of smokers; proportion of patients with two or more comorbidities and mean of two laboratory indicators Glomerular Filtration Rate (GFR) and Hemoglobin (Hgb) levels at dialysis initiation.

Variables

Dependent and primary explanatory variable

We included dialysis facility performance scores as the outcome and facility size as the independent variable. We treated performance scores as a continuous variable. In 2013, Medicare calculated the QIP score using six clinical and four reporting criteria. A 75% weightage was assigned to clinical criteria and 25% to reporting criteria, with a maximum score of 100. Medicare designated a cut-off of 60 for facilities to avoid a penalty. The clinical criteria included the proportions of patients with Hemoglobin (Hgb) > 12g/dl; Arteriovenous fistula (AVF); central venous catheter (CVC) and adult and pediatric hemodialysis patients and peritoneal dialysis patients with a Kt/V of >1.2, where "K" stands for dialyzer clearance, "t" stands for time and "V" stands for volume of water in patient's body (National Institute of Diabetes and Digestive and Kidney Disease, 2014b). The reporting measures include reporting on anemia management, mineral metabolism, and on two surveys including In-Center Hemodialysis Survey Consumer

Assessment of Healthcare Providers and Systems (ICH CAHPS) survey and National Healthcare, Safety Network (NHSN).

Our main explanatory variable was facility size. Facility size was determined using a variable number of dialysis stations per facility. We determined the distribution of QIP scores and total stations using normal plot (Appendix B). To determine whether to treat facility size as a continuous variable, we plotted a scatter graph between QIP scores and number of dialysis stations and included squared and cubic terms of stations in the model. The scatter plot showed a non-linear relationship (Appendix C). Further, the linear (stations; p-value <.0001), squared ($stations^2$; p-value <.0001) and cubic ($stations^3$; p-value <.0001) terms were also significantly associated with the QIP scores, showing a non-linear relationship between QIP scores and stations. Therefore, we categorized dialysis stations using Yoder et al.'s criteria, small (≤10 stations), medium (11-25 stations) and large (>25 stations) (Yoder, et al., 2013).

Facility level covariates

Membership in a chain of dialysis facilities was identified with five different options. For the three largest chains, we assigned each chain a number (1 – 3); all facilities affiliated with the smaller or regional chains were consolidated into a single category (chain 4). Remaining facilities, not in a chain, were grouped together. Chain 1 and 3 are two distinct large for-profit chains.

We calculated the number of patients per dialysis station per facility. Moreover, using Yoder et al method, we categorized mean number of patients per station into a binary variable using average patients per dialysis station in all facilities (Yoder, et al., 2013). First, we calculated the average of mean number of patients per station per facility

(5.4 patients per station). We summed the facility staff including registered fulltime nurse, technicians, nursing practitioner, dietitian and social worker and calculated total staff per facility. Further, we also calculated the total staff per 100 patients.

The other covariates included whether a facility offers hemodialysis, home hemodialysis, peritoneal dialysis and late shift. We also included facility for-profit and low volume status; number of dialysis treatments; number of dialysis hours per session and number of dialysis sessions per week per patients.

Facility-level aggregate of patient data

To calculate travel distances, first, we calculated centroid (straight line) distances between patient and facility ZIP Codes. The patient and facility zip codes were extracted from the USRDS' Patient file and facility file, respectively. The "SAS zip code file of January 2015" file, was used to extract longitude and latitude of patient and facility ZIP Codes (SAS support, 2014; SAS support., 2015). We used the SAS "zipcitydistance" macro (SAS support, 2014) to calculate straight line distances between patient and facility ZIP codes (Bliss, Katz, Wright, & Losina, 2012). Second, we calculated a median travel distance of all patients in each facility. Finally, the facilities were categorized into quartiles based on mean distance, <5.4; ≥5.4-<8.5; ≥8.5-<13.9 and ≥13.9 miles.

We deconcatenated the variable 'comorbid' that included the information about multiple comorbidities for each patient. We then summed up the valid counts across the deconcatenated variables for each patient to determine the number of comorbidities. The mean comorbidities per patient was 2. We calculated the proportion of patients with two or more comorbidities per facility. Further, we also aggregated patient characteristics including gender (Male); race (Hispanic and black); obesity; insurance (Medicaid and uninsured); access to a nephrologist; catheter use; comorbidities (>2 comorbidities) and smoking.

Ecological covariates

Using AHRF data, we included the proportion of Hispanic and of black residents, unemployment rate among 16 or more, median household income and percent of persons in poverty in the county facilities was located. Proportions of Hispanic and black residents were estimated by dividing the Hispanic population and black population by total population per county.

Based on the criteria devised by the United States Department of Agriculture Economic Research Services, we categorized facility rurality into three groups using Urban Influence Codes (UIC): "Urban" (UIC 1, 2), "micropolitan rural" (UICs 3, 5 and 8), and all other rural (UICs 4, 6, 7, 9, 10, 11 and 12) (United States Department of Agriculture Economic Research Service: Economic Research Service, 2013). Because of the smaller counts of remote rural facilities (n=112), we merged remote rural and small adjacent rural facilities into a single category. ESRD networks were consolidated into four regions including South, Midwest, Northeast and West.

We included Hirschman-Herfindahl Index (HHI) as an indicator of market competition. The HHI was calculated in three steps. First, we calculated proportion of treatments produced by a facility, also called facility's market share, by dividing treatments rendered by a facility with the total treatments rendered by all facilities in the county (Held & Pauly, 1983). Second, we squared the market share. Finally, we summed the squared market share of all facilities in a county to get county level HHI.

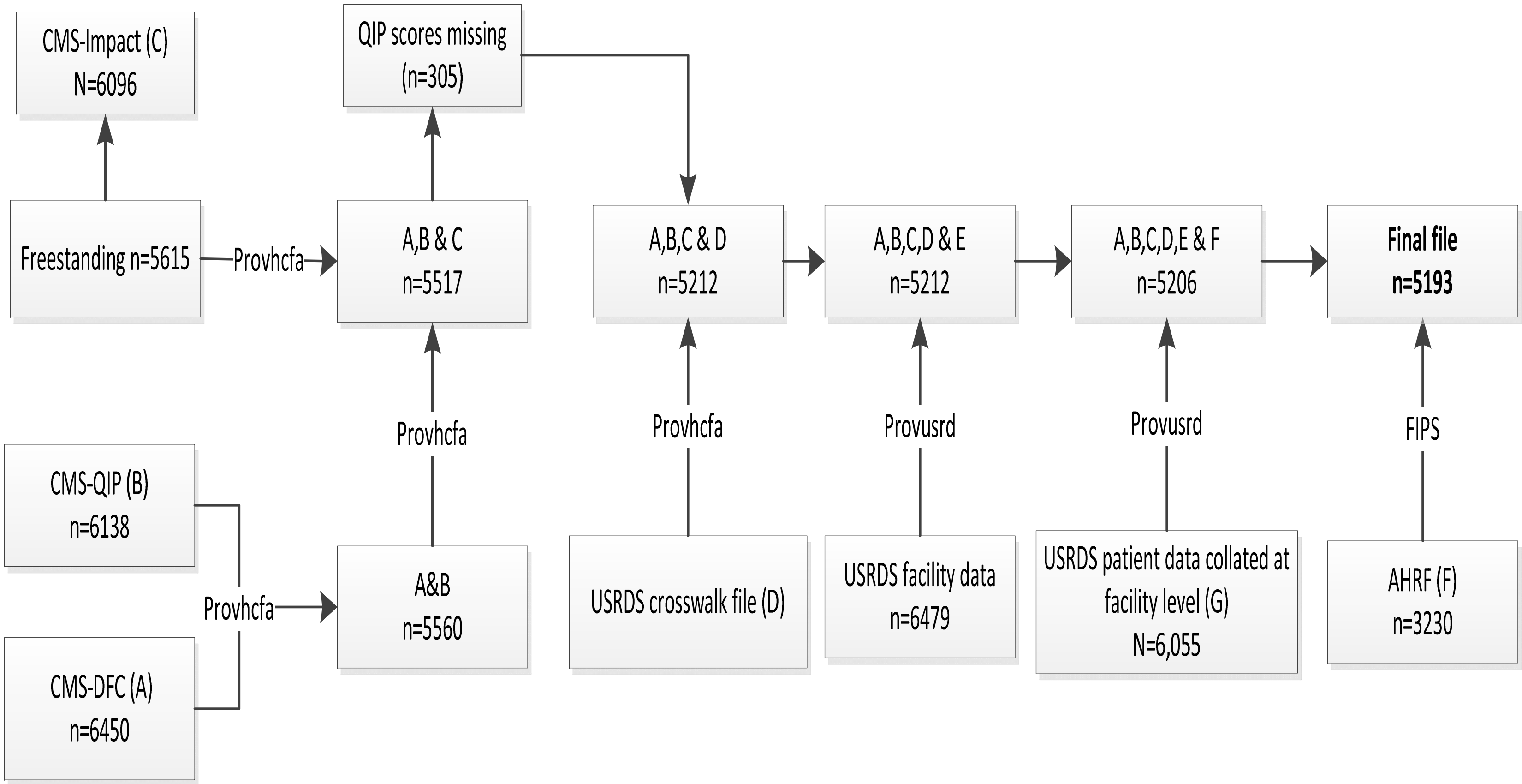

Figure 4.1: Data sources and merging

Data Management

Data merging

We merged the Medicare files including DFC, QIP and impact, using Medicare identification number, "PROVIDER_ID", as a unique identifier. The merged data included 5,517 records. Excluding records with missing QIP scores (n=305) yielded 5,212 records. Medicare does not report scores for facilities rendering fewer than 11 cases for each QIP measure (Centers for Medicare & Medicaid Services, 2012) . We then merged USRDS facility and patient data aggregated by facility using the USRDS crosswalk file. Finally, AHRF files were merged using the county FIPS as a unique identifier. The final merged file included 5,193 facilities.

Analytical Approach

We calculated mean and standard deviation (SD) and median and interquartile range (IQR) for continuous variables and proportions for categorical variables. We also checked the distribution of covariates across categories of facility size using Chi-Square for categorical variables and t-test or ANOVA for continuous variables. Multivariable linear regression was done using Generalized Linear Modeling approach to test the association between performance scores (outcome) and facility size (independent), after adjusting for the covariates, at alpha=0.05. We also tested the known interactions.

4.4 RESULTS

Characteristics of free standing dialysis facilities

Table 4.1 and 4.2 presents the distribution of facility factors. Most dialysis facilities included 10-25 station (77.1%). Further, mean stations per facility were 18.9 (SD; 7.8); mean hours per dialysis session were 3.8 (SD;0.3); mean patients per facility were 5.4 (SD; 4.2), and mean staff per 100 patients were 14.3 (SD; 11.8) (Table 4.1). We found an overall mean QIP score of 81.3 (SD; 12.4).

Most facilities were chain affiliated (90.6%) and for-profit (92.2%) (Table 4.2). All facilities offered in-center hemodialysis, while 49.1% and 27.5%, respectively offered peritoneal and home hemodialysis (Table 4.2). Most facilities were located in South (44.6%) and metropolitan areas (81.6%) and did not offer a night shift (80.9%). About 5% facilities operated on a low volume.

Table 4.3 presents the distribution of patients and ecological factors. Mean age of the patient population was 62.6 years (±3.9). The median travel distance was 9.3 miles (IQR, 10.4). Further, about 68% patients reported more than two comorbidities and 27.7 % were obese (Table 4.3). Average proportion of Hispanic and black patients were higher in the counties where large facilities were located.

Factors associated with facility size

Most covariates varied by facility size (Table 4.2). The small facilities were also more likely to be rural (42.8%), not chain affiliated (18.1%) and low volume (23.2%). Conversely, no large facility operated on a low volume. Large facilities were more likely to offer home hemodialysis (40.3%) and night shift (32.4%). Further, large facilities also reported lesser number of staff per 100 patients (Mean, 12.1; SD, 10.4) (Table 4.1) and a higher number of patients (>5.4) per station (Mean, 66.9%) (Table 4.2).

Table 4.3 compares patient covariates by facility size. All the patient characteristics varied by facility size, except hemoglobin level at the initiation of dialysis. The large facilities included a higher proportion of black (42%) and Hispanic (20.8%) patients. Conversely, the median travel distance was the highest among small (Mean:17.7; SD: 22.0) followed by medium (Mean:12.1; SD: 29.9) and large (Mean:9.5; SD: 12.2) facilities.

The analysis of ecological factors (Table 4.3) showed large facilities were located in counties that included a higher proportion of Hispanics (20.3 % vs. 11.7% in small), black population (21% vs. 12.3% in small) and persons living in poverty (19.1 % vs. 16.3% in small). Further, median household income was lower in large facility counties while unemployment was higher in larger facility (8.4 vs. 7.5 in small) counties.

Unadjusted analysis: factors associated with performance scores

Table 4.4 presents unadjusted associations between QIP score and categorical facility covariates. Performance scores did not vary across facility size (p-value, 0.1124; Table 4.4); however, performance did vary across multiple characteristics that are associated with size. Chain affiliation was associated with better performance scores (p-value, <.0001). Facilities not offering peritoneal dialysis (p-value, 0.0007) or home hemodialysis (p-value, <.0001) demonstrated higher scores. For-profit (p-value, 0.0288), rural facilities (p-value, 0.0188) and facilities located in the West (p-value, 0.0024) performed better.

Table 4.5 presents bivariate analysis between QIP score as the outcome and continuous facility covariates. Conversely, hours per dialysis session (p-value, 0.0024) and staff per 100 patients (p-value, 0.0044) were associated with lower performance scores (Table 4.5).

Table 4.6 presents bivariate analysis of aggregated patients and ecological factors and QIP scores (Table 4.6). We noted facility with a higher proportion of Hispanics per facility (β, 0.04; SE, 0.01; p-value, <0.001) and patients with access to pre ESRD nephrology care (β, 0.05; SE, 0.01; p-value, <0.001) were positively associated with the performance score. Competition index was also associated with better performance scores (β, 1.47; SE, 0.47; p-value, 0.0018) (Table4.6).

However, a higher proportion of black patients (β, -0.04; SE, 0.01; p-value, <0.001) and patients mean glomerular filtration rate (GFR) (β, -0.44; SE, 0.10; p-value, <0.001), with ≥ 2 comorbidities (β, -0.03; SE, 0.01; p-value, 0.0106) and with catheter as vascular access modality (β, -0.07; SE, 0.01; p-value, <0.001) were negatively associated with performance scores (Table 4.6). Further, the comparison of quartiles of median patient distance from facility with QIP scores indicated a significant negative association (p-value, .0003), with scores generally decreasing with longer travel distances.

Among ecological factors (Table 4.6), county level Hispanic population (β, 0.04; SE, 0.01; p-value, <0.001) was positively associated with the performance scores, while Black population (β, -0.06; SE, 0.01; p-value, <0.001) and unemployment rate (β, -0.17; SE, 0.08; p-value, 0.0344) were negatively associated.

Multivariable Analysis

Medium (β, 3.67; SE, 1.06, p-value 0.0005) and large facilities (β, 2.81; SE, 1.23; p-value, 0.0219) demonstrated better scores than small facilities (Table 4.7). Facilities affiliated with Chain 1, a large for-profit chain (β, 10.46; SE, 0.73; p-value, <.0001); Chain 2, a large and not for-profit (β, 4.22; SE, 1.46; p-value, 0.0038), other chains (β, 2.98; SE, 0.76; p-value, <.0001), not offering peritoneal dialysis (β, 1.98; SE, 0.46; p-value, <.0001); located in South (β, 1.66; SE, 0.73; p-value, 0.0234) were positively associated with performance scores. The average hours per dialysis session (β, 2.39; SE, .79; p-value, 0.0026) were also positively associated with performance scores.

Among the patient characteristics aggregated by facility, patient traveling distance of more than 8.5 to <13.9 miles (β, -1.88; SE, 0.55; p-value, <0.0006) and ≥13.9 miles (β, -1.64; SE, 0.66; p-value, 0.0068); proportion of blacks (β, -0.05; SE, 0.02; p-value, 0.0016) and proportion of catheter as vascular access at the initiation of dialysis (β, -0.11; SE, .02; p-value, <.0001) were associated with a decline in performance scores. However, proportion of Hispanic patients (β, 0.10; SE, 0.02; p-value, <.0001) and proportion of patients with nephrology care in pre-ESRD period (β, 0.08 SE, 0.01; p <.0001) were associated with an increase in performance scores. The interaction between size and profit status was insignificant (p= 0.1000).

Sensitivity analysis

We replicated Zhang’s model using the linear and squared term for the stations (Appendix D). We noted that the squared term was significant and negative. The significant squared term demonstrated that the relationship between QIP scores and stations was non-linear. The negative estimate for the squared term showed that increase in stations resulted in decline in QIP scores. Using the model below, we found an inflection point, i.e. QIP scores demonstrated a decrease at 32 stations or more. This is aligned with Zhang's findings that smaller facilities performed better.

$$\hat{Y} = 76.93 + 0.194 * \text{x} + 2 * (-0.003)$$

Where,

Y = QIP scores; x = Number of stations

On differentiating in terms of x, that is, total stations, we got an inflection point at about 32 stations,

$$0 = 0.194 - 2 * 0.003 * stations \quad \rightarrow \quad 32.33\ stations$$

Further, we also added the patient, facility and ecological factors incrementally to determine the change in the model with the addition of each level of factors (Appendix E). The R^2 for the model with facility factors only was 15.7%. Meaning, facility factors explained 15.7% variation in the QIP scores. Adding ecological factors increased the R2 to 17% and patient factors increased it to 25.1%. Therefore, our final model explained 25.1% of variation in the QIP score.

4.5 DISCUSSION

We determined the association between QIP scores and the size of the freestanding dialysis facility, measured as number of dialysis stations, after adjusting for facility-level aggregates of patient data and facility and ecological characteristics. We found an association between QIP scores and facility size. In fully adjusted analysis, medium sized facilities scored highest on QIP criteria, followed by large compared to small facilities.

Our findings differ from prior research findings which reports that small facilities perform better than the medium and large dialysis facilities (Yue Zhang, 2015). Notably, our methods also differ from the work done by Zhang. First, while Zhang used dialysis stations as continuous, however, we found the relationship between QIP and stations non-linear, therefore, we categorize them using Yoder's criteria. Second, Zhang used Medicare DFC data, which do not allow delineation of facility type i.e. freestanding and hospital based. We restricted our analysis to freestanding facilities. Third, the QIP assessment criteria also change between 2012 (Zhang's data) and 2013 (our data). Fourth, we adjusted for patient factors which was noted as a major limitation in Zhang's article. Therefore, our results cannot be compared with Zhang's data.

While studies exist on determining facility and ecological factors associated with specific clinical indicators including hemoglobin level, Kt/V, urea reduction ration (URR), vascular access and albumin level and profit and chain affiliation (Hirth, et al., 2010; M. R. Saunders & Chin, 2013; Szczech, et al., 2006), there is a dearth of studies reporting factors associated with QIP scores, especially the association between size, profit status and chain affiliation and QIP scores. Our study expands on prior research by relating profit and chain status with QIP scores after adjusting for facility-level aggregates of patient data. Generally, for-profit organizations maximize profits to gain dividends for their shareholders (Held, et al., 1990; Yoder, et al., 2013). Prior research also indicates for-profit facilities being associated with a better URR (Hirth, et al., 2010; M. R. Saunders & Chin, 2013; Szczech, et al., 2006) (Van Wyck, et al., 2010) and hemoglobin level (Foley, et al., 2008; Szczech, et al., 2006). Therefore, we expected for-profit facilities to provide better quality and demonstrate higher QIP scores. However, we noted no association between profit status and QIP scores.

Comparing chain affiliated facilities with non-chain facilities, we noted that while one large for-profit chain facility scored better on QIP criteria, the other did not. Saunders also reported variation in dialysis adequacy and hemoglobin levels among facilities associated with different chains (M. R. Saunders & Chin, 2013). Zhang et al. reported that all chain facilities performed better than non-chain facilities (Yue Zhang, 2015). Evaluating specific clinical outcomes against chain status, Hirth et al. reported large chains showing better URR, but not hematocrit (Hirth, et al., 2010). We recommend more research on the processes of care delivery associated with variation in the performance of chain affiliated facilities.

Notably, our study is the first to adjust for facility-level aggregate of patient factors. The finding demonstrating that higher patient travel distance to access dialysis treatments was associated with lower QIP scores is novel. Prior studies have shown that patients living in remote areas are less likely to achieve specific clinical measures (Chao, et al., 2015; Rucker, et al., 2011). However, rurality was not associated with the QIP scores. The changes in reimbursement are expected to negatively affect the performance of rural and small size facilities. This underscores the importance of considering patient travel distance as distinct covariates of care quality.

Our study had several limitations. First and foremost, we could not determine causal associations due to the cross-sectional study design. Second, we did not adjust for dialysis processes including dialysis dose, dialyzer reuse, and access to a nephrologist during dialysis and staff hours per patient. These factors can affect dialysis adequacy and cause blood stream infections. Third, we did not ascertain the referrals of rural patients to the urban facility due to complications. Fourth, we did not have information about severity of comorbidities. USRDS reported comorbidities as binary variables (yes/no) for incident cases. Fifth, we had no information about facility transitions that patient had during dialysis treatment. Sixth, we could not determine the validity of self-reported factors including smoking status.

That said, however, our study adds significantly to the current literature. This is the first study that included patient factors aggregated at the facility level. These factors constitute important demand side covariates of quality of care. The study adds to the recent work conducted by Zhang et al. relating facility size with QIP scores by using the recent data.

4.6 CONCLUSIONS

We demonstrated an association between facility size and QIP size after adjusting for facility characteristics, facility-level aggregates of patient data and ecological factors. Medium and large sized dialysis facilities performed better than small facilities. Other than size, a higher proportion of black population in the facility was associated with lower QIP scores, even after adjusting for the county poverty, unemployment and household median income. Conversely, a higher Hispanic population in the facility was associated with a better QIP scores. Unfortunately, the data did not allow us to determine the factors associated with better QIP scores among facilities with more Hispanics than facilities with more black population. The examples of such factors include type of housing, lifestyle factors including diet and exercise. Further, although the USRDS reports history of smoking and alcohol use once at the time of initiation of dialysis. However, the data do not report on the duration and quantity of smoking during dialysis.

Similarly, finding that facilities showing higher patient travel distances were associated with lower QIP scores needs consideration. More research in the area will better guide Medicare in including patient characteristics, distance from the facility and facility size as adjustment factors in calculating QIP scores.

Table 4.1: Facility characteristics by facility size, calendar year 2013

	Dialysis stations							
	All	Large size (>25 stations)		Medium size (11-25 stations)		Small size (≤ 10 stations)		
	5193	737		4003		453		
	Mean (SD)	Mean	SD	Mean	SD	Mean	SD	P-value*
QIP scores	81.3 (12.4)	80.5	11.4	81.5	12.0	81.0	17.5	0.1124
Stations	18.9 (7.8)	32.8	7.2	17.7	4.2	7.9	2.5	<.0001
Dialysis treatments per facility	7645.4 (4752.0)	13926.5	6167.6	6924.9	3473.1	3794.4	2623.8	<.0001
Total staff/ 100 patients†	14.3 (11.8)	12.1	10.4	14.2	11.3	18.6	16.6	<.0001
Hours per dialysis session	3.8 (0.27)	3.8	0.3	3.8	0.3	3.7	0.3	<.0001
Dialysis session per week per patient	3.0 (0.2)	3.0	0.1	3.0	0.1	3.1	0.5	<.0001

***ANOVA at α = 0.05**
†Total staff/ 100 patients = Sum of registered nurses, technicians, licensed practitioner nurses, social workers, dietitians)/100 patients

Table 4.2: Facility characteristics by dialysis facility size, calendar year 2013

	All facilities	Large size (> 25 stations)	Medium Size (11-25 stations)	Small size (≤ 10 stations)	P-value*
	n=5193	n=737	n=4003	n= 453	
	%	%	%	%	
Chain Affiliation					
Chain 1 (Large for-profit)	33.7	27.5	33.8	42.2	**<.0001**
Chain 2 (Large not-for-profit)	4.0	4.5	3.9	3.5	
Chain 3 (Large for-profit	32.4	36.9	32.7	21.9	
Chain 4 (Other chains)	20.6	22.0	21.1	14.4	
No chain	9.4	9.1	8.4	18.1	
Offers Hemodialysis					
Yes	100.0	100.0	100.0	100.0	N/A†
Offers Home hemodialysis					
No	72.5	59.7	74.6	74.4	**<.0001**
Offers Peritoneal dialysis					
No	50.9	34.7	52.5	62.7	**<.0001**
Offers late shift					
No	80.9	67.6	82.4	89.0	**<.0001**
Own type					
Non-Profit	7.8	10.6	7.2	8.8	0.0054
Profit	92.2	89.4	92.8	91.2	
Low volume facility					
No	94.9	100.0	96.0	76.8	**<.0001**
Rural					
Micropolitan rural	11.5	6.7	11.3	20.8	**<.0001**
Small adjacent/remote rural	7.0	1.6	6.2	22.1	
Urban	81.6	91.7	82.5	57.2	
Number of patients per station					
<=5.4	50.1	33.1	51.8	62.0	**<.0001**
>5.4	49.9	66.9	48.2	38.0	
Location of facility in regional ESRD network					
Midwest	23.7	14.3	23.8	38.2	**<.0001**
Northeast	13.7	15.2	13.9	9.3	

	All facilities	Large size (> 25 stations)	Medium Size (11-25 stations)	Small size (≤ 10 stations)	P-value*
South	44.6	51.7	44.4	34.7	
West	18.0	18.9	17.9	17.9	

*Chi Square at α = 0.05
† Not applicable

Table 4.3: Distribution of aggregated patient and ecological characteristics, by facility size, calendar year 2013

	All facilities		Large size (≥25 stations)		Medium Size (11-25 stations)		Small size (≤ 10 stations)		p-value*
	Average	SD	Average	SD	Average	SD	Average	SD	
Patients characteristics									
Distance travel by patients (median)	9.3	(10.4)	9.5	(12.2)	12.1	(29.9)	17.7	(22.0)	**<.0001**
Age of patients per facility	62.6	(3.9)	60.9	(3.4)	62.8	(3.7)	64.4	(5.1)	**<.0001**
Proportion of male per facility	56.6	(7.7)	55.8	(5.1)	56.7	(7.4)	57.4	(12.1)	**0.0024**
Proportion of Blacks per facility	33.6	(27.7)	42.02	(28.6)	32.6	(27.2)	28.1	(26.3)	**<.0001**
Proportion of Hispanic per facility	17.1	(21.8)	20.8	(26.6)	16.5	(20.7)	14.6	(19.4)	**<.0001**
Proportion of patients with >2 morbidities	67.5	(14.1)	62.2	(13.5)	67.9	(13.7)	72.8	(16.)	**<.0001**
Proportion of patient with catheter at the initiation	63.7	(15.9)	55.7	(15.3)	64.9	(15.)	67.2	(20.3)	**<.0001**
Proportion of obese patients	27.7	(6.5)	27	(4.5)	27.7	(6.5)	28.2	(9.2)	**0.003**
Proportion of patients on Medicaid	13.7	(8.6)	15.1	(8.9)	13.7	(8.5)	12.3	(8.3)	**<.0001**
Proportion of uninsured patient †	10.2	(7.6)	12.1	(8.9)	9.9	(7.4)	9.4	(6.9)	**<.0001**
Proportion of patients with pre-ESRD care (Nephrology care)	51.8	(18.3)	46.5	(17.1)	52.0	(17.7)	58.9	(22.4)	**<.0001**
Proportion of smokers	7	(5.5)	6.1	(4.6)	6.9	(5.4)	9.3	(7.3)	**<.0001**
GFR	9.3	(1.7)	8.4	(1.3)	9.3	(1.6)	10.0	(2.)	**<.0001**
Hemoglobin	10.1	(2.5)	10.0	(1)	10.1	(2.6)	10.1	(2.7)	0.2609
Ecological characteristics									
Proportion of Hispanic /county	16.2	17.4	20.3	19.6	18.3	18.3	11.7	13.9	**<.0001**
Proportion of black /county	15.9	15.4	21.0	16.9	17.3	15.5	12.3	14.2	**<.0001**

Unemployment Rate, 16+	7.7	2.2	8.4	2.3	7.8	2.1	7.5	2.2	**<.0001**
Median Household Income	51557.0	13483.8	49596.1	11995.9	51836.9	13255.1	51452.9	1412 8.0	**0.0011**
Percent Persons in Poverty	17.1	5.8	19.1	5.7	17.4	5.7	16.3	5.9	**<.0001**
Competition index	0.34	(0.34)	0.25	(0.25)	0.33	(0.33)	0.55	(0.39)	**<.0001**

*ANOVA at $\alpha = 0.05$
† uninsured at the time of filling 2728 form

Table 4.4: Facility characteristics associated with QIP scores, calendar year 2013

Dialysis facility size	N	Mean	SD	p-value
Large size (>25 stations)	737	80.5	11.4	0.1124†
Medium size (11-25 stations)	4003	81.5	12.0	
Small size (≤ 10 stations)	453	81.0	17.5	
Chain type				
Chain 1 (Large for-profit)	1748	87.5	9.8	**<.0001†**
Chain 2 (Large not-for-profit)	205	81.5	11.6	
Chain 3 (Large for-profit)	1681	76.3	11.4	
Chain 4 (Other chains)	1072	81.0	11.8	
No chain	487	76.8	16.1	
Offers Home hemodialysis				
No	3765	81.8	12.2	**<.0001***
yes	1428	79.9	13.1	
Offers Peritoneal dialysis				
No	2641	81.9	12.3	**0.0007***
yes	2552	80.7	12.7	
Offers late shift				
No	4199	81.2	12.7	0.0746*
yes	994	82.0	11.5	
Own type				
Non-Profit	407	80.0	12.9	**0.0288***
Profit	4786	81.4	12.4	
Low volume facility				
No	264	82.2	14.7	0.2101*
Yes	4929	81.3	12.4	
Rural				
Micropolitan	595	82.4	11.9	**0.0068†**
Small adjacent/remote rural	361	82.6	13.5	
Urban	4237	81.1	12.5	
State				
Midwest	1232	80.6	13.3	**0.0024***
Northeast	710	81.2	12.3	
South	2316	81.2	12.0	
West	935	82.6	12.6	
Number of patients per station				
<=5.4	2598	81.1	13.0	0.3089*
>5.4	2595	81.5	11.9	
Significant p-values are bolded				
*t-test at 0.05 level of significance; † ANOVA at 0.05 level of significance				

Table 4.5: Facility characteristics associated with QIP scores, calendar year 2013

	B_0	B_1	B (SE)	p-value
Dialysis treatments per facility	80.8	0.00	0.00	**0.0453**
Total staff/ 100 patients	81.9	-0.04	0.02	**0.0044**
Hours per dialysis session	91.8	-2.77	0.63	**<.0001**
Dialysis session per week per patient	79.9	0.49	1.11	0.6575
Significant p-values are bolded				
*Simple linear regression				

Table 4.6: Bivariate association between facility-level aggregates of patient and ecological factors and QIP scores, calendar year 2013

	B_0	B_1	B (SE)	p-value*
Patient characteristics				
Distance from the facility				
>=13.9 miles	81.5	**-**	13.7	**0.0003†**
>=8.5- < 13.9 miles	80.6	**-**	12.7	
>=5.4- < 8.5 miles	81.7	-	11.9	
<5.4 miles	82.3	-	11.5	
Age of patients per facility	86.2	-0.08	0.04	0.0788
Proportion of male per facility	78.0	0.06	0.02	**0.0092**
proportion of blacks per facility	82.4	-0.04	0.01	**<.0001**
proportion of Hispanic per facility	80.7	0.04	0.01	**<.0001**
Proportion of patients with >2 morbidities	83.4	-0.03	0.01	**0.0106**
Proportion of patient with catheter at initiation	85.7	-0.07	0.01	**<.0001**
Proportion of obese patients	80.3	0.04	0.03	0.1589
Proportion of patients on Medicaid	81.2	0.01	0.02	0.6116
Proportion of uninsured patient	81.4	0.01	0.02	0.6277
Proportion of patient with Nephrology care	78.8	0.05	0.01	**<.0001**
Proportion of smokers	81.7	-0.04	0.03	0.2486
Average GFR of patients/ facility	85.3	-0.44	0.10	**<.0001**
Average Hemoglobin of patients/ facility	79.9	0.14	0.07	0.051
Ecological characteristics				
Proportion of Hispanic /county	80.7	0.04	0.01	**<.0001**
Proportion of blacks /county	82.4	-0.06	0.01	**<.0001**
Unemployment Rate, 16+	82.6	-0.17	0.08	**0.0344**
Median Household Income	80.6	0.00	0.00	0.2587
Percent Persons in Poverty	82.2	-0.05	0.03	0.1237
Competition index	81.0	1.47	0.47	**0.0018**
*Simple linear regression; † ANOVA at 0.05 level of significance				

Table 4.7: Adjusted analysis for association between facility size and performance scores, calendar year 2013

Parameter	Estimate	Standard Error	p-value	95% Confidence Limits	
Intercept	72.92	9.61	<.0001	54.08	91.76
Facility factors					
Dialysis facility size (ref: small)					
Large	2.81	1.23	**0.0219**	0.41	5.21
Medium	3.67	1.06	**0.0005**	1.60	5.74
Chain Type (ref: No chain affiliation)					
Chain 1: Large for-profit chain†	10.46	0.73	**<.0001**	9.03	11.88
Chain 2: Large not for-profit chain	4.22	1.46	**0.0038**	1.36	7.08
Chain 3: Large for-profit chain†	-1.40	0.76	0.0634	-2.88	0.08
Chain 4: Other Chains	2.98	0.76	**<.0001**	1.49	4.48
HOME Hemodialysis (ref: Yes)					
No	0.72	0.49	0.1456	-0.25	1.69
Peritoneal Dialysis (*ref: Yes)*					
No	1.98	0.46	**<.0001**	1.09	2.88
SHIFT *(ref: Yes)*					
No	-0.77	0.47	0.1029	-1.69	0.15
Own type *(ref: Profit)*					
Non-Profit	-1.71	0.96	0.0742	-3.58	0.17
Low volume facilities *(ref: Yes)*					
Yes	2.80	1.46	0.0555	-0.07	5.66
Region *(ref: West)*					
Midwest	0.11	0.71	0.8724	-1.27	1.50
Northeast	1.10	0.77	0.1504	-0.40	2.60
South	1.66	0.73	**0.0234**	0.22	3.09
Patients per station *(ref: >5.4/stations)*					
<=5.4/station	-0.46	0.49	0.3532	-1.42	0.51
Dialysis treatments	0.00	0.00	0.7809	0.00	0.00
Total staff per 100 patients	0.04	0.03	0.2347	-0.03	0.11
Average hours per session	2.39	0.79	**0.0026**	0.84	3.95
Average dialysis treatment session per week per patient	-0.08	1.79	0.9656	-3.58	3.42
Patient factors					
Distance travelled by patients (*ref= <5.4 miles)*					
>=13.9 miles	-1.64	0.60	**0.0068**	-2.82	-0.45

>=8.5- < 13.9 miles	-1.88	0.55	**0.0006**	-2.96	-0.80
>=5.4- < 8.5	-0.33	0.53	0.5272	-1.36	0.70
Age of patients per facility	-0.05	0.09	0.5968	-0.21	0.12
Proportion of male per facility	0.05	0.03	0.1678	-0.02	0.11
Proportion of Black patients per facility	-0.05	0.02	**0.0016**	-0.08	-0.02
Proportion of Hispanic patients per facility	0.10	0.02	**<.0001**	0.06	0.14
>= 2 comorbidities	0.01	0.02	0.5354	-0.03	0.06
Proportion of catheter at initiation of dialysis treatment	-0.11	0.02	**<.0001**	-0.14	-0.07
proportion of obese/facility	0.03	0.04	0.3993	-0.04	0.11
Medicaid insured /facility	0.04	0.03	0.2498	-0.02	0.09
Uninsured /facility	0.03	0.03	0.3726	-0.04	0.10
Pre-ESRD Nephrology care by facility	0.08	0.01	**<.0001**	0.06	0.11
Tobacco users per facility	-0.01	0.05	0.8141	-0.11	0.09
Average GFR per facility	-0.70	0.17	0.3833	-1.03	0.37
Average Hemoglobin per facility	0.09	0.08	0.2633	-0.07	0.25
Ecological factors					
Rural *(ref: Urban)*					
Small adjacent /remote rural	2.28	1.27	0.0722	-0.21	4.77
Micropolitan	1.51	0.83	0.0685	-0.12	3.14
Proportion of Hispanics population in county	-0.02	0.03	0.3611	-0.07	0.03
Proportion of Blacks population in county	0.02	0.03	0.4184	-0.03	0.08
Proportion of Unemployment Rate, 16+	0.00	0.00	0.535	0.00	0.00
Median Household Income	-0.14	0.08	0.0863	-0.29	0.02
Proportion Persons in Poverty	-0.01	0.12	0.9018	-0.24	0.21
Competition index	1.46	0.91	0.1111	-0.34	3.25

*Proc GLM at α= 0.05
† refers two distinct large for-profit chains

CHAPTER V: MANUSCRIPT TWO: Association of freestanding dialysis facility Quality Incentive Program scores and mortality among incident hemodialysis patients in the United States in 2013[2]

[2] Ajmal F., Probst J.C., Brooks J.M., Hardin J.W., & Qureshi Z. Association of freestanding dialysis facility Quality Incentive Program scores and mortality among incident hemodialysis patients in the United States in 2013. To be submitted to *American Journal of Kidney Disease and Kidney International*

5.1 ABSTRACT

Introduction

Medicare included end-stage renal disease (ESRD) as the first disease-based eligibility in 1972. Since then, Medicare has worked to bring efficiency into ESRD care. In its latest initiative, Medicare launched a bundled payment reform along with a quality incentive program (QIP) to address ESRD care cost and quality. The bundle payment component included a fixed payment of $230 per dialysis treatment and QIP was implemented to evaluate facilities using clinical and reporting measures.

QIP scores have been criticized for the inclusion of easy to measure clinical criteria with a concern that there is a limited association between the measures and patient outcomes. However, no study has empirically tested the association between QIP scores and patient outcomes, including patient survival.

Methods

We used a retrospective cohort design. The data files included Medicare dialysis facility compare; Medicare facility level impact; Medicare Quality Incentive program; United State Renal Data System (USRDS) facility and patient data and Area health resource file (AHRF). We restricted data files to service year 2013, the most recent USRDS data available at the time of study. All the incident ESRD patients from January, 2013 to December, 2013, who survived for the first 90 days after the first ESRD service, were included (n=117,129). Linking patient data with USRDS and Medicare free standing dialysis facility data yielded information on 89,540 patients and 5,194 facilities.

We categorized QIP scores into 9 based on smoothing splines with optimal degrees of freedom. We used a multivariable Cox proportional hazard model at the 5% level of significance to assess whether there was an association between facility QIP scores and 1-year survival.

Results

Overall, 11.8% of patients died within one year of follow up (after excluding deaths of the first 90 days of first ESRD service). The unadjusted mortality rates by QIP categories were given by [0,60) (15.6%); [60,65) (12.5%); [65,70) (11.9%); [70,75) (12.5%); [75,80) (11.5%); [80,85) (11.9%); [85,90) (11.3%); [90,95) (11.1%); and [95,100] (11.1%).

We found an association between QIP scores and one year patient survival after adjusting for other covariates. Patients receiving treatment from facilities scoring < 60 showed a higher mortality, compared with patients receiving treatment from facilities scoring ≥ 95.

Conclusions

Contrary to the concerns that QIP criteria include easy to measure clinical criteria, we found an association between QIP scores and 1-year patient survival. Notably, Medicare also uses a cutoff QIP score of 60 to classify underperforming facilities and apply 0-2% penalties. We recommend more studies to confirm our results.

5.2 BACKGROUND

End stage renal disease (ESRD) is a chronic, irreversible and costly disease requiring renal transplant or frequent dialysis for survival (Centers for Disease Control and Prevention, 2014; Levey & Coresh, 2012). Most ESRD patients remain on dialysis due to lack of donors and mismatch of renal tissue (National Kidney and Urologic Diseases Information Clearinghouse, 2013). Considering the high cost of care, Medicare included ESRD as the first disease based edibility in 1972 (A. W. Williams, 2015). The program's ESRD population grew from 10,000 in 1972 to 399,455 in 2014 (United States Renal Data System, 2014). The cost also showed a continuing rising trend over the last four decades (United States Renal Data System, 2015). Medicare continued to promulgate reforms to bring efficiency in ESRD care.

In its most recent reform in 2011, Medicare proposed an 'expanded bundle payment program'(Iglehart, 2011). Given that fixed payments could potentially result in lower quality of services, Medicare implemented a quality incentive program (QIP) as part of bundle payment reform (Watnick, et al., 2012; A. W. Williams, 2015). Failing to meet or exceed QIP criteria reduces reimbursements by 0-2% for facilities (Fishbane & Hazzan, 2012). These criteria have varied over time, with the inclusion of additional measures each year (Center for Medicare and Medicaid Services, 2016b).

In 2013, QIP scores were defined using six clinical and four reporting measures to define a facility score between 0-100 (Centers for Medicare & Medicaid Services 2013). The clinical measures included hemoglobin (Hgb) > 12; urea clearance adequacy for adult and pediatric hemodialysis (Kt/V >1.2 and Kt/V >1.7, respectively) and adult peritoneal dialysis (Kt/V >1.2); catheter use, and the presence of an arteriovenous fistula

(AVF) (Centers for Medicare & Medicaid Services 2013). Reporting measures included reporting on anemia management, mineral metabolism, blood stream infections and patient satisfaction (Centers for Medicare & Medicaid Services, 2012).

Since the QIP was implemented without a prior pilot study, the impact of the program on health outcomes such as survival is still unknown (Vandecasteele & Tamura, 2014; A. W. Williams, 2015). The QIP is criticized for including easy to measure narrow clinical criteria, with a limited focus on patient health outcomes (Chambers, et al., 2013; Moss & Davison, 2015; Nissenson, 2013). The literature has used survival/ mortality as the most common outcome among dialysis patients (Brooks, et al., 2006; Foley, Gilbertson, Murray, & Collins, 2011; Perl, et al., 2011; Thompson, et al., 2012; Yan, Norris, Xin, et al., 2013). However, to the best of our knowledge, no study has yet empirically investigated an association between QIP scores and patient survival. The mortality among ESRD incident patients is considerably higher in the first year of dialysis (Collins, Foley, Gilbertson, & Chen, 2009). Therefore, in the current study, we determined an association between QIP scores and one year mortality.

5.3 METHODS

Study design, study population

We used retrospective cohort design. We included ESRD incident cases of age 18 and over from January 2013 to December 2013 (n=117,129). We tracked 1-year patient mortality from April 1, 2013 to March 31, 2014. We used USRDS 2013-14 data as these were the latest data for which Medicare facility data were available at the time of study. Medicare reports data two years after the service year or calendar year (CY) (Centers for Medicare & Medicaid Services 2013). For instance, services rendered in CY 2013 are reported in 2015, called payment year (PY). Therefore, we used Medicare publicly available data reported in 2015 for our study. Medicare data included dialysis facility compare (DFC), facility level impact and Quality improvement program (QIP) of the CY 2013.

The publicly available datasets and their URLs include, QIP: [Available at URL:https://data.medicare.gov/data/archives/dialysis-facility-compare], DFC: [Available at URL: https://data.medicare.gov/data/archives/dialysis-facility-compare]; facility level impact: [Available at URL: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1614-F.html]. The AHRF file was accessed from, [Available at URL: https://datawarehouse.hrsa.gov/topics/ahrf.aspx].

Data merging

We included information on 96,102 incident cases of patients who received care from freestanding dialysis facilities between January 1 and December 31, 2013. Excluding patients who died in the first 90 days (n=5,205); who received transplant in the initiation of treatment (n=36) and who were lost to follow up (n=334) yielded 90,527 records.

We then merged Medicare facility data with USRDS patient data. Merging Medicare QIP, DFC and impact files yielded 5,212 facility records. We merged AHRF data with Medicare facility data using county Federal Information Processing Standards (FIPS). We used the USRDS crosswalk file to merge Medicare data with the USRDS data, using Medicare facility identification as a unique identifier (PROVHCFA). Merging Medicare and USRDS data yielded 85,187 records. Excluding cases with missing information on any of the variables of interest yielded 84,493 incident patients.

Comparison of included versus excluded cases

Comparing included and excluded records by patient demographic and health factors revealed no difference: gender (p-value, 0.836); ethnicity (p-value, 0.789), age (p-value, 0.053); primary disease causing ESRD (p-value, 0.483); and transplants (p-value, 0.345).

Variables

Dependent and primary explanatory variable

Outcome: Patient survival

We followed only incident cases for patients who had survived the initial 90 days after the first ESRD service (n=84,493). We applied the 90-day rule because USRDS recommends beginning outcome analysis after 90 days of the first ESRD service, partly because of delay in enrollment of new patients with Medicare and partly to stabilize patients on a suitable dialysis modality (United states renal Data System, 2015) . The one-year follow up started from April 1, 2013, the date when the first case was expected to complete a 90-day survival, and ended on March 31, 2014.

Time to death and censoring

We created a binary variable called status – indicating death as 'event' and survival till end of the study or transplantation after 90 days of dialysis initiation as 'censored'. We calculated follow-up time by subtracting the date of death or the date of transplantation

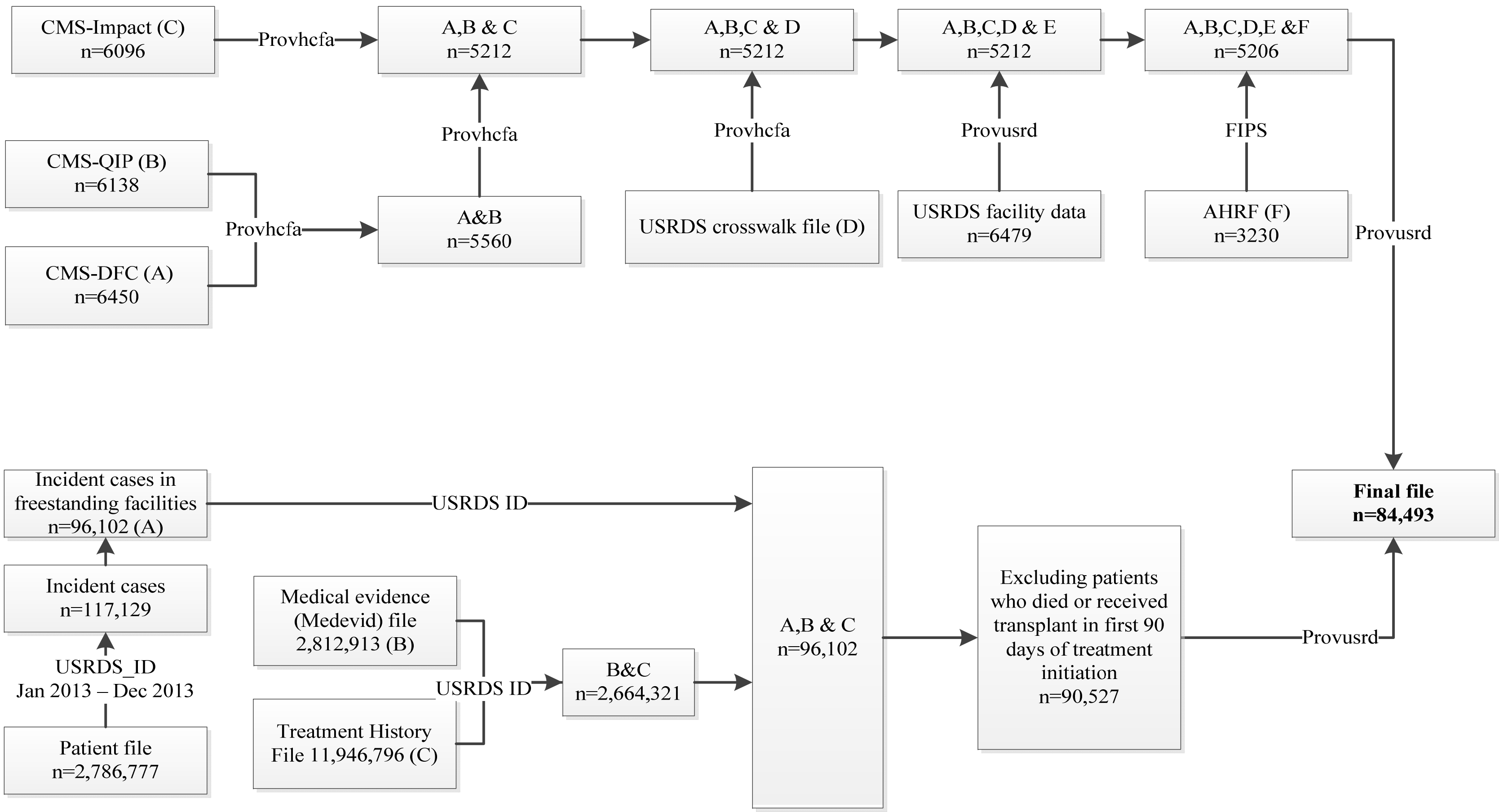

Figure 5.1: Data sources and merging

from date of first service. For patients who did not die or undergo transplantation, time until March 31, 2014 was included as the follow-up period.

Independent variable: Facility QIP scores

We included 2013 facility QIP scores, ranging from 0-100, as the independent variable. We tested the linearity between time to death and QIP scores by adding squared and cubic terms for the QIP scores in separate bivariate models. We found both the squared (p-value <.0001) and cubic terms (p-value <.0001) significantly associated with the patient survival. Therefore, we classified QIP scores into 9 categories based on smoothing splines using optimal degrees of freedom (Therneau & Grambsch, 2013).

Covariates

Patient characteristics

Patient characteristics included age; race; ethnicity; sex; insurance; body mass index (BMI); current employment; smoking status, primary dialysis modality, number of comorbidities including history of diabetes, hypertension, atherosclerotic heart disease (ASHD), Cerebrovascular attack (CVA), peripheral vascular disease (PVD); pre-ESRD care including nephrologist care, use of Epoetin, dietary care, mature arteriovenous fistula or arteriovenous graft.

Age was calculated at the time of treatment initiation. We consolidated race and ethnicity to include white-non-Hispanic, black-non-Hispanic, Hispanic only and others categories. We included three binary (yes/no) variables for insurance status at the time of initiation of ESRD service: Medicaid, private and no insurance.

We calculated the number of patient comorbidities and categorized the variable into four categories, “One or less”, “two”, “three” and “four or more”. We included six distinct binary variables for comorbidities including diabetes, hypertension, atherosclerotic heart disease (AHSD), peripheral vascular disease (PVD), cerebrovascular attack (CVD), and no comorbidity.

The primary cause of ESRD was classified into four categories: diabetes, hypertension, glomerulonephritis and other. We also included four components of pre-ESRD care, including Epoetin, nephrologist care, the presence of mature AVF/AVG and diet care as distinct variables. BMI was categorized using the Center For Disease Control (CDC) criteria into four categories underweight (<18.5); normal (≥ 18.5-<25); overweight (≥ 25-<30) and obese (≥30) (Center for disease control and Prevention, 2015a).

To calculate centroid (straight line) distances between travel points, first, we calculated centroid (straight line) distances between patient and facility ZIP Codes. The SAS ZIP Code file of January 2015 was used to extract longitude and latitude of patient and facility ZIP Codes (SAS support, 2014; SAS support., 2015). We used the SAS “zipcitydistance” macro (SAS support, 2014) to calculate straight line distances between patient and facility ZIP codes (Bliss, et al., 2012). The continuous distances were then grouped into quartiles - <1.9; ≥1.9-<6.9; ≥6.9-<15.0 and ≥15.0 miles.

<u>Facility level covariates</u>

Facility covariates included chain affiliation; for-profit and low volume status; number of dialysis treatments; number of registered nurses, number of dialysis hours per session; number of dialysis sessions per week per patients and services such as home hemodialysis; peritoneal dialysis; and late shift.

Membership in a chain of dialysis facilities was identified with five different options. For the three largest chains, we assigned each chain a number (1 – 3); all facilities affiliated with the smaller or regional chains were consolidated into a single category (chain 4). Remaining facilities, not in a chain, were grouped together.

Ecological covariates

Ecological covariates were measured at the county level. We included the proportions of the population represented by Hispanics and black residents and people in poverty; unemployment rate among age 16 years or more and median household income in the county.

We classified rurality into four groups using Urban Influence Codes (UIC): "Urban" (UIC 1, 2), "Micropolitan rural" (UICs 3, 5 and 8), and "small adjacent rural" (UICs 4 6 and 7) and "remote rural" (UICs 9 10 11 and 12). (United States Department of Agriculture Economic Research Service: Economic Research Service, 2013). We also included facility ESRD regional networks in our analysis and merged them into facilities located in South, West, Midwest and Northeast.

Analysis

We used SAS version 9.4 (SAS Institute, Cary, NC) and R software version 3.4.0 for analysis. We also checked the distribution of covariates across categories of performance scores using Chi-Square for categorical variables and ANOVA for continuous variables.

Bivariate analysis was conducted using time to death as an outcome and performance scores as the predictor. One-year survival probabilities were calculated using the Kaplan–Meier method. The Log Rank test was used to assess equality of survival across QIP categories.

A multivariable Cox regression model was estimated to assess the association of mortality and performance scores using performance score [95,100] as a reference category. Confidence intervals (CI) and p-values were calculated for each covariate. We performed an analysis that sequentially adjusted for three sets of variables for all incident hemodialysis patients. All analyses were conducted at the 5% level of significance.

5.4 RESULTS

Overall study population, facilities and county characteristics

The data included 89,514 incident ESRD cases between January, 2013 and December, 2013, of patients who survived the initial 90 days after receiving their first ESRD service, remained on dialysis and did not receive transplants before death or until the end of follow up period (March 31, 2014).

Patient characteristics

The mean age of the patients at the time of treatment initiation was 63.8 (±14.5) years (Table 5.1). Most patients were male (57.2%), white Non-Hispanic (52.3%), unemployed (29.3%) or retired (61.6%) and obese (40.5%). Hypertension (58.6%) was the most common comorbidity and diabetes (47.6%) was the most common cause of ESRD, followed by hypertension (31.6%). About 7% patients were uninsured and 9%

were employed. The most common vascular access at dialysis initiation was central venous catheter (CVC) (73.8%).

Patient' facility characteristics

Table 5.2 presents Patients' facility characteristics. Most patients were served by medium (10-25 stations) (71.9%); large chains — Chain 1 (32.9%), Chain 3 (32.0%); for-profit facility (92.4%) and the facilities providing >10,000 treatments (61.8%) (Table 5.2). All patients had access to hemodialysis. Additionally, about 57% had access to facilities providing peritoneal dialysis, 33% to facilities conducting home hemodialysis and 24.6% to the facilities offering late night shifts.

Patients' county Characteristics

Table 5-3 presents patients' county characteristics. Most patients lived in urban areas (86.9%) and South (41.3%) (Table 5.3). The average proportions of black and Hispanic residents in patients' counties were 15.6 (SD=14.8) and 18.3 (SD=18.3), respectively. The average unemployment rate was 7.9 (SD=2.3)

Unadjusted analysis: Comparison of patient, facility and county characteristics by QIP scores

Comparison of Patient factors by QIP scores

We found a significant association between all patient characteristics and QIP scores, except BMI, smoking status, and history of hypertension (Table 5.1). Facilities reporting ≥ 90 total scores were more likely to treat Hispanics (17.1%), retired (62%), diabetic (59.3%) and hypertensive (88.3%) patients and patients who saw a nephrologist

(62.5%) as part of pre-ESRD care. Facilities scoring <73 were more likely to have a higher proportion of non-Hispanic black patients (28.7%), with ≥4 comorbidities (35.3%), catheter at initiation of dialysis (73.8%) and absence of a pre-ESRD mature arteriovenous fistula or graft (63.0%).

Comparison of patients' facility factors by QIP scores

Most patients (27.9%) visited facilities with ≥90 QIP score (Table 5.2). Our bivariate analysis showed a significant association between facility characteristics and QIP scores. A total of 27.9% patient visited facilities scoring ≥ 90. Patients served by facilities scoring ≥90 were more likely to visit facilities affiliated with chain 1 (59.5%), for-profit facilities (93.8%), late shift (26.2%) and low volume facilities (2.5%), while facilities scoring ≥73-<83 were more likely to have 10-25 stations and provided >10,000 treatments (Table 5.1) Conversely, facilities scoring <73 were more likely to be affiliated with chain 3 (another large for-profit), offer PD (60.3%), home hemodialysis (38.7%).

Comparison of patients' county factors by QIP scores

All patient county factors were associated with QIP scores in our bivariate analysis. Patients being treated at the facility scoring <73 were in counties with a higher proportion of residents who were black (16.9%), unemployed (8.1%), and persons in poverty (17.4%). Conversely, facilities scoring >90 were in the counties with a higher proportion of Hispanic residents (20.2%). Among the facilities scoring ≥73- <83, most were in South (43.3%).

Unadjusted hazard ratio of one-year mortality by patients, facility and county factors

Table 5.4 presents the bivariate relationships between patient characteristics and one-year mortality. Briefly, all patient characteristics except the distance between patient and facility ZIP Codes were associated with mortality (Table 5.4). Age was associated with increased risk of mortality (HR: 1.04; 95% CI: 1.04- 1.05). Further, unemployed (HR: 2.34; 95% CI: 2.07- 2.64]), retired (HR: 4.22; 95% CI: 3.76- 4.73) and underweight (HR: 1.35; 95% CI: 1.24- 1.47]) demonstrated a higher risk of mortality. Patients covered by Medicaid at the initiation of treatment (Medicaid covered vs. no Medicaid (HR: 1.08; 95% CI: 1.03- 1.13), private insurance (private insurance vs. No private insurance (HR: 1.67; 95% CI: 1.59- 1.75) and no coverage (No coverage vs. any coverage (No coverage vs. any coverage — HR: 3.07; 95% CI: 2.71- 3.47) showed a higher risk of mortality.

We also found pre-ESRD care, including nephrologist care (HR: 0.70; 95% CI: 0.67- 0.72), dietary care (HR 0.80; 95% CI: 0.73- 0.87), mature AVF/AVG (HR 0.67: 95% CI: 0.63- 0.70) and Epoetin use (HR 0.88: 95% CI; 0.83- 0.94] to be associated with lower mortality risk. Compared with non-Hispanic White patients, we found a lower risk Black non-Hispanic (HR: 0.55; 95% CI: 0.52- 0.58), Hispanic (HR: 0.52; 95% CI: 0.49- 0.55) and other races (HR: 0.48; 95% CI: 1.04- 1.05). Lower mortality risk was found among obese (HR 0.84 [95% CI 0.80- 0.88]) and overweight (HR 0.68 [95% CI 0.65- 0.72]) patients, compared with underweight. Catheter use at the initiation of therapy was (HR 2.27 [95% CI 2.12- 2.42]) associated with higher risk.

Table 5.5 presents an unadjusted hazard ratio for one-year mortality associated with facility characteristics. We found a lower mortality risk among patients visiting medium (HR: 0.65; 95% CI: 0.59- 0.71) and large size facilities (HR: 0.76; 95% CI: 0.70- 0.82), compared with small facilities (Table 5.5). Similarly, a higher mortality risk was found among patients visiting facilities providing <4000 treatments (HR: 1.13; 95% CI 1.05- 1.21), and 4000-9999 treatments (HR: 1.15; 95% CI: 1.10- 1.20) and low volume facilities (HR 1.19; 95% CI: 1.04- 1.35). Mortality risk was lower among chain affiliated facilities (Chain 1 (HR: 0.87; 95% CI: 0.81- 0.93), Chain 2 (HR: 0.81; 95% CI: 0.71- 0.92), Chain 3; (HR: 0.81; 95%: CI 0.75- 0.86) and Chain 4 (HR: 0.91; 95% CI: 0.84- 0.94), compared with non-chain affiliated facilities. Mortality risk was also lower among patients visiting facilities offering a higher number of hemodialysis sessions per patient per week (HR 0.87 [95% CI 0.84- 0.90]).

We found a lower risk of mortality among patients living in South (HR: 0.85; 95% CI: 0.80- 0.89) and West (HR: 0.74; 95% CI: 0.69- 0.79) (Table 5.6). The risk of mortality was higher among patients living in micropolitan rural (HR 1.11 [95% CI 1.04- 1.19]), compared with Urban patients.

Examining QIP scores: unadjusted and fully adjusted results

Table 5.7 presents unadjusted hazard ratios of one-year mortality rate by QIP scores. Overall, 11.8% patients died within one year of follow up (after excluding deaths of the first 90 days of first ESRD service). The unadjusted mortality rate by QIP is shown in the table 5.7.

The hazard ratio varied by QIP score. Mortality was markedly higher among patients visiting facilities scoring < 60 (HR: 1.44; 95% CI: 1.31- 1.58) and scoring and >=70- <75 (HR: 1.12; 95% CI: 1.03- 1.22), when compared to mortality at facilities with the highest QIP scores. Notably, patients visiting facilities scoring >=60- <65, >=65- <70 and 75 or more demonstrated no difference compared with those scoring ≥95 (referent category).

We used incremental modelling approach, first adjusting for patient and then for facility and finally for ecological factors. In the model adjusted for patient, facility and ecological covariates (Table 5.8; model 1-c), we found a higher mortality rate among patients visiting facilities scoring a QIP score of < 60 (HR: 1.21; 95% CI: 1.09- 1.34), compared with facilities scoring ≥95 (Table 5.7). We found interaction between rurality and race and rurality and distance insignificant. The association of other covariates from the final adjusted model (model 1-c) is presented in the supplemental table (Appendix F).

5.5 DISCUSSION

We determined the association between dialysis facility performance scores and patient survival among incident patients who had survived for the first 90 days after the first ESRD treatment. Patients visiting facilities scoring <60 on QIP criteria demonstrated a higher risk of mortality than the reference group, i.e., patients visiting facilities scoring ≥95. We found no difference in mortality among patients visiting facilities scoring more than 60 and reference group. To the best of our knowledge, we are first to demonstrate an association between QIP scores and patient survival. Notably, Medicare uses a QIP score of <60 to apply payment penalties of 0-2% of facilities.

Notwithstanding that no prior study has determined an association between facility QIP scores and patient survival, the literature reports an association of survival and specific QIP measures, including hemoglobin >12 and vascular access treatment (AVF) and patient survival (Chand, et al., 2008; Lankhorst & Wish, 2010; National

Institute of Diabetes and Digestive and Kidney Disease, 2014a; Ravani, et al., 2013). For instance, normal levels and lower variation of hemoglobin are associated with fewer complications and better survival. One g/dl increase in standard deviation of hemoglobin was associated with a 33% increase in mortality (Yang, et al., 2007). Similarly, higher use of AVF and lower use of catheter are associated with lower blood stream infections and better patient survival (Chand, et al., 2008; Perl, et al., 2011; Santoro, et al., 2014). Conversely, studies have also shown that normal levels of URR and Kt/V are not or modestly associated with patient survival (Desai, Nissenson, et al., 2009; Moss & Davison, 2015).

The patient survival among facilities scoring ≥60 was not different from the survival in facilities scoring ≥ 95. Research has demonstrated a strong association between some of the factors not included in the QIP criteria and patient survival. For instance, inflammatory and nutritional biomarkers such as tumor necrosis factor (TNF), C-reactive protein (CRP) and pre-albumin are found strongly associated with survival of hemodialysis patients (Desai, Nissenson, et al., 2009). The inclusion of these biomarker might increase the discriminatory effect of QIP scores on patient survival. We recommend future studies on associations between these factors and patient survival.

In their review, Nissenson et al., and Moss et al., proposed including patient prognosis and preferences in ESRD QIP to effectively improve quality and health outcomes among patients (Moss & Davison, 2015; Nissenson, 2013). Medicare has recently revised QIP criteria to include facility reported standardized readmission ratio as a clinical criterion in 2017 (Center for Medicare and Medicaid Services, 2016a). The ratio measures unplanned patient readmission to the hospital after adjusting patient risk factors (The University of Michigan Kidney Epidemiology and Cost Center, 2016). This shows Medicare's shift in focus from clinical-centric to patient-centric criteria. The facility reported patient survival rate can also be considered as a QIP criterion.

This study has several limitations. The data only included the information on the facility from where patients received the first service, therefore, we could not adjust our analysis for number of transitions if patient visited multiple facilities during dialysis treatments. Similarly, we could not adjust our analysis for transitions in treatment modality, if there were any. Further, our data did not include information about a few potential covariates of patient survival, including dialysis dose and its variation, dialyzer reuse and availability of on-site nephrologist.

Despite these limitations, we are first to report association between QIP scores and one year patient survival, using national data. Further, our analysis accounted for multilevel covariates including the patient, facility and ecological factors.

5.6 CONCLUSIONS

We found facilities scoring <60 on QIP criteria associated with higher one year patient mortality. Medicare defines such facilities as "failed facilities" and reduces their reimbursements by 0-2%. However, patient survival in facilities scoring more than 60 was not different from patient survival in facilities scoring ≥95. We recommend research on possibility of inclusion of more patient centric measures such as facility reported patient survival in QIP criteria.

Table 5.1: Patient characteristics by QIP scores in calendar year (CY), 2013

Characteristics	All	QIP Scores ref= <73	QIP Scores ≥73-<83	QIP Scores ≥ 83-<90	QIP Scores ≥ 90	
n	89,519	21031	20,887	22,621	24,980	P-value
%	100	23.5	23.3	25.3	27.9	
Patients gender						
Male	57.2	56.8	57.5	57.3	57.3	<.0001*
Age at incidence mean (SD)	63.8 (14.5)	64.2 (14.5)	63.7 (14.6)	63.6 (14.5)	63.8 (14.3)	**<.0001†**
Race						
White Non-Hispanic	52.3	52.4	54.0	50.4	52.4	<.0001*
Black Non-Hispanic	27.2	28.7	28.1	28.0	24.5	
Hispanic only	15.4	15.1	13.0	16.1	17.1	
Others	5.1	3.7	4.9	5.5	6.1	
Body Mass Index						
Underweight (<18.5)	3.9	4.0	4.0	4.1	3.7	
Normal (≥ 18.5-<25)	27.8	27.2	27.7	28.0	28.1	0.0837*
Overweight (≥ 25-<30)	27.8	27.7	27.4	27.9	28.0	
Obese (≥30)	40.5	41.1	40.9	40.0	40.3	
Insurance						
Medicaid	26.4	25.9	25.4	27.6	26.7	<.0001*
Private insurance	18.0	83.0	82.1	81.7	81.4	<.0001*
No insurance	6.8	6.6	6.7	7.3	6.8	0.0125
Employed						
Not employed	29.3	29.7	29.2	29.7	28.7	0.0084*
Employed	9.1	8.6	9.3	9.3	9.4	
Retired	61.6	61.7	61.5	61.1	62.0	
Vascular access						
AVF/AVG	18.2	16.0	18.8	18.6	19.3	**<.0001***
Catheter	73.8	76.7	73.2	73.2	72.4	
Others	8.0	7.3	8.0	8.2	8.3	
Distance						
<1.9 miles	25.0	22.4	24.9	25.9	26.5	**<.0001***
≥1.9- <6.9 miles	25.0	24.3	24.6	26.0	25.0	
≥6.9- <15.0 miles	25.0	26.2	25.2	24.5	24.3	

Characteristics	**All**	**QIP Scores ref= <73**	**QIP Scores ≥73-<83**	**QIP Scores ≥ 83-<90**	**QIP Scores ≥ 90**	
≥15.0 miles	25.0	27.1	25.3	23.6	24.3	
Primary disease causing ESRD						
Diabetes	47.6	46.5	47.1	47.2	49.2	**<.0001***
Hypertension	31.6	33.3	31.9	32.0	29.4	
Glomerulonephritis	6.7	6.1	6.8	7.0	6.9	
Others	14.2	14.1	14.3	13.8	14.6	
Number of Comorbidities						
≤1	20.8	19.8	20.6	21.8	20.6	**<.0001***
2	25.8	24.9	26.0	26.1	26.2	
3	20.7	20.0	20.8	21.1	20.8	
≥4	32.8	35.3	32.6	31.0	32.4	
Comorbidities						
Diabetes	58.6	58.7	57.6	58.3	59.6	**0.0003***
Atherosclerotic heart disease (ASHD)	16.2	16.6	16.6	15.3	16.3	**0.0004***
Congestive heart failure (CHF)	30.3	31.6	30.3	29.9	29.5	**<.0001***
Chronic obstructive pulmonary disease (COPD)	9.8	10.5	10.1	9.0	9.7	**<.0001***
Hypertension (HTN)	88.0	87.8	88.0	87.8	88.3	0.1904*
Cerebrovascular accident (CVA)	8.9	9.4	9.3	8.6	8.5	**0.0005***
Peripheral vascular disease (PVD)	11.8	12.8	12.0	11.3	11.1	**<.0001***
None	1.9	1.8	1.9	2.0	1.8	0.1049*
Current smoker)	6.4	6.6	6.7	6.1	6.4	0.0853*
Pre-ESRD care						
Epoetin						
Yes	14.6	12.8	15.2	14.3	15.7	**<.0001***
No	56.0	54.7	56.2	56.4	56.8	
Not reported	29.4	32.5	28.6	29.3	27.5	
Dietary care						
Yes	6.3	5.7	6.4	5.9	7.0	**<.0001***
No	70.3	68.4	70.5	71.1	71.0	

Characteristics	**All**	**QIP Scores ref= <73**	**QIP Scores ≥73-<83**	**QIP Scores ≥ 83-<90**	**QIP Scores ≥ 90**	
Not reported	23.4	25.9	23.1	23.0	22.0	
Presence of mature AVF/AVG						
Yes	19.0	16.6	18.8	19.3	20.8	**<.0001***
No	57.8	63.0	57.6	57.1	54.3	
Not reported	23.2	20.3	23.6	23.6	24.9	
Nephrologist care						
Yes	60.3	56.1	61.0	61.0	62.5	**<.0001***
No	26.2	27.6	25.8	26.2	25.4	
Not reported	13.6	16.34	13.2	12.9	12.2	

Notes:
*Chi-Square at Alpha 5%
† ANOVA at Alpha 5%
n=89,519

Table 5.2: Patient's facility characteristics by QIP scores, 2013

n	All 89519	QIP Scores ref= <73 21031	QIP Scores ≥73-<83 20887	QIP Scores ≥ 83-<90 22621	QIP Scores ≥ 90 24980	p-value
%	100	23.5	23.3	25.3	27.9	
Size (stations)						
Large (> 25)	23.0	24.3	22.0	25.6	20.4	**<.0001***
Medium (11-25)	71.9	68.3	74.9	71.0	73.3	
Small (≤11)	5.1	7.4	3.1	3.4	6.4	
Chain type						
Chain 1: Large for-profit	32.9	8.4	20.7	37.4	59.6	**<.0001***
Chain 2: Large not for-profit	3.2	2.8	4.0	3.4	2.6	
Chain 3: Large for-profit	32.0	49.4	42.1	28.8	11.9	
Chain 4: Others	21.7	22.9	22.9	22.3	19.2	
No chains	10.3	16.6	10.4	8.2	6.7	
Dialysis treatment						
<4000	9.2	12.4	9.4	6.5	8.7	**<.0001***
4000-9999	29.1	29.0	32.3	27.5	27.9	
>=10000	61.8	58.6	58.3	66.1	63.4	
For-Profit	92.4	92.2	90.8	92.4	93.8	**<.0001***
Offers Peritoneal dialysis	57.2	60.3	58.3	56.4	54.4	**<.0001***
Offers home hemodialysis	33.1	38.7	33.7	32.2	28.9	**<.0001***
Offers night shift	24.6	22.5	24.6	24.8	26.2	**<.0001***
Low volume	1.9	1.7	2.0	1.4	2.5	**<.0001***
Hemodialysis hours per session, (mean (±SD)	3.8 (0.5)	3.9 (0.5)	3.8 (0.5)	3.8 (0.5)	3.8 (0.5)	**<.0001†**
Hemodialysis session per week, mean (±SD)	3.0 (0.2)	3.0 (0.2)	3.0 (0.2)	3.0 (0.2)	3.0 (0.2)	**0.0376†**
Patient Care Technicians mean, (±SD)	7.7 (5.1)	7.4 (5.2)	7.4 (5.1)	8.1 (5)	7.7 (5.2)	**<.0001†**

	All	QIP Scores ref= <73	QIP Scores ≥73-<83	QIP Scores ≥ 83-<90	QIP Scores ≥ 90	
n	89519	21031	20887	22621	24980	**p-value**
Registered Nurses, mean(±SD)	5.6 (4.2)	6.1 (5.6)	5.6 (4.0)	5.5 (3.4)	5.2 (3.5)	**<.0001†**
Notes: *Chi-Square at Alpha 5%; † ANOVA at Alpha 5% n=89,519						

Table 5.3: Patient's county characteristics by facility QIP scores, 2013

	All	QIP Scores ref= <73	QIP Scores ≥73-<83	QIP Scores ≥ 83-<90	QIP Scores ≥ 90	p-value
n	89519	21031	20887	22621	24980	
%	100	23.5	23.3	25.3	27.9	
Regions						
Midwest	21.4	26.6	21.8	18.2	19.7	**<.0001***
Northeast	16.7	17.3	17.6	16.1	16.0	
South	41.3	38.9	43.3	43.0	39.9	
West	20.6	17.2	17.3	22.8	24.4	
Rurality						
Micropolitan	9.4	7.3	9.6	9.6	10.7	**<.0001***
Remote	1.2	1.0	1.1	1.1	1.6	
Small adjacent	2.6	1.9	2.9	2.1	3.3	
Urban	86.9	89.7	86.5	87.2	84.5	
Proportion of black, Mean (±SD)	15.5 (14.8)	16.9 (14.3)	16.5 (15.4)	15.9 (15.5)	13.4 (13.5)	**<.0001†**
Proportion of Hispanics, Mean (±SD)	18.3 (18.4)	17.2 (17.3)	15.9 (17.0)	19.2 (19.2)	20.2 (19.5)	**<.0001†**
Unemployment Rate, 16+, Mean (±SD)	7.9 (2.3)	8.06(2.2)	7.9 (2.2)	7.9 (2.1)	7.8 (2.4)	**<.0001†**
Percent Persons in Poverty 2013, Mean (±SD)	17.2 (5.7)	17.4(5.4)	17.2 (5.8)	17.3 (5.8)	16.9 (5.6)	**<.0001†**

	All	QIP Scores ref= <73	QIP Scores ≥73-<83	QIP Scores ≥ 83-<90	QIP Scores ≥ 90	p-value
n	89519	21031	20887	22621	24980	
%	100	23.5	23.3	25.3	27.9	
Median Household Income, Mean (±SD)	52077.9 (13359.6)	51458.2 (12494.7)	51773.6 (13432.9)	52415.7 (13665.9)	52525.3 (13670.0)	**<.0001**†

Notes:
*Chi-Square at Alpha 5%
† ANOVA at Alpha 5%
n=89,519

Table 5.4: Unadjusted hazards ratio of 1-year mortality by Patients characteristics, 2013

Patient Characteristics	Parameter Estimate	SE	Chi-Square	p-value	Hazard Ratio	95% Cis	
Sex (Ref = Female)							
Male	0.00	0.02	0.01	0.9344	1.00	0.96	1.04
Age at incidence	0.04	0.00	2679.02	**<.0001**	**1.04**	**1.04**	**1.05**
Race (Ref = Non-Hispanic White)							
Black Non-Hispanic	-0.60	0.03	551.87	**<.0001**	0.55	0.52	0.58
Hispanic only	-0.66	0.03	402.87	**<.0001**	0.52	0.49	0.55
Others	-0.73	0.06	170.89	**<.0001**	0.48	0.43	0.54
Medicaid (Ref= No)	0.07	0.02	9.83	**0.0017**	1.08	1.03	1.13
Private insurance (Ref= No)	0.51	0.03	419.36	**<.0001**	1.67	1.59	1.75
No insurance (Ref= No)	1.12	0.06	313.60	**<.0001**	3.07	2.71	3.47
Employment status (Ref= Employed)							
Unemployed	0.85	0.06	189.92	**<.0001**	2.34	2.07	2.64
Retired	1.44	0.06	599.68	**<.0001**	4.22	3.76	4.73
Body Mass Index (Ref= Normal)							
Overweight	-0.18	0.03	47.16	**<.0001**	0.68	0.65	0.72
Obese	-0.38	0.02	240.10	**<.0001**	0.84	0.80	0.88
Underweight	0.30	0.04	44.64	**<.0001**	1.35	1.24	1.47
Vascular access treatment at initiation of service (Ref= AVF/AVG)							
Catheters	0.82	0.03	609.75	**<.0001**	2.27	2.12	2.42
Others	-0.10	0.06	2.81	0.0936	0.91	0.81	1.02
Distance (Ref= <1.9 miles)							
≥1.9- <6.9 miles	0.01	0.03	0.06	0.8146	1.01	0.95	1.07
≥6.9- <15.0 miles	0.03	0.03	1.28	0.258	1.03	0.98	1.09
≥15.0 miles	0.12	0.03	18.53	**<.0001**	1.13	1.07	1.19
Primary disease causing ESRD (Ref= Others)							
Diabetes	-0.49	0.03	314.92	**<.0001**	0.62	0.58	0.65

Patient Characteristics	**Parameter Estimate**	**SE**	**Chi-Square**	**p-value**	**Hazard Ratio**	**95% Cis**	
Hypertension	-0.34	0.03	138.77	**<.0001**	0.71	0.67	0.75
Glomerulonephritis	-0.84	0.05	256.51	**<.0001**	0.43	0.39	0.48
Severity of comorbidities (Ref= 0-1 comorbidities)							
2 comorbidities	0.17	0.04	22.57	**<.0001**	1.18	1.10	1.27
3 comorbidities	0.41	0.04	132.76	**<.0001**	1.51	1.40	1.61
≥4 comorbidities	0.92	0.03	890.36	**<.0001**	2.52	2.37	2.68
Comorbidities							
Diabetes (Ref=No)	-0.07	0.02	12.26	**0.0005**	0.93	0.90	0.97
Atherosclerotic heart disease (ASHD) (Ref= No)	0.44	0.02	331.99	**<.0001**	1.55	1.48	1.63
Congestive heart failure (CHF) (Ref= No)	0.62	0.02	929.35	**<.0001**	1.85	1.78	1.93
Chronic obstructive pulmonary disease (COPD) (Ref= No)	0.61	0.03	479.75	**<.0001**	1.84	1.74	1.94
Hypertension (Ref= No)	-0.40	0.03	210.76	**<.0001**	0.67	0.64	0.71
Cerebrovascular accident (CVA) (Ref= No)	0.32	0.03	101.37	**<.0001**	1.37	1.29	1.46
Peripheral vascular disease (PVD) (Ref= No)	0.44	0.03	262.62	**<.0001**	1.55	1.47	1.64
None (Ref= No)	0.49	0.09	28.56	**<.0001**	1.64	1.37	1.97
Current smoker (Ref= No)	-0.02	0.04	0.31	**0.5771**	0.98	0.90	1.06
Pre ESRD care							
Nephrologist care (Ref= No)							
Yes	-0.34	0.02	217.63	**<.0001**	0.72	0.68	0.75
Not reported	0.08	0.03	7.30	**0.0069**	1.09	1.02	1.15
Presence of mature AVF/AVG (Ref= No)							
Yes	-0.40	0.03	222.88	**<.0001**	0.67	0.63	0.70
Not reported	-1.00	0.03	1008.23	**<.0001**	0.37	0.35	0.39

Patient Characteristics	Parameter Estimate	SE	Chi-Square	p-value	Hazard Ratio	95% Cis	
Received Epoetin (Ref= No)							
Yes	-0.13	0.03	16.75	**<.0001**	0.88	0.83	0.94
Not reported	0.12	0.02	27.80	**<.0001**	1.13	1.08	1.18
Dietary care (Ref= No)							
Yes	-0.23	0.05	25.15	**<.0001**	0.80	0.73	0.87
Not reported	0.07	0.02	8.97	**0.0027**	1.07	1.03	1.12
Notes: Sample n=84,493							

Table 5.5: Unadjusted Hazard Ratios of 1-year mortality by facility characteristics, 2013

Facility characteristics	Parameter Estimate	SE	Chi-Square	p-value	HR	95% CI	
Facility size (ref=<11 stations)							
Medium (11-25 stations	-0.43	0.05	92.10	**<.0001**	0.65	0.59	0.71
Large (>25 stations)	-0.28	0.04	46.59	**<.0001**	0.76	0.70	0.82
Chain affiliation (ref= No chains)							
Chain 1: Large for-profit	-0.15	0.03	18.06	<.0001	0.87	0.81	0.93
Chain 2: Large not for-profit	-0.22	0.07	10.79	0.001	0.81	0.71	0.92
Chain 3: Large for-profit	-0.22	0.03	38.41	<.0001	0.81	0.75	0.86
Chain 4: Others	-0.09	0.04	6.76	0.0093	0.91	0.85	0.98
Number of treatment (ref= ≥ 10,000)							
<4000 treatments	0.12	0.03	12.08	0.0005	1.13	1.05	1.21
4000-9999 treatments	0.14	0.02	38.14	<.0001	1.15	1.10	1.20
For-profit (ref= No)	0.07	0.04	2.91	0.0883	1.07	0.99	1.15
Offers peritoneal dialysis (ref= No)	-0.01	0.02	0.45	0.504	0.99	0.95	1.03
Offers home Hemodialysis (ref= No)	-0.02	0.02	0.58	0.4481	0.98	0.94	1.03
Offers late shift (ref= No)	-0.04	0.02	2.73	0.0983	0.96	0.92	1.01
Low volume facility (ref= No)	0.17	0.07	6.30	0.0121	1.19	1.04	1.35
Hemodialysis hours per session	-0.13	0.02	38.48	<.0001	0.88	0.84	0.92
Hemodialysis session per week	-0.15	0.06	6.55	0.0105	0.86	0.77	0.97
Patient care technicians	-0.02	0.00	76.50	<.0001	0.98	0.98	0.99
Registered nurses	0.00	0.00	1.10	0.2953	1.00	0.99	1.00
n=84,493							

Table 5.6: Unadjusted Hazard Ratios of 1-year mortality of patient's county characteristics, 2013

Ecological Characteristics	**Parameter Estimate**	**SE**	**Chi-Square**	**p-value**	**HR**	**95% CI**	
Regions (ref= Northeast)							
Midwest	-0.04	0.03	1.80	0.1793	0.96	0.90	1.02
South	-0.17	0.03	36.62	<.0001	0.85	0.80	0.89
West	-0.31	0.03	85.32	<.0001	0.74	0.69	0.79
Rurality (ref= Urban)							
Micropolitan rural	0.10	0.03	9.85	0.0017	1.11	1.04	1.19
Remote rural	0.03	0.09	0.08	0.7822	1.03	0.86	1.23
Small adjacent rural	0.07	0.06	1.42	0.2326	1.08	0.95	1.21
Proportion of Hispanic	0.00	0.00	58.43	<.0001	1.00	0.99	1.00
Proportion of black	0.00	0.00	39.74	<.0001	1.00	0.99	1.00
Unemployment rate among 16+	0.00	0.00	0.79	0.3733	1.00	0.99	1.01
Proportion of persons in poverty	0.01	0.00	47.69	<.0001	0.99	0.98	0.99
Median household income	0.00	0.00	2.09	0.1483	1.00	1.00	1.00

Table 5.7: Unadjusted 1-year mortality and unadjusted Hazard ratio, 2013 incident patients

	Unadjusted Mortality (%)	**Parameter**	**SE**	**Chi-Square**	**p-value**	**HR**	**95% confidence**	
QIP score (ref= ≥95)								
< 60	15.6	0.36	0.05	59.50	**<.0001**	**1.44**	**1.31**	**1.58**
≥60- <65	12.5	0.10	0.05	3.35	0.0673	1.10	0.99	1.22
≥65- <70	11.9	0.06	0.05	1.79	0.1811	1.06	0.97	1.16
≥70- <75	12.5	0.12	0.04	7.17	**0.0074**	**1.12**	**1.03**	**1.22**
≥75- <80	11.5	0.02	0.04	0.34	0.5582	1.02	0.95	1.11
≥80 - <85	11.9	0.05	0.04	1.95	0.1631	1.06	0.98	1.14
≥85- <90	11.3	0.01	0.04	0.04	0.8432	1.01	0.94	1.09
≥90- <95	11.1	-0.02	0.04	0.28	0.5957	0.98	0.91	1.06
≥ 95	11.1	*	*	*	*	*	*	*

Table 5.8: Adjusted Hazard Ratios of 1-year mortality in 2013

	Parameter	SE	Chi-Square	p-value	HR	95% confidence	
Model 1a*							
Score (Ref= ≥95)							
< 60	**0.18**	**0.05**	**14.36**	**0.0002**	**1.20**	**1.09**	**1.31**
≥60- <65	-0.01	0.05	0.02	0.9007	0.99	0.90	1.10
≥65- <70	0.02	0.05	0.18	0.6683	1.02	0.93	1.12
≥70- <75	0.06	0.04	2.15	0.1425	1.07	0.98	1.16
≥75- <80	0.03	0.04	0.38	0.5375	1.03	0.95	1.11
≥80 - <85	0.02	0.04	0.25	0.6198	1.02	0.94	1.10
≥85- <90	0.02	0.04	0.20	0.6548	1.02	0.94	1.10
≥90- <95	-0.01	0.04	0.09	0.7592	0.99	0.92	1.07
Adjusted model 1b†							
Score (ref= ≥95)							
< 60	**0.19**	**0.05**	**13.94**	**0.0002**	**1.21**	**1.10**	**1.34**
≥60- <65	0.01	0.06	0.04	0.8473	1.01	0.91	1.13
≥65- <70	0.05	0.05	0.94	0.3332	1.05	0.95	1.16
≥70- <75	0.08	0.05	3.19	0.0742	1.09	0.99	1.19
≥75- <80	0.04	0.04	0.78	0.3784	1.04	0.95	1.13
≥80 - <85	0.04	0.04	0.84	0.3605	1.04	0.96	1.13
≥85- <90	0.04	0.04	1.03	0.3106	1.04	0.96	1.12
≥90- <95	-0.01	0.04	0.10	0.7545	0.99	0.91	1.07
Adjusted Model 1c‡							
Score (ref= ≥95)							
< 60	**0.19**	**0.05**	**13.36**	**0.0003**	**1.21**	**1.09**	**1.34**
≥60- <65	-0.02	0.06	0.09	0.7588	0.98	0.88	1.10
≥65- <70	0.06	0.05	1.61	0.2044	1.07	0.97	1.18
≥70- <75	0.09	0.05	3.33	0.068	1.09	0.99	1.20
≥75- <80	0.03	0.04	0.51	0.4743	1.03	0.95	1.13
≥80 - <85	0.04	0.04	0.76	0.3843	1.04	0.96	1.13
≥85- <90	0.04	0.04	0.98	0.3222	1.04	0.96	1.12
≥90- <95	-0.02	0.04	0.16	0.689	0.98	0.91	1.07
Notes:							
* Adjusted for patient factors including patients race, age, sex, insurance status, currently employed, smoker, primary disease causing renal failure, severity of comorbidities, comorbidities (diabetes, Hypertension, peripheral vascular disease, congestive heart disease, chronic obstructive pulmonary disease, cerebrovascular accident, None), presence of catheter at the time of treatment initiation, pre-ESRD care (nephrologist care, dietary care, Epoetin, presence of mature AVF/AVG)							

† Model 1b: Adjusted for covariates in model 1a and facility factors including chain affiliation, size, dialysis treatment, low volume, for-profit, offer Peritoneal dialysis, offer home hemodialysis, offer late night shift, presence of registered nurse, dialysis session per week per patient, dialysis hours per session
‡ Adjusted for covariates in model 1a and 1b and county factors including proportion of Hispanic per county, proportion of black per county, proportion of persons in poverty, unemployment rate in 16+, medical household income, rurality and regions

CHAPTER VI- CONCLUSIONS

The CMS has been working on bending the continuing rise in the Medicare cost curve. In pursuit of that, it focuses on areas of high cost and inefficiency. The ESRD care is one such area. ESRD is a costly disease. Medicare included the disease as the first disease based eligibility in 1972, which enabled the program to enroll ESRD patients irrespective of their age. ESRD care uses disproportionate Medicare funds, that is, although the ESRD population comprises about 1% of the Medicare patients, it uses 7% of the program funds. Considering the high and constantly increasing cost of ESRD care, Medicare introduced an ESRD bundled payment reform and the associated Quality Incentive Program (QIP) in 2011. QIP rates facilities on clinical and reporting criteria. It sets a target score for the facilities for them to avoid financial penalties of 0-2%.

The reform can impact small facilities adversely (Iglehart, 2011; A. W. Williams, 2015). Such facilities are mostly rural, low volume and low profit margin. The combinations of these factors and the bundled reform can make small and rural facilities more vulnerable to closure or consolidation. The closure or consolidation of small facilities will result in ESRD patients traveling longer distances to access dialysis. ESRD patients are frail and need timely and recurrent dialyses. Therefore, closure of nearby facilities can impact the patients seriously. The patient, facility and ecological factors associated with small facilities can be different from that in medium and large facilities. Therefore, in our study 1, we determined the association between the factors and QIP scores, adjusting for the patient, facility and ecological factors.

After including three clinical indicators at the time of inception of QIP, Medicare has increased the number of indicators over the years (Centers for Medicare & Medicaid Services, 2012). The program, however, is critiqued for including easy to measure clinical and reporting indicators (Moss & Davison, 2015; Nissenson, 2013). The patient outcomes are missing among QIP criteria. The association of QIP scores with survival is still an unanswered question. Therefore, in our study 2, we also attempted to determine the association between patient survival and QIP scores.

The majority (91%) dialysis facilities are freestanding in the U.S (Medicare Payment Advisory Commission (US), 2015). Therefore, we focused on freestanding dialysis facilities in the current research. We investigated the association between freestanding dialysis facility size and QIP scores as its first study and association between QIP scores and patient survival as the second. The study used Medicare DFC, QIP and impact files and USRDS and AHRF data for the year 2013. To the best of our knowledge, we are first to report the association between facility size, QIP scores and patient survival after adjusting for the facility, patient and ecological factors.

We found an association between facility size and QIP scores. We determined the facility size using a supply side indicator, number of dialysis stations. We noted that the medium (11-25 stations) and large facilities (>25 stations) achieved a higher QIP score, compared with small facilities. Further, facility aggregated patient factors were also significantly associated with the QIP scores. For instance, facilities where patients travelled more distances to access care were associated with lower QIP scores. Therefore, such facilities are more at risk of receiving QIP penalties and closure. The closure of such facilities will result in patients using alternate facilities and traveling longer distances.

Further, we found black and Hispanic populations in the ESRD facilities implicated difference in QIP scores. For instance, while a higher black population in the facility was associated with lower QIP scores, a higher Hispanic population was associated with higher QIP scores. The finding warrants more research into further explore these findings.

In our study 2, which focused on determining association between QIP scores and 1-year patient survival, we included incident ESRD cases from Jan-Dec 2013, who survived the first 90 days after the first ESRD service. We noted that the facilities receiving <60 on QIP criteria demonstrated a lower patient survival than those achieving 95 or more scores.

We found that patient mortality varied by the facility QIP scores. Although, the QIP has been critiqued for using easy to measure clinical indicators, however, the association between QIP scores and patient mortality shows that the composite score (QIP score) comprising of clinical and reporting measures (QIP criteria) have relevance to the patient survival. However, we did not find any difference in 1-year patient survival in facilities scoring more than a score of 60 (the target QIP score), compare with those scoring 95 or more. Notably, we found that facility scoring the Medicare recommended target QIP score of 60 and more did not show a statistically different 1-year mortality. However, we do not know the reason behind this indifferent association between the QIP scores of 60 and more and 1-year mortality. We recommend further research on this and to determine the association between QIP scores and other patient outcomes including hospitalization and readmissions.

In the current ESRD care landscape, the bundled payment reform, QIP and further payment rebasing have broad based implications for ESRD care providers. The penalties have both financial and organizational implications. Therefore, considering both clinical and contextual factors in assigning the QIP scores is important. For instance, adjusting for the population racial mix at the facility might provide more appropriate QIP scores. Further, the mean travel distances of patients from the facility can also influence the quality of care in a facility. Patients traveling longer distances may skip dialysis treatment schedules and therefore show more complications (deranged clinical/laboratory indicators) due to non-compliance to treatment. While we did not find association with rurality however, with closure and consolidation, rural patients will be more adversely affected in the future. We also found patient distances associated with a higher 1-year mortality among ESRD patients in our study 2.

The Medicare currently does not adjust facility scoring for QIP score calculation except for not giving scores to the facilities with fewer than 11 in-center dialysis patients during the performance period (Centers for Medicare & Medicaid Services 2013). QIP scores have high implications on the facility with penalties being applied. We explored associations of higher number of covariates with the QIP scores, including the facility size. Facility size was also found associated with one year of survival in the current and previous research. The earlier research mostly used demand side facility size factors including number of treatments and number of patients. We found the supply side size factor, that is, number of dialysis stations associated with QIP scores. Further, research can highlight if these factors need to be adjusted to appropriately rate facilities on QIP criteria.

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APPENDIX A: SUMMARY OF THE STUDIES INCLUDED IN THE LITERATURE REVIEW

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Sanatan Shreay, 2014	2010	Freestanding dialysis facilities	Cross-sectional, retrospective analysis	2010 Medicare Renal Cost Reports, 2010 U.S. Census	Facility characteristics	Efficiency: dialysis treatments	26.6 %of facilities were technically efficient, Facilities that were members of large chains were less likely to be efficient, No association of competition, for-profit and efficiency. Little effect of labor or cost saving on the efficiency
Yi Zhang, 2011	2004	Medicare dialysis population	Retrospective cohort	USRDS, Medicare DFC, cost reports	Chain affiliation of dialysis facility	Mortality	Mortality was lesser in small non- profit chains while higher at large chain and for-profit dialysis facilities
Hacer Ozgen, 2006	1994 – 2000	Freestanding dialysis facilities	Multiple time series	The Independent Renal Facility Cost Report Data file (IRFCRD)	Chain affiliation of dialysis facility	Efficiency: sum of outpatient dialysis, dialysis training, and home dialysis treatments	The efficiency of the chain affiliated dialysis facilities are not different form independent dialysis facilities

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Yi Zhang, 2013	2006	Patients, facilities file	Cross sectional	USRDS, Medicare DFC	Large for-profit chain facilities	use of IV drugs, mortality	large for-profit and chain facilities are more likely to give IV drugs however, survival was not association with the large for-profit chain facilities giving more IV drugs
Guofen Yan, 2013	2003 – 2009	Patients 385074 from 4633 dialysis facilities	Cross sectional	USRDS: facility file, 2728 form, Census data	number of hemodialysis stations	1-year survival from day 91 of the dialysis initiation, with censoring at transplant, dialysis modality switch, or administrative end of study (August 31, 2010)	Significantly higher mortality associated with facilities comprising #15 stations, and within this group, mortality increased as the number of stations decreased. The association was stronger for racial minorities and patients with diabetes or cardiovascular diseases.

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Milda R. Saunders, 2013	2007	Facilities (5616)	Cross sectional	Medicare DFC, USRDS, Census data	Facility, Neighborhood and Region	survival, adequate dialysis, targeted hemoglobin	Facilities with the highest proportion of African-Americans in the neighborhood had worse patient survival, were less likely to have adequate dialysis, and achieve targeted hemoglobin compared to those with the lowest proportion. Worse than expected survival was associated with for-profit status, increasing number of stations, increasing length of operation, and increasing proportion of poverty in the neighborhood. Increasing dialysis adequacy is associated with for-profit status, being part of Chain 2, and having a greater number of stations. Dialysis facilities in the South had worse than expected patient survival (OR 2.0) and were negatively associated with achieving targeted hemoglobin

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Yi Zhang, 2016	2014	Patients	Cross sectional	Medicare DFC, USRDS, Census data	Facility characteristics, regional factors	Dialysis facility quality	Quality performance was better in for-profit, chain affiliated organization, however not good with large size facilities. Neighborhoods with a higher proportion of African Americans have significantly lower quality. Regional differences also existed
Eric L. Eisenstein, 2008	1996 - 1999	number of hemodialysis patients at year's end (small ≤60, medium 61–120, and large ≥120).	Retrospective cohort design	USRDS, annual CMS cost files & census	Facility size	Mortality	Increasing facility size was associated with a reduced risk of mortality at 4 years for both diabetic and non-diabetic patients

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Ozgen, 2002	1997	Freestanding dialysis facilities	Cross-sectional	IRFCRD	market competition and facility characteristics	Efficiency: sum of outpatient dialysis, dialysis training, and home dialysis treatments	21.1% facilities were efficient, market competition, nonprofit and policy of dialyzer reuse are not associated with the efficiency, higher the % of nonprofit in mixed market, higher will the chance of efficient facilities.
Navdeep Tangri, 2011	2004	12,747 patients	Retrospective cohort	Darwin, CMS 2744 form	Dialysis facility, Patients factors	Dialysis adequacy (URR>=65%)	6.7% of Variation in the URR attainment is attributable to facility level while 12 % to the patient characteristics. Younger age, shorter dialysis vintage, African-American race, and male sex were more likely to not meeting the URR target. 42% reduction in center effect after adjusting for the patients' factors

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
JEFFREY C. FINK, 2001	1997	4971 patients in 189 facilities	Retrospective analysis of hemodialysis patients in Network 5	data from ESRD network 5	Dialysis facility, Patients factors	Dialysis adequacy (URR>=65%)	The variation in URR attributable to the center effect, was greater than that related to individual-level dialysis factors. There center effect on dialysis adequacy within a regional network. Wide between-center variation and strong within-center correlation in dialysis adequacy
Navdeep Tangri, 2010	2004,	Patients (10,112)	Retrospective cohort	DARWIN, Medical Evidence Form (Form 2728), CMS Institutional and Physician/Supplier Claims 2002-04	Dialysis facility, Patients factors	usage and variation in use of AVF	38% were dialyzed using AVFs, 7.1% after case-mix adjustment (little effect of patients' factor)

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Jeffrey C. Fink, 2007	2000 and 2001	229,295 individuals at 3761 facilities	Retrospective, observational study	US Renal Data System (USRDS) standard analysis files (SAF), Area Resource File	Dialysis center	Hematocrit	Center effect was found associated with anemia management independent of commonly titrated epo, higher correlation of the hematocrit values within the center however wide variation exist across center despite controlling the effect of processes used at the facilities to improve the performance
LA Szczech, 2006	1995-2000	31 515 patients form 2685 for-profit, 15085 from 1018 NP	Retrospective cohort	US Renal Data System and CMS' ESRD Clinical Performance Measures (CPM)	Profit versus non profit	mortality, clinical benchmarks	For-profit facilities had a greater death risk, however increased URR, hematocrit >33% and serum albumin
Richard A. Hirth, 2013	2004	234,158 Medicare hemodialysis patients, 995 facilities	Retrospective cohort	Medicare claims for renal dialysis patient	Influence of physicians, facilities, and chains	Achievement of hematocrit (HCT) and urea reduction ratio (URR) targets	The largest chains were more likely than independent dents to achieve the URR target, however no difference in HCT achievement in large nonprofit versus independent facilities. Utilization was associated with HCT achievement.

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Yoshio N. Hall, 2014	2005-08	320,046 patients who initiated dialysis during 2005-2008	retrospective cohort study,	CMS 2005 Medical Evidence Form	Racial/ethnic composition of the dialysis facilities	facility-level survival and achievement of performance targets for anemia and dialysis adequacy	Worse than expected survival for the minority serving facilities as compared to the whites serving facilities, no difference in URR and Hgb
Deborah L. Regidor	July 2001 to June 2003	Cohort of 58,058 maintenance hemodialysis patients from a large dialysis organization (DaVita) in the United States	retrospective cohort study	National database of DaVita, Inc	Longitudinal changes in hemoglobin or administered ESA	Changes in hemoglobin or administered ESA	A decrease or increase in hemoglobin over time was associated with higher or lower death risk, respectively, independent of baseline hemoglobin. Administration of any dose of ESA was associated with better survival, whereas among those who received ESA, requiring higher doses were surrogates of higher death risk Greater survival was associated with a baseline hemoglobin between 12 and 13 g/dl, treatment with ESA, and rising hemoglobin

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Michael V. Rocco, 2006	1999 - 2000	15 287 patients	Cohort study	CMS- ESRD Clinical Performance Measures Project	Clinical measures: Hgb value; serum albumin, use of a fistula and Kt/V urea	Survival and hospitalization	The risk for death and hospitalization increased for each additional guideline indicator that was not met.
Laura C Planting a, 2007	1995 - 1998	668 inci dent hemodialy sis patients from 74 non profit dialysis centers	Prospective cohort study	The ESRD Quality (EQUAL) study	Attainment of albumin, Hgb, Kt/V, vascular access, calcium-phosphate	Mortality, hospital admissions, hospital days & hospital costs	Attainment of each of the five targets was associated individually with better outcomes except cost which was marginally significant
Ajay K. Singh, 2006	2003	717 and 715 in each group of patients;	open-label trial	Primary data from clinical trial	Epoetin alfa targeted to achieve 13.5g/dl in one group and 11.53 g/dl in another group	Composite of death, myocardial infarction, hospitalization for congestive heart failure (without renal replacement therapy), and stroke	The use of a target hemoglobin level of 13.5 g per deciliter (as compared with 11.3 g per deciliter) was associated with increased risk and no incremental improvement in the quality of life.

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Tricia L. Roberts	1998-2000	93 087 patients	Retrospective study	Medicare claims for renal dialysis patient	Hgb during hemodialysis is ranging form <10 g/d->=13 g/d	Mortality	Lower level of Hgb <10 g/d were associated with higher mortality as compared to 12 to <13 g/dl
Wei Yang, 2007	Not mentioned	34,963 hemodialysis	retrospective cohort	Fresenius Medical Care (FMC) database	Hem variability	Mortality	Hgb variability is associated with increased mortality. One g/dl increase in residual standard deviation of Hgb is associated with 33% increase in mortality
Francisco Maduell, 2016	October 2013-September 2015	6129 patients	Prospective, observational, multicenter study	Primary data	Different level of KT	Mortality and hospitalization	Mortality was reduced with level of more than target dose of KT than lower than target dose of KT
Leslie J. Ng, 2011	1996–2004	2635 incident patients	US Dialysis Outcomes and Practice Patterns Study	Primary data	AVF, catheter and graft use	All cause hospitalization, infection related and VA related	baseline catheter use was associated with an increased risk of all-cause hospitalization and infections

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Ronald L. Pisoni, 2009	1996 to 2004	96 HD patients from more than 300 dialysis units participating in the DOPPS in 12 countries	A prospective observational study of HD practices	Primary data	Patient-level or case-mix–adjusted facility-level vascular access use	Mortality and hospitalization risks	Vascular access practice differences accounted for nearly 30% of the greater US mortality
Deepa H. Chand, 2008	2003	12501 patients	Data from The Renal Network Data System	Retrospective data	AVF, catheter and graft use	Hgb value, URR, Kt/V, albumin concentration	CVC patients had lower mean URR, Kt/V, albumin concentration ($p < 0.001$) than AVF and AVG. non difference in HGB level however EPO dose was higher in patient with catheter

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Yanhong Li, 2009	2004-2005	3359 patients	The randomized, placebo-controlled, double-blind, phase 3 clinical trial was conducted at 164 sites	Primary data	Blood stream and non blood stream infection	Mortality, hospitalization	Approximately one in 12 patients receiving dialysis via arteriovenous fistula or synthetic or heterologous tissue graft developed S. aureus infection during a 1-yr period. All-cause mortality at 12 weeks was 20.2% for patients hospitalized with S. aureus bacteremia and 15.7% for patients with other types of S. aureus infection. Patients with either type of infection were hospitalized 11 to 12 d and incurred inpatient costs of approximately $20,000 during the 12 weeks after hospitalization with S. aureus infection.
Dayana Fram, 2014	2010 - 2013	32 patients in Group 1 and 61 in Group 2.	Nested case–control	Primary data	BSI	Mortality, hospitalization	Patients with BSI caused by Staphylococcus aureus had an 8.67 times higher chance of progressing to death or hospitalization, multiresistant organism are more likely to increase early mortality and hospitalization

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Priti R. Patel, 2013	Jan-DEC 2009	Patients from 17 outpatient hemodialysis facilities	Quality improvement project.	Primary data	CDC sponsored project to decrease BSI	BSI and access related BSI	Pooled mean BSI and access-related BSI rates decreased to d 0.89 and 0.42 events per 100 patient-months during the intervention period, respectively from 1.09 and 0.73 events per 100 patient-month
Eduardo Lacson, 2009	Jan-DEC 2006	1,085 Fresenius Medical Care, providing care to atleast 25 patients	Prospective observational study.	Primary data	Achievement of each goal for equilibrated Kt/V, missed HD treatments, hemoglobin level, bicarbonate level, albumin level, phosphorus level, fistulae, and HD catheters	Mortality and hospitalization	Achieving more than 5 goals averaged 3.5 fewer hospital days/patient-year and 20% lower standardized mortality ratios. The incremental number of goals met al.so was associated with improvement in facility mortality (P 0.001) and hospital days (P 0.001)

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
William M. McClellan, 2010	2003-2006	28,135 patients treated by 1127 hemodialysis centers	cross-sectional study	secondary analysis of data collected by the U.S. ESRD Network Program	County poverty where centers are located	prevalence and incidence of AVF use	County poverty inversely associated with incident and baseline prevalence of AVF use (P for trend 0.001), substantial increases in prevalent AVF rates among treatment centers did not associate with county poverty
Robert N Foley, 2008	198-2003	205076 patients	Retrospective cohort	Medicare data system	Profits vs nonprofit facilities	mortality rates	Dialysis at for-profit facilities was associated with higher urea reduction ratios, hemoglobin levels, Epoetin doses, and use of intravenous iron, and less use of blood transfusions and lower proportions of patients on the transplant waiting-list. Patients dialyzed at for-profit and at not-for-profit facilities had similar mortality risks

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
John M. Brooks, 2005	1996–1999	Patients	Observational risk adjustment and instrumental variable methods	Patient and provider-level retrospective data	Profit status of the dialysis facility	patient's survival	Using only the variation in initial dialysis center profit status that was related to the relative proximity of for-profit and nonprofit dialysis centers to the patient, no relationship between dialysis center profit status and patient survival was found
David Van Wyck, 2010	2005-2007	Prevalent long-term hemodialysis patients from 606 before and 504 facilities during 2005-07	Prospective observational study.	Primary data from DaVita Inc. database	Existing facilities (until December 2004) compared to newly enrolled facilities in DaVita 2005-07)	Survival, anemia management and dialysis adequacy	Length of ownership is associated with the better clinical outcomes. existing compared with newly acquired DaVita facilities showed optimum anemia management and dialysis adequacy however, the there was no difference in mortality after two years

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Francesca Tentori, 2007	198-2004	13,792 Patients	Retrospective analysis	Data were obtained from DCI's proprietary computerized medical information system (DARWIN)	Attainment of optimum Dialysis dosage (single-pool Kt/V), hematocrit, serum albumin, calcium, phosphorus, parathyroid hormone	Survival	Values within guidelines for single-pool Kt/V, hematocrit, Serum albumin, calcium, phosphorus, and parathyroid hormone were associated with decreased mortality. The largest survival benefit was found for serum albumin.
Saugar Maripuri, 2012	Initiated dialysis in 2006 - 2007	204463 patients	Retrospective Cohort Study	U.S. Renal Data System SAF files	Rural - urban residence	All-cause mortality and kidney transplantation	Early mortality or long-term hemodialysis (HD) mortality did not significantly differ by geographic residence. micropolitan and rural PD patients had higher risk for long-term mortality than urban PD patients, kidney transplantation was more likely in micropolitan and rural HD patients

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
AM O'Hare, 2006	1995-2002	552 279 patients	Retrospective Cohort Study	U.S. Renal Data System SAF files	degree of rurality	Annualized mortality and transplant rates	Survival among rural dwellers was better than rural patients among black population, however, rural patients were less likely to receive renal transplant
Stephanie Thompson, 2012	1995-2007	726,347 adults initiating chronic hemodialysis	Retrospective Cohort Study	U.S. Renal Data System SAF files	rural/urban and remote dwelling	Survival	Remote dwelling (>100 miles) rather rural dwelling is associated with increased risk of mortality

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Fadi Almachraki, 2016	performance year 2011	Dialysis facilities 6506	Descriptive study	DFC, QIP data	SES of counties	Performance penalties	Dialysis clinic performance penalties did vary by SES, poorer outcomes observed for clinic locations with lower SES. By poverty category, approximately 5% of dialysis clinics received QIP penalties (low poverty, 4.8%; average poverty, 4.3%; high poverty, 4.5%). By clinic setting (ie, rural/urban status), 4.7% of all clinics received penalties. Of dialysis clinics in rural counties, 6.2% received a QIP penalty, whereas only 4.6% of clinics in urban counties received penalties for poor quality.

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Paul L. Kimmel, 2013	started hemodialysis from 2000 through 2008	589,036 patients	Retrospective Cohort Study	USRDS, 2000 U.S. Census data,	Income distributional inequality, residential segregation	Survival	Residence in areas with higher median household income was associated with improved survival. Among whites, income inequality was associated with mortality, among blacks exclusively, residence in highly segregated areas was associated with increased mortality
William M. McClellan, 2010	June 1, 2005 and May 31, 2006	28,135 patients treated by 1127 centers at 16 states	cross-sectional study	USRDS, 2000 U.S. Census data,	Geographical poverty at county level	use of AVF	County poverty inversely associated with incident AVF use. substantial increases in prevalent AVF rates among treatment centers did not associate with county poverty

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Hua Hao, 2015	2007-2010	patients from 5387 facilities	observational cohort study	USRDS, DFC	Geographic and SES factors	Use of AVF and mortality	67% patients using AVF with the wide range of 3-99%. Dialysis facilities with the lowest rates of pre-ESRD care were more likely to be located in urban counties with high African-American populations and low educational attainment. A 10% higher proportion of patients receiving pre-ESRD care was associated with 1.3% lower patient mortality as reflected by facility-level mortality.
Tanya S. Johns, 2014	2006-2009	11027 patients	Retrospective Cohort Study	USRDS, 2000 U.S. Census data,	Neighborhood SES and racial difference	Mortality	Among patients living in low SES, black young patients were at higher risk of mortality than white patients. The difference in mortality between black and white were attenuated in high SES.

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Rudolph A. Rodriguez, 2007	Patients who initiated dialysis1 995-2002	399 424 patients, dialysis facilities in operation in December 2004 (n= 3244)	Retrospective cohort study for patients' sample, cross sectional study for the facilities	U.S. Renal Data System SAF files, (CMS) Dialysis Facility Compare database	Urban residential segregation	Patient level: Mortality and time to transplantation; facility level: (anemia management, dialysis adequacy, and facility-level mortality rates).	Mortality rates were higher among white patients but not among black patients living in areas with a higher percentage of black residents. Time to transplantation was longer among both black and white patients in areas with higher percentage of black residents. Dialysis facilities located in areas with a higher percentage of black residents were more likely to have higher-than expected mortality rates and were less likely to meet performance targets.

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Stephen F. Derose, 2013	2003–2009	Adult members of Kaiser Permanente Southern California (526,498 whites, 350,919 Hispanics, 136,923 blacks, and 105,476 Asians)	Retrospective cohort	Secondary data of members of Kaiser Permanente Southern California, an integrated health system	Race/ethnicity	ESRD (dialysis, transplantation); mortality	Blacks had more extreme rates of e GFR decline, Hispanics, and Asians. Black were at the highest risk of projected kidney failure followed by Hispanic and Asian as compared to the Whites. Mortality among those with projected kidney failure was highest in whites.
Andy I. Choi, 2010	2001 to 2005	201, 5891 veterans	Retrospective cohort	Secondary data of VA	white/black differences	ESRD risk, mortality	Rates of end-stage renal disease among black patients exceeded those among white patients at all levels of baseline eGFR. Equal or higher rates of death among black persons at all levels of eGFR. No difference in mortality between whites and black at eGFR <15 ml/min/1.75m2 while mortality was higher among black as compared to white at eGFR 45-59

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Cristina M. Arce, 2013	1997-2005 (initiated dialysis)	615,618 white patients	retrospective cohort study.	Secondary data: USRDS	Hispanic ethnicity (vs non-Hispanic whites), year of end-stage renal disease incidence, age	All-cause and cause-specific mortality	Hispanics initiating dialysis therapy experienced lower mortality than non-Hispanic whites, but age modified this association. Mortality in Hispanics was 33%, lower at ages 18-39 years and 40-59 years, 19% and 6% lower at ages 60-79 and 6% at age 80 years, respectively. Differential access to kidney transplantation was responsible for much of the apparent survival benefit noted in younger Hispanics
Guofen Yan, 2013	1995 and 2009	1,282,201 incident dialysis patients	retrospective cohort study.	Secondary data: USRDS	Race/ethnicity	mortality	The mortality risk was lowest in Hispanics, intermediate in non-Hispanic blacks, and highest in non-Hispanic whites for all age groups except 18- to 30-years group (black adjusted mortality rates were higher than white NH)

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Lauren M. Kucirka , 2011	1995-2009	1 330 007 incident patients	observational cohort study	Secondary data: USRDS	Race/ethnicity/age	mortality	overall Black patients have higher mortality than white. Black were at lesser risk of mortality at age more than 50 years while at higher risk at age lesser than 50 years
Csaba P. Kovesdy , 2013	2004-2006	518,406 white and 52,402 black male US veterans non-dialysis dependent CKD stages 3–5.	Historical cohort.	Secondary data: VA-Medicare data merge project	Black race	CKD stage-specific all-cause mortality	The survival advantage for blacks was attenuated after adjustment for age (HR, 1.14; 95% CI, 1.12–1.16), but was even magnified after full multivariable adjustment (HR, 0.72; 95% CI, 0.70–0.73; $p<0.001$).

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Saugar Maripuri, 2013	Patients who initiated dialysis in 2006 and 2007	Patients 204463	Retrospective cohort study	Secondary data: USRDS	US micropolitan and rural dialysis patients	Rate of pre-ESRD care, mortality and rate of transplantation	No significant geographic differences in attainment of early nephrology care or permanent dialysis access. Both micropolitan and rural patients received less dietary education. Receiving care reduced all-cause mortality and increased the likelihood of transplantation to a similar degree regardless of geographic residence.
Szu-Chia Chen, 2010	1997-2006	192 hemodialysis patient	Retrospective cohort study	Secondary data	Early nephrology referral vs late referral	survival	ER is significantly associated with prolonged survival after exclusion of lead-time bias

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Brenda W. Gillespie , 2015	2006 - 2010.	443 761 incident ESRD patients	Retrospective cohort study	Secondary data: USRDS	longer pre ESRD nephrology care	Survival	Predictors of >12 months of nephrology care included having health insurance, white race, younger age, diabetes, hypertension and US region. Longer pre-ESRD nephrology care was associated with lower first-year mortality, higher albumin and hemoglobin, choice of peritoneal dialysis and native fistula and discussion of transplantation options. Living in a state with a 10% higher proportion of patients receiving >12 months of pre-ESRD care was associated with a 9.3% lower relative mortality rate
Takeshi Hasegawa, 2009	1996-2001, 2002-2004	8500 incident HD patients	Prospective data collection in phase I & II	Dialysis Outcomes and Practice Patterns Study (DOPPS)	early and frequent pre-nephrology visit (PNV)	mortality in the first year	PNV was associated with significantly lower risk for death at patient and facility level.

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Louise M. Moist, 2008	1996 to 2001, 2002-2004	n 20,994).	Prospective observational cohort	Dialysis Outcomes and Practice Patterns Study (DOPPS)	One-way travel time to hemodialysis treatment	mortality, withdrawal from dialysis therapy, hospitalization, and transplantation	Longer travel time was associated with greater adjusted relative risk (RR) of death. No association with other outcomes
Aminu K. Bello, 2012	2005-2006	We identified 31 337 individuals with diabetes and eGFR 15–59 mL/min/1.73 m2	Retrospective cohort study	Alberta Kidney Disease Network and the provincial health ministry [Alberta Health and Wellness (AHW)]	Residence location (0–50, 50.1–100, 100.1–200 and >200 km) from nephrologist	Markers of quality health care, mortality	The hazard ratio of all-cause mortality and hospitalization increased with increasing distance among patient with CKD stage 3 and 4 living at more than 50 km. remote dwellers were less likely to visit a nephrologist, less likely to have hemoglobin A1c and urinary albumin measured within 1 year of the index eGFR, and less likely to receive an angiotensin converting enzyme inhibitor, angiotensin receptor blocker or statin

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Diana Rucker, 2011	Jan 2005-Dec2005	31,452 outpatients	Retrospective cohort study	Alberta Kidney Disease Network and the provincial health ministry [Alberta Health and Wellness (AHW)]	Residence location (0–50, 50.1–100, 100.1–200 and >200 km) from nephrologist	All-cause mortality, dates of hospitalization, and the date of first renal replacement therapy for people who developed ESRD	Remote dwellers were less likely to visit a nephrologist or a multidisciplinary CKD clinic within 18 months of the index measurement of the eGFR, receive an angiotensin converting enzyme inhibitor or receptor blocker in the setting of diabetes or proteinuria. remote dwellers with diabetes were significantly less likely to have hemoglobin A1c evaluated within 1 year of the index eGFR measurement, to have urinary albumin assessed biannually. Remote-dwelling participants were also significantly more likely to die or be hospitalized during follow-up than those living closer

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Chia-Ter CHAO, 2014	Not mentioned	46 chronic, stable elderly hemodialysis patients	Prospective observational cohort	Data from the hospital located in the rural outskirts of New Taipei City in Taiwan	rural and remote dwelling	anemia	travel distance between the patient's residence and the dialysis unit led to an incremental elevation of risk of anemia in chronic hemodialysis patients
Brian D. Bradbury, 2007	1996-2004	4802 incident patients	Retrospective cohort study	DOPPS	patient characteristics	Mortality in the first year	Mortality risk was higher in initial 120 day after HD initiation. 20% of all deaths in the first 120 d occurred subsequent to withdrawal from dialysis. Older age, catheter vascular access, albumin <3.5, phosphorus <3.5, cancer, and congestive heart failure all were associated with elevated mortality. Pre-ESRD nephrology care was associated with a significantly lower risk for death before 120 d. Older age, catheter vascular access, albumin <3.5, phosphorus <3.5, cancer, and congestive heart failure all were associated with elevated mortality.

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
Dinanda J. de Jager, 2009	1994-2007	123 407	Retrospective cohort study	European Renal Association–European Dialysis and Transplant Association registry	cardiovascular and non-cardiac causes	Mortality	Patients starting dialysis have a generally increased risk of death that is not specifically caused by excess cardiovascular mortality
Pisoni RL, 2015	Aug 2010-Aug 2013	Patients (n=3,442)	Prospective observational cohort study	The Dialysis Outcomes and Practice Patterns Study(DOPPS) Practice Monitor	Country, patient demographics, time period.	Vascular access use, pre–end-stage renal disease access timing of first nephrologist care and arteriovenous access placement, patient self-reported vascular access preferences	Arteriovenous fistula (AVF) use increased, Catheter use decreased since the introduction of PPS. AVF use at dialysis therapy initiation remains low. AVF use was 2 folds higher in blacks

Author	Year	Unit of analysis	Design	data type	Main exposure	Outcome	Study Findings
John Kalbfleisch	2007–2010	5920 dialysis facilities during calendar year 2010	Prospective observational cohort study	CMS ESRD data, Social Security Death Master File	Facilities with more black population treated	Standardized mortality ratio (SMR)	facilities with higher proportions of black patients had poorer survival outcomes among black and non-black patients; facilities with the highest percentage of black patients (top 10%) had mortality rates approximately 6% worse than expected

APPENDIX B: DISTRIBUTION OF DIALYSIS STATIONS AND QIP SCORES AND ASSOCIATION BETWEEN THE STATIONS AND QIP

Study 1: descriptive Statistics total stations

The UNIVARIATE Procedure
Variable: TOTSTATS (TOTSTATS)

Moments

N	5193	**Sum Weights**	5193
Mean	18.9472468	**Sum Observations**	98412
Std Deviation	7.78185075	**Variance**	60.5572012
Skewness	1.31178711	**Kurtosis**	4.31143661
Uncorrected SS	2179110	**Corrected SS**	314473.546
Coeff Variation	41.0711426	**Std Error Mean**	0.10797717

Basic Statistical Measures

Location		**Variability**	
Mean	18.94725	**Std Deviation**	7.78185
Median	18.00000	**Variance**	60.55720
Mode	12.00000	**Range**	80.00000
		Interquartile Range	11.00000

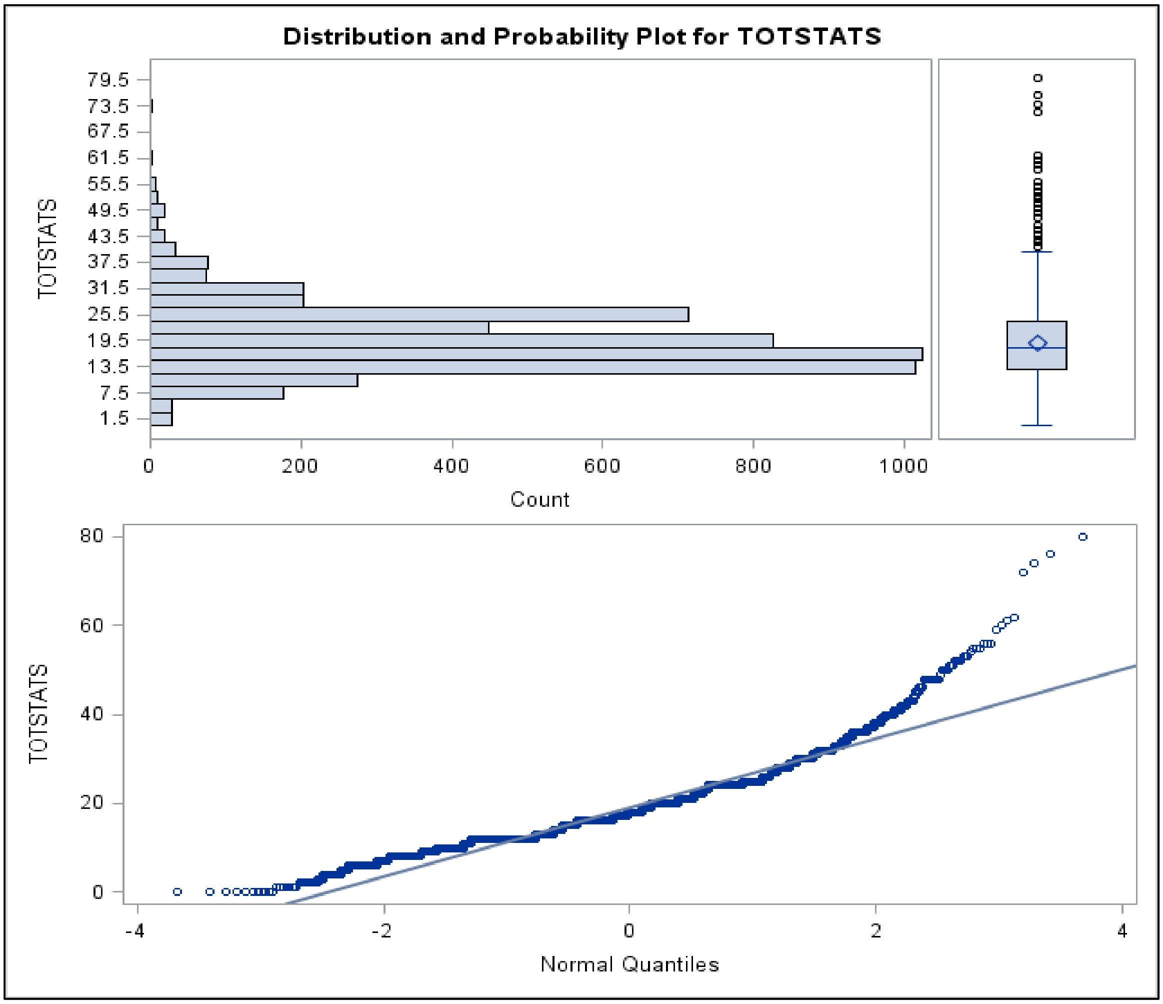
Tests for Location: Mu0=0

Test	**Statistic**		**p Value**	
Student's t	**t**	175.4746	**Pr > |t|**	<.0001
Sign	**M**	2592	**Pr >= |M|**	<.0001
Signed Rank	**S**	6719760	**Pr >= |S|**	<.0001

Tests for Normality

Test	**Statistic**		**p Value**	
Kolmogorov-Smirnov	**D**	**0.096781**	**Pr > D**	**<0.0100**

Cramer-von Mises	W-Sq	11.59547	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	72.40248	Pr > A-Sq	<0.0050



Study 1: descriptive statistics QIP scores

The UNIVARIATE Procedure
Variable: QIP (Quality Incentive Program)

Moments

N	5193	**Sum Weights**	5193
Mean	81.3045822	**Sum Observations**	422296
Std Deviation	12.4789841	**Variance**	155.725044

Moments

Skewness	-0.9495545	**Kurtosis**	1.57754604
Uncorrected SS	35143280	**Corrected SS**	808680.151
Coeff Variation	15.3484388	**Std Error Mean**	0.1731523

Basic Statistical Measures

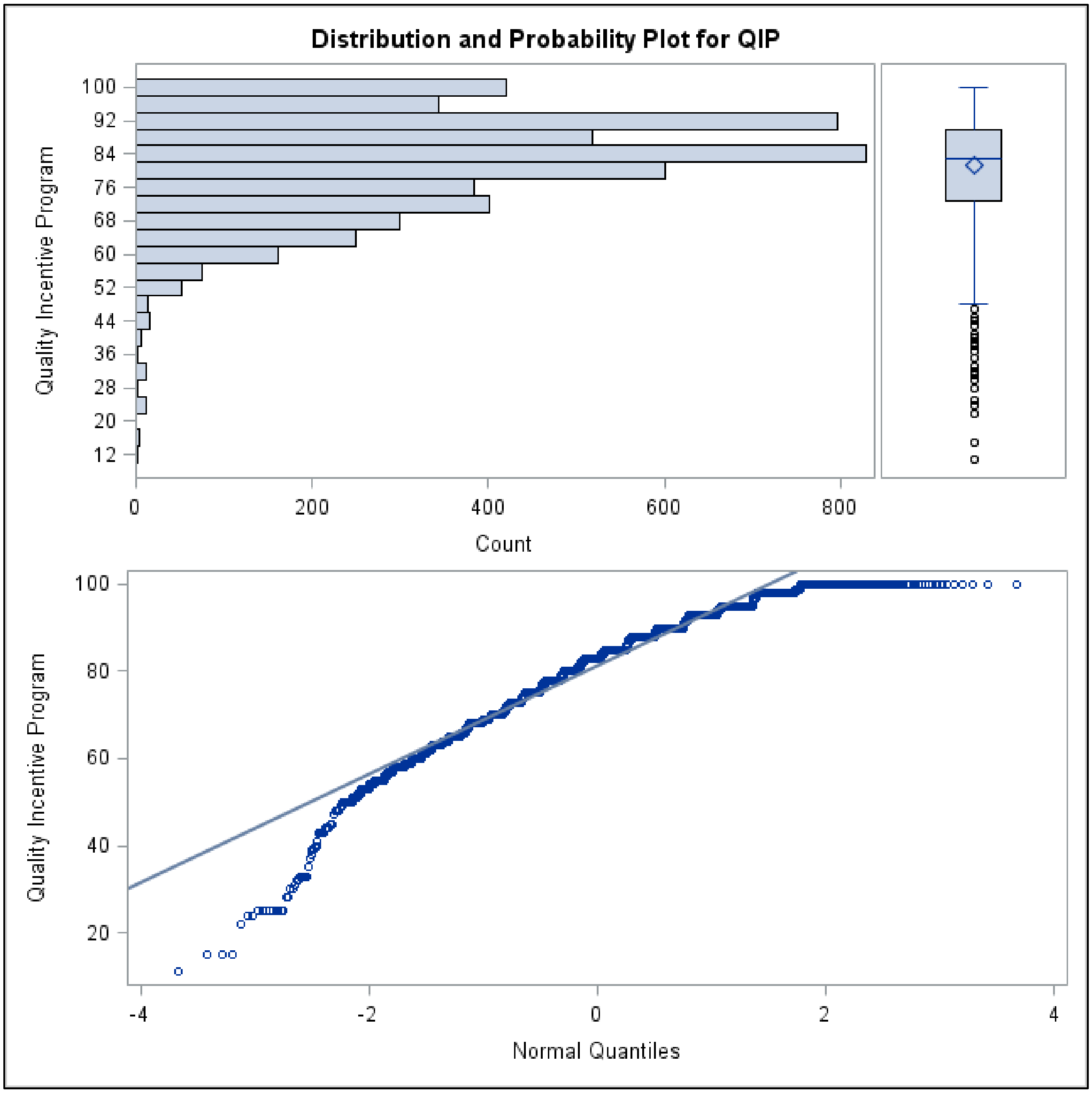
Location		**Variability**	
Mean	81.30458	**Std Deviation**	12.47898
Median	83.00000	**Variance**	155.72504
Mode	88.00000	**Range**	89.00000
		Interquartile Range	17.00000

Tests for Location: Mu0=0

Test	**Statistic**		**p Value**	
Student's t	**t**	469.5553	**Pr > |t|**	<.0001
Sign	**M**	2597	**Pr >= |M|**	<.0001
Signed Rank	**S**	6745708	**Pr >= |S|**	<.0001

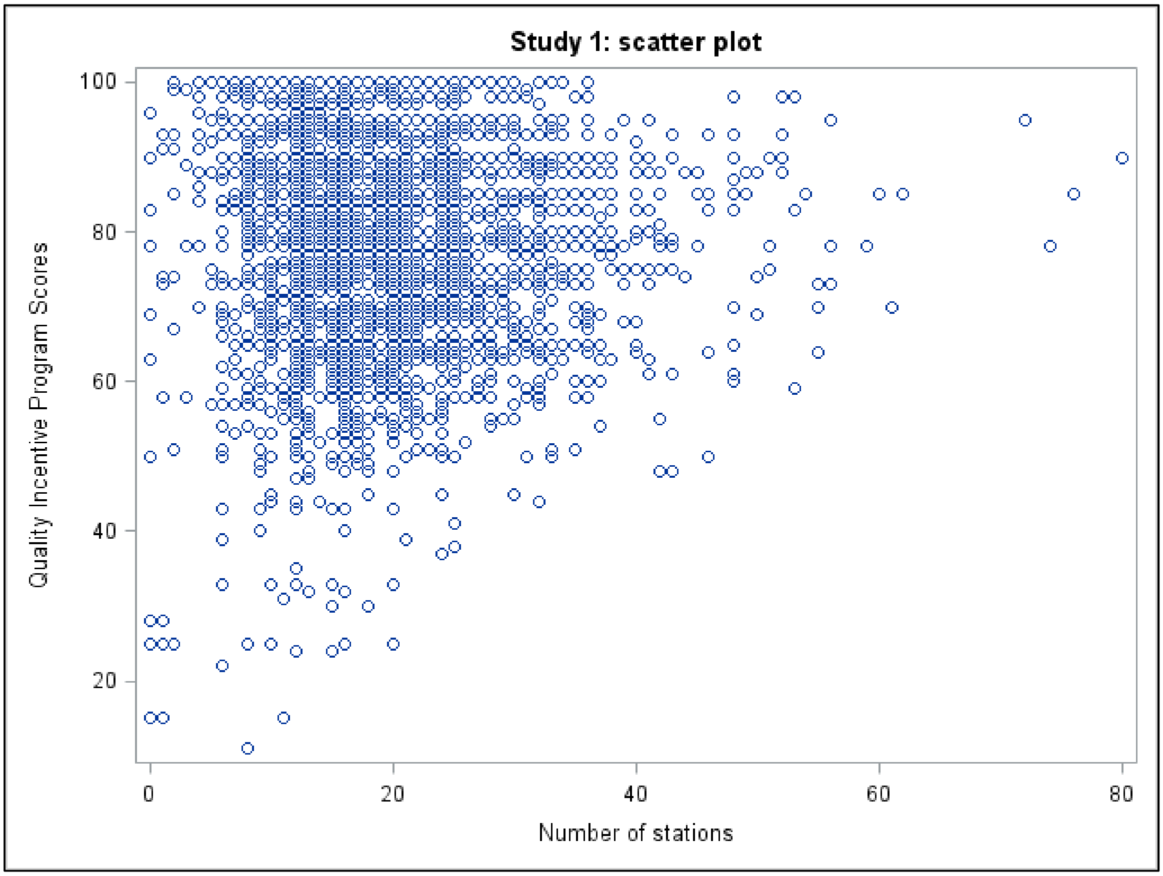
Tests for Normality

Test	**Statistic**		**p Value**	
Kolmogorov-Smirnov	**D**	0.103515	**Pr > D**	<0.0100
Cramer-von Mises	**W-Sq**	8.791008	**Pr > W-Sq**	<0.0050
Anderson-Darling	**A-Sq**	53.74832	**Pr > A-Sq**	<0.0050


Distribution and Probability Plot for QIP
Quality Incentive Program
100
92
84
76
68
60
52
44
36
28
20
12
0
200
400
600
800
Count
Quality Incentive Program
100
80
60
40
20
-4
-2
0
2
4
Normal Quantiles

APPENDIX C: SCATTER PLOT SHOWING RELATIONSHIP

BETWEEN DIALYSIS STATIONS AND QIP SCORES



APPENDIX D: ZHANG'S MODEL USING DIALYSIS STATIONS AS A SQUARED TERM

<table>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Parameter</td><td>Estimate</td><td>Standard error</td><td>Pr > |t|</td></tr>
<tr><td>Intercept</td><td>76.926</td><td>1.264</td><td><.0001</td></tr>
<tr><td>Stations</td><td>0.194</td><td>0.066</td><td>0.003</td></tr>
<tr><td>Stations*stations</td><td>-0.003</td><td>0.001</td><td>0.006</td></tr>
<tr><td>chain 1</td><td>6.562</td><td>0.464</td><td><.0001</td></tr>
<tr><td>chain 2</td><td>1.308</td><td>1.196</td><td>0.274</td></tr>
<tr><td>chain 3</td><td>-4.798</td><td>0.469</td><td><.0001</td></tr>
<tr><td>No chain</td><td>-3.961</td><td>0.635</td><td><.0001</td></tr>
<tr><td>For-profit</td><td>1.495</td><td>0.922</td><td>0.105</td></tr>
<tr><td>Rural</td><td>1.762</td><td>0.468</td><td>2E-04</td></tr>
<tr><td>Midwest</td><td>-0.897</td><td>0.528</td><td>0.09</td></tr>
<tr><td>Northeast</td><td>1.234</td><td>0.609</td><td>0.043</td></tr>
<tr><td>South</td><td>0.690</td><td>0.512</td><td>0.178</td></tr>
<tr><td>Persons in poverty</td><td>0.003</td><td>0.034</td><td>0.936</td></tr>
<tr><td>Black population in county</td><td>-0.069</td><td>0.013</td><td><.0001</td></tr>
<tr><td>Length of certification</td><td>0.067</td><td>0.018</td><td>2E-04</td></tr>
<tr><td>R-square= 16.04%</td><td></td><td></td><td></td></tr>
</table>

APPENDIX E: SUMMARY OF INCREMENTAL MODEL PREDICTING PERFORMANCE SCORES

	Estimate	Standard Error	p-value
Model A			
Dialysis facility size (ref: small)			
Large	-0.44	0.85	0.6022
Medium	0.82	0.63	0.1942
Model B			
Dialysis facility size (ref: small)			
Large	1.08	0.87	0.2107
Medium	1.67	0.64	0.0093
Model C			
Dialysis facility size (ref: small)			
Large	2.81	1.23	0.0219
Medium	3.67	1.06	0.0005
Model A: adjusted for facility factors including chain type, home hemodialysis, peritoneal dialysis, for-profit status, shift, low volume, regional networks, patients per station, staff per 100 patients, dialysis treatment per facility, hemodialysis session per week per patients, hours per session (Model R-square = 15.7%)			
Model B: adjusted additionally for ecological factors including median household income, unemployment rate among 16+, proportion of person in poverty/county, proportion of black patients per county, proportion of Hispanic patients per county, rurality, region, competition index (Model R-square = 17%)			
Model C: adjusted additionally for patients factor including per facility average distance from facility, average age of patients, proportion of male patients, proportion of black patients, proportion of Hispanic patients, proportion of ≥ 2 comorbidities, proportion of obese, proportion of Medicaid insured, proportion of uninsured, proportion with catheter at the time of treatment initiation, proportion of pre-ESRD nephrologist care, proportion of smokers, average hemoglobin level, average glomerular filtration rate (Model R-square = 25.1%)			

APPENDIX F: ADJUSTED HAZARD RATIOS OF 1-YEAR MORTALITY OF PATIENT BY PATIENT, FACILITY AND COUNTY CHARACTERISTICS FROM FINAL ADJUSTED MODEL, CALENDAR YEAR 2013

Characteristics	**Parameter estimate**	**SE**	**Chi-Square**	**p-value**	**Hazard ratio**	**95% Confidence Limits**	
Patient factors							
Sex (Ref=Female)							
Male	0.05	0.02	4.91	**0.0266**	1.05	1.01	1.09
Age at ESRD incidence	0.03	0.00	846.92	**<.0001**	1.03	1.03	1.03
Race (Ref= White non-Hispanics)							
Black Non-Hispanic	-0.36	0.03	146.97	**<.0001**	0.70	0.66	0.74
Hispanic only	-0.53	0.04	156.74	**<.0001**	0.59	0.54	0.64
Others	-0.56	0.06	85.65	**<.0001**	0.57	0.51	0.64
Vascular access treatment (ref= AVF/AVG)							
Catheters	0.38	0.07	32.13	**<.0001**	1.46	1.28	1.66
Others	0.41	0.22	3.40	0.065	1.51	0.98	2.35
Distance (Ref= <1.9 miles)							
≥1.9- <6.9 miles	0.05	0.03	2.96	0.0851	1.05	0.99	1.12
≥6.9- <15.0 miles	0.03	0.03	1.02	0.3118	1.03	0.97	1.09
≥15.0 miles	0.08	0.03	8.45	**0.0037**	1.09	1.03	1.15
Insurance							
Medicaid (ref=No)	0.11	0.03	16.49	**<.0001**	1.12	1.06	1.18

Characteristics	Parameter estimate	SE	Chi-Square	p-value	Hazard ratio	95% Confidence Limits	
Private insurance (ref=No)	-0.13	0.03	13.66	**0.0002**	0.88	0.83	0.94
No insurance (ref=No)	0.46	0.07	44.04	**<.0001**	1.59	1.39	1.83
Employment status (Ref= Employed)							
not employed	0.48	0.07	48.97	**<.0001**	1.61	1.41	1.84
Retired	0.53	0.07	63.54	**<.0001**	1.70	1.49	1.94
Basal metabolic index (Ref= Normal Weight)							
Obese	-0.18	0.03	46.85	**<.0001**	0.90	0.86	0.95
Overweight	-0.10	0.03	14.22	**0.0002**	0.83	0.79	0.88
Underweight	0.24	0.05	27.13	**<.0001**	1.28	1.16	1.40
Primary disease causing ESRD (Ref= Others)							
Diabetes	-0.28	0.03	68.54	**<.0001**	0.76	0.71	0.81
Hypertension	-0.25	0.03	68.00	**<.0001**	0.78	0.73	0.82
Glomerulonephritis	-0.31	0.06	31.05	**<.0001**	0.74	0.66	0.82
Severity of comorbidities (Ref= 0-1 comorbidities)							
2 comorbidities	0.22	0.04	31.50	**<.0001**	1.25	1.16	1.35
3 comorbidities	0.34	0.04	65.43	**<.0001**	1.41	1.30	1.54
≥4 comorbidities	0.72	0.05	257.92	**<.0001**	2.07	1.89	2.26
Comorbidities							
diabetes (Ref= No)	-0.11	0.03	14.50	**0.0001**	0.90	0.85	0.95
ASHD (Ref= No)	-0.08	0.03	8.52	0.0035	0.92	0.87	0.97
CHF (Ref= No)	0.15	0.02	37.30	**<.0001**	1.16	1.11	1.21
COPD (Ref= No)	0.06	0.03	3.50	0.0614	1.06	1.00	1.12
Hypertension (Ref= No)	-0.47	0.03	234.24	**<.0001**	0.63	0.59	0.67
CVA/TIA (Ref= No)	-0.05	0.03	2.06	0.1507	0.95	0.89	1.02
PVD (Ref= No)	0.02	0.03	0.57	0.449	1.02	0.96	1.09
Comorbidity (REF=No)	0.42	0.10	17.10	**<.0001**	1.52	1.25	1.86
Current smoker (Ref= No)	-0.05	0.04	1.46	0.2264	0.95	0.87	1.03

Characteristics	Parameter estimate	SE	Chi-Square	p-value	Hazard ratio	95% Confidence Limits	
Pre ESRD care							
Nephrologist care (Ref= No)							
Yes	-0.20	0.03	54.80	**<.0001**	0.82	0.78	0.86
Not reported	0.06	0.04	1.80	0.1797	1.06	0.97	1.15
Dietary care (Ref=No)							
Yes	0.01	0.05	0.02	0.8977	1.01	0.91	1.11
Not reported	-0.03	0.04	0.69	0.4076	0.97	0.91	1.04
Presence of mature AVF/AVG (Ref= No)							
Yes	-0.32	0.03	126.86	**<.0001**	0.73	0.69	0.77
Not reported	-0.46	0.07	38.83	**<.0001**	0.63	0.55	0.73
Received Epoetin (Ref= No)							
Yes	0.00	0.04	0.02	0.8899	1.00	0.93	1.07
Not reported	0.09	0.03	8.29	**0.004**	1.09	1.03	1.16
Facility Factors							
Size (ref=small)							
Medium (11-25 stations	-0.15	0.06	7.30	**0.0069**	0.86	0.77	0.96
Large (>25 stations)	-0.11	0.05	5.62	**0.0178**	0.90	0.82	0.98
Chain affiliation (ref= No chains)							
Chain 1: Large for-profit	0.02	0.04	0.27	0.6013	1.02	0.95	1.10
Chain 2: Large not for-profit	-0.12	0.08	2.28	0.131	0.89	0.76	1.04
Chain 3: Large for-profit	-0.10	0.04	6.73	**0.0095**	0.91	0.84	0.98
Chain 4: Others	0.05	0.04	1.82	0.1767	1.05	0.98	1.14
Dialysis treatments (ref=>10,000)							
<4000	-0.01	0.04	0.10	0.7495	0.99	0.91	1.07
4000-9999	0.03	0.03	1.34	0.2471	1.03	0.98	1.09
For-profit (ref= No)	0.06	0.05	1.58	0.2087	1.07	0.97	1.18

Characteristics	Parameter estimate	SE	Chi-Square	p-value	Hazard ratio	95% Confidence Limits	
Offer Peritoneal dialysis (ref= No)	0.01	0.02	0.10	0.7519	1.01	0.96	1.06
Offer Home Hemodialysis (ref= No)	-0.07	0.03	5.84	**0.0157**	0.94	0.89	0.99
Offer Late shift (ref= No)	0.02	0.03	0.60	0.4388	1.02	0.97	1.08
Low volume (ref=No)	0.01	0.08	0.01	0.9088	1.01	0.87	1.18
Hemodialysis hours per session	-0.013	0.023	0.348	0.5554	0.987	0.944	1.032
Hemodialysis session per week	-0.032	0.056	0.331	0.5652	0.968	0.867	1.081
Patient Care Technicians	-0.004	0.003	1.134	0.287	0.996	0.990	1.003
Registered Nurses	0.014	0.005	9.379	**0.0022**	1.014	1.005	1.023
Patient's county factors							
Regions (ref= Northeast)							
Midwest	-0.03	0.04	0.57	0.4495	0.97	0.91	1.04
South	0.06	0.04	3.28	0.0703	1.07	1.00	1.15
West	-0.09	0.04	5.05	**0.0246**	0.91	0.85	0.96
Rurality (ref= Urban)							
Micropolitan rural	0.02	0.04	0.19	0.665	1.02	0.94	1.10
Remote rural	-0.04	0.10	0.21	0.6468	0.96	0.79	1.16
Small adjacent rural	-0.09	0.07	1.76	0.1842	0.92	0.80	1.04
proportion of Hispanic	0.001	0.001	1.904	0.1676	1.001	0.999	1.003
proportion of blacks	0.002	0.001	2.445	0.1179	1.002	1.000	1.004
Unemployment Rate, 16+	-0.004	0.007	0.308	0.5787	0.996	0.983	1.010
Percent Persons in Poverty	-0.005	0.004	1.448	0.2288	0.995	0.987	1.003
Median Household Income	0.000	0.000	0.799	0.3714	1.000	1.000	1.000