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Racial and Socioeconomic Differences in Infection Control Quality at Dialysis Centers

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An abstract of

A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Science in Public Health in Health Policy and Health Services Research 2022

#### Abstract

Racial and Socioeconomic Differences in Infection Control Quality at Dialysis Centers

#### By Jacob Thomas

Racial minorities and individuals of lower socioeconomic status with end stage renal disease experience disparities across many dimensions in the quality of dialysis care they receive. Differences in one measure of quality, infection control at dialysis facilities, have received little attention in the literature. This study uses data from the End Stage Renal Disease Quality Incentive Program (ESRD-QIP) from 2014 to 2019 to assess racial and socioeconomic differences in infection control quality at dialysis centers. It also examines trends in these differences over time, and facility, patient, and community characteristics that contribute to the observed inequalities. I find that facilities that treat a disproportionately high proportion of Black patients and those located in low-income areas are associated with lower infection control quality than facilities that treat low proportions of Black patients and those in high-income areas, respectively. In models adjusting for facility, patient, and community characteristics, dialysis centers in low-income areas continued to be associated with higher infections than facilities in high-income areas, but there was no significant association between the proportion of Black patients treated at a facility and dialysis infection control quality. Although dialysis centers overall experienced annual decreases in infections over time, the socioeconomic and racial differences in infection control quality did not change over the study period. Finally, two-stage Oaxaca-Blinder decomposition identified facility patient volume, patient age, area income, and facility profit status as the primary factors contributing to high infections at dialysis centers serving disproportionately high proportions of Black patients. These findings suggest that reducing patient volume at dialysis centers can mitigate the racial disparity in hemodialysis infections. Further improvements in health equity in dialysis care may require broader interventions that address social determinants of health in underserved patient groups.

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#### **Chapter 1: Introduction**

Over half a million Americans suffering from kidney failure depend on dialysis,<sup>1</sup> a medical procedure that must be intermittently performed for the rest of their lives if they do not receive a functioning kidney transplant. Dialysis is rife with disparities in healthcare quality. Racial minorities and low-income groups experience delayed nephrology care,<sup>2</sup> reduced access to kidney transplants,<sup>3</sup> suboptimal dialysis delivery regimes,<sup>4,5</sup> and lower use of home dialysis, a modality that delivers greater patient autonomy and satisfaction.<sup>6,7</sup>

This study examines dialysis-related infections as a major measure of dialysis quality. Dialysis infections are responsible for a third of all hospitalizations and 11% of deaths in dialysis patients, costing Medicare \$3 billion per year in inpatient costs.<sup>1,8,9</sup> Despite the high burden of infections and their impact on health outcomes, very little research has examined racial and socioeconomic differences in the quality of dialysis infection control. A few studies have shown that racial minorities and low-income patients are at greater risk for infection during peritoneal dialysis, a dialysis type used by only 10.5% of all dialysis patients.<sup>10-13</sup> One analysis found that Black patients are at increased risk for infection during hospitalization following in-center hemodialysis,<sup>14</sup> the dialysis type used by 87.5% of dialysis patients.<sup>1</sup> However, these results were limited to one specific pathogen and a subset of metropolitan hospitals in 9 US states.

Medicare regulates dialysis quality, including infection control, through a value-based purchasing program called the End-Stage Renal Disease Quality Incentive Program (ESRD-QIP). Under the ESRD-QIP, facilities that perform poorly on quality measures are penalized by Medicare withholding a portion of reimbursement. Reflecting differences in dialysis quality, facilities that disproportionately served racial minorities and low-income neighborhoods were more likely to receive penalties under the ESRD-QIP in 2012 and 2018.<sup>15,16</sup> If dialysis centers were to respond to higher penalties with greater improvements in quality, this penalization pattern might serve to narrow racial and socioeconomic differences in dialysis quality. However, penalization does not seem to affect quality overall: facilities penalized in one year failed to improve their performance on any quality measure in a subsequent year.<sup>17</sup> Further, if providers do not improve quality in response to penalization, they may instead be incentivized to offset the revenue loss from penalties by using cost-saving measures that reduce dialysis quality.<sup>18</sup> If there are broad racial and socioeconomic differences in dialysis infection control, it is important to examine whether trends in these differences have narrowed or widened since the ESRD-QIP included infections as a quality measure in 2014.

This thesis aims to answer the following questions: Are the racial/ethnic mix of facility patients and community socioeconomic status associated with lower quality infection control? If this is the case, have trends in racial and socioeconomic differences in infection control quality changed between 2014-2019? Additionally, what is the relative contribution of facility, patient, and community characteristics to these differences?

This research uses nationally representative data from annual ESRD-QIP reports to answer these questions using multivariate log-linear regression models and Oaxaca-Blinder decomposition analysis. I examined these questions within Donabedian's model of healthcare quality,<sup>19</sup> which specifies an ordered framework for assessing quality through the domains of structure, process, and outcome. The results of this study will inform policymakers of the scope of racial and socioeconomic differences that exist in dialysis infection control, a key measure of dialysis quality, and potential improvements that can be achieved through future regulation and policy change.

# Chapter 2: Background and Literature Review

#### End Stage Renal Disease and dialysis

End Stage Renal Disease (ESRD) is irreversible renal failure that necessitates kidney replacement therapy, affecting more than 785,000 US residents.<sup>1</sup> ESRD patients represent one of only two disease-eligible Medicare populations due to high costs of care: in 2018, they represented <1% of Medicare beneficiaries but accounted for 7.2% of Medicare fee for service spending - \$49.2 billion.<sup>1</sup> Although kidney transplantation is the most cost-effective replacement therapy and results in the best health outcomes, the supply of donors is limited, and two-thirds of ESRD patients receive dialysis several times a week as an alternate treatment.<sup>20,21</sup> Dialysis is a procedure by which waste products that accumulate in the bloodstream due to kidney failure are mechanically removed using specialized medical equipment. Over half a million people with End Stage Renal Disease (ESRD) in the US are dependent on frequent dialysis for survival following kidney failure.<sup>1</sup>

The two modalities employed in dialysis are peritoneal dialysis and hemodialysis. Peritoneal dialysis is primarily performed at home and uses frequent fluid exchanges in the abdominal cavity to indirectly clean the bloodstream through waste diffusion. This modality results in superior outcomes for patient autonomy and satisfaction.<sup>1,22,23</sup> However, 87.5% of patients dependent on dialysis (nearly two-thirds of all ESRD patients) receive maintenance hemodialysis at one of ~7900 US dialysis centers.<sup>1</sup> Hemodialysis is a procedure typically performed in four-hour sessions, about three times a week, in which a patient's blood is removed, cleaned using dialysis machines, and returned. The vast

majority of hemodialysis patients receive dialysis in dedicated facilities staffed by registered nurses and technicians.<sup>1</sup>

#### History of access to dialysis

Hemodialysis was first offered to patients with ESRD in 1960, but due to its prohibitive costs and lack of coverage by private insurance, was limited to less than 1% of the ESRD population at the time.<sup>24</sup> In 1962, the Seattle Artificial Kidney center began selecting recipients on the basis of their anticipated societal worth through committees composed of physicians and laypeople. These committees were later described as 'God panels' since their selections determined the death or survival of ESRD patients.<sup>25</sup> Public outrage over this subjective rationing of medical care was one of several factors that led to federal coverage of medical care for all ESRD patients that were eligible for Social Security under Medicare in 1972.<sup>26</sup> Today, ESRD remains one of only two disease-eligible categories for Medicare coverage, which initiates 90 days after treatment begins and is not subject to an age requirement.

Although Medicare coverage of ESRD care was intended to be near-universal, currently 12% of the nonelderly ESRD population do not gain Medicare coverage after the 90-day waiting period due to work history or legal residence requirements.<sup>27</sup> A large proportion of these patients are poor, belong to racial or ethnic minority groups, and remain uninsured or dependent on Medicaid coverage for dialysis care.<sup>28</sup> This ESRD patient group relies on a safety net of non-profit, often hospital-associated dialysis facilities for maintenance dialysis. Without access to this informal safety net, they are forced to depend on dialysis at emergency departments after long interdialytic gaps that result in severe complications.<sup>29-31</sup> However, despite the growing number of dialysis facilities in the

US, the informal dialysis safety net is shrinking. In 2015, 73% of safety-net-reliant patients depended upon for-profit centers for maintenance dialysis.<sup>27</sup>

# Racial and socioeconomic disparities in dialysis quality

Racial and ethnic minorities and low-income groups also receive lower-quality dialysis care. Black dialysis patients are given delayed pre-dialysis kidney care,<sup>2</sup> lower rates of kidney transplantation referrals,<sup>3</sup> suboptimal hemodialysis access types and delivery regimes,<sup>4,5</sup> and fewer opportunities for home dialysis.<sup>6,7</sup> Similarly, poor patients face higher mortality rates,<sup>32,33</sup> lower likelihood of transplantation referrals,<sup>34,35</sup> and lower use of home dialysis<sup>36</sup> than high-income patients. These racial and socioeconomic disparities in dialysis quality are mediated by a wide range of processes operating at the patient, provider, and community levels.<sup>5,37,41</sup>

# **Dialysis Infections**

Disparities in dialysis infection control quality are underexamined in the literature.<sup>42-44</sup> Infection risk is high among dialysis patients due to disease transmission from contaminated dialysis equipment and the need for frequent inpatient and emergent care, which increases exposure to pathogens. Infections can lead to sepsis, often resulting in hospitalization and death if they are not managed in ambulatory settings.<sup>45</sup> 61% of ESRD patients are diabetic, which increases infection risk due to reduced peripheral blood flow and elevated blood glucose concentrations.<sup>46</sup> Vascular access sites, points on a patient's circulatory system from which blood is transferred to a dialysis machine for cleaning, form portals of entry for bloodstream infections.<sup>47</sup> 35% of hemodialysis patients contracted infections in 2019, which were responsible for a third of all hospitalizations and 11% of deaths in individuals receiving dialysis.<sup>1,8</sup> Moreover, infections significantly increase the risk of hospital readmission and account for \$3 billion in annual inpatient costs for dialysis patients.<sup>9</sup> Do racial minorities and low-income groups experience differences in infection risk, as with other dialysis quality measures? A small number of studies assess this question, mostly in peritoneal dialysis patients and using data prior to 2001. Farias and coworkers found that among peritoneal dialysis patients in a single southeastern dialysis network in 1991, Black patients were 60% more likely to have an episode of peritonitis during a two-year period after dialysis initiation than non-Hispanic White patients.<sup>11</sup> However, a later study of a smaller cohort of patients in a single dialysis center between 1994-2000 did not find an association between race and peritonitis.<sup>10</sup> In the hemodialysis setting, a study using national data from 1994-1996 found that Black dialysis patients were at greater risk of mortality caused by septic infection than non-Hispanic White patients.<sup>48</sup> Black hemodialysis patients are also at increased risk of contracting antibiotic-resistant infections after hospitalization.<sup>14</sup>

Research assessing the association between socioeconomic status and dialysis infections is more limited and was largely conducted outside the US. One study examined patients in seven dialysis centers in China and found an increased risk of peritonitis in low-income peritoneal dialysis patients compared to high-income patients but found no association with education.<sup>13</sup> However, an analysis of peritoneal dialysis patients at 114 Brazilian centers found that education but not family income was associated with infection risk.<sup>12</sup> Similar socioeconomic differences in infection risk may exist in US hemodialysis patients, but this remains to be determined.

#### Incentives in dialysis quality

Dialysis centers face competing incentives for providing high-quality dialysis care. On the one hand, facilities are incentivized to increase their revenue by increasing their patient load. This can be accomplished without corresponding increases in productivity, labor, or capital if quality standards are relaxed.<sup>18</sup> On the other hand, dialysis centers are incentivized to increase or maintain quality in response to intermittent inspections by state regulators<sup>49</sup> and nephrologist referrals, which are motivated in part by reported quality measures.<sup>50</sup>

Facilities are also penalized for poor quality by value-based programs based on performance on measures that include healthcare-associated infections.<sup>51</sup> The End Stage Renal Disease Quality Initiative Program (ESRD-QIP) is a federal value-based purchasing program that began imposing financial penalties on dialysis centers in 2012.<sup>52</sup> The Center for Medicare and Medicaid Services penalizes poorly performing dialysis centers by withholding up to 2% of their total Medicare reimbursements, based on a total performance score calculated from ESRD-QIP measures. As of 2021, dialysis centers are evaluated on thirteen quality measures including bloodstream infections, dialysis adequacy, and hospital readmission ratios.<sup>53</sup>

Under ESRD-QIP, facilities located in low-income areas and those that served a larger proportion of Black and Medicaid-insured patients were more likely to score poorly on quality measures and receive payment penalties.<sup>15,16</sup> However, a recent study found that penalization may be an ineffective incentive for improving quality. A national sample of dialysis centers that were penalized in 2015 did not improve quality over the next two years, and penalization was not associated with improvement in any individual quality measure.<sup>17</sup> This is consistent with a growing body of literature demonstrating that pay for performance programs in other healthcare settings exact disproportionate financial penalties on facilities that care for underserved populations while effecting, at best, minor improvements in healthcare quality.<sup>54,67</sup> The patients at these facilities are more likely to be covered by Medicare or Medicaid rather than private insurers, which reimburse costs at higher rates,<sup>27</sup> resulting in decreased revenue. If dialysis centers that serve racial minorities and low-income communities are excessively penalized without subsequent quality improvement, the excess financial burden may incentivize them to use other cost-cutting measures that come at the expense of quality, such as increasing patient volume without concomitant increases in labor or capital. It might be expected that this will lead to widening racial and socioeconomic differences in dialysis quality over time. Assessments of the trends in these differences in the time period following ESRD-QIP implementation is needed to gain a broader understanding of the program's longer-term impacts.

#### Racial and Socioeconomic differences in dialysis infections

Previous research has not identified whether racial and socioeconomic differences exist in hemodialysis infections as they do in many other dialysis quality measures. This study is the first to use a nationally representative sample of US dialysis centers to assess these differences in infection control quality over a six-year time period following the adoption of infections as a quality measure under the ESRD-QIP. In addition, it is the first to evaluate the role of patient, facility, and community characteristics in infection control quality.

Examining the trends in dialysis quality provides valuable evidence for assessing whether these differences have narrowed or widened since ESRD-QIP implementation. Further, evaluating facility, patient, and community characteristics associated with infection control quality may lead to actionable paths to reduce these differences.

#### Chapter 3: Methodology

# 3A: Conceptual framework

I draw upon Donabedian's model of healthcare quality in developing a theoretical framework to guide analysis of the association between patient race and socioeconomic status with the quality of dialysis center infection control (Fig 1). This model defines an ordered framework for assessing quality in three domains: structure, process, and outcomes.<sup>68,69</sup> Structures, both internal and external to organizations, provide the environment for processes, which in turn determine healthcare outcomes. In the context of patient safety in dialysis centers, structure comprises the conditions for care. It includes characteristics of healthcare facilities, patients, the communities in which they are located, and the regulations and policies forming the environment in which these facilities operate. In the context of dialysis center infections, process refers to the implementation of clinical policies and guidelines aimed at improving patient safety and reducing infection risk. It also includes processes that may have an indirect impact on infection control. Process effectiveness is constrained by current knowledge and the structures in which it operates. Finally, outcomes refer to the results of clinical care, in this case, dialysis quality as measured by the risk of dialysis infections.

#### Focal relationship

The focal relationship at the center of this model is the association of area-level socioeconomic status and patient racial/ethnic mix with the quality of dialysis center infection control. *Dialysis center infection control quality* refers to the adjusted number of bloodstream infections per year reported by dialysis centers to the National Health Surveillance Network.<sup>70</sup>



Fig 1: Conceptual model for the relationship between patient race and socioeconomic status and dialysis center infection risk

*Race* is a social construct rather than a biological one and refers to 'the shared social, cultural, and historical experiences stemming from common national or regional backgrounds' that inform an identity shared by subgroups of a population.<sup>71</sup> Previous studies have reported that Black patients are at greater risk of infection while undergoing maintenance hemodialysis<sup>72</sup> and peritoneal dialysis<sup>10,11,73</sup> than White patients.

*Socioeconomic status* is a measure of an individual's combined economic and social status, assessed at the area level by population education, income, and occupation.<sup>74</sup> At the patient level, low income and education have also been associated with higher risks of peritonitis and sepsis during hospitalization relative to high income and education.<sup>12,13,75</sup>

#### Mediator: Infection control practices

The proposed route by which patient race and socioeconomic status influence dialysis center infection control quality is through *infection control practices*, hypothesized as a mediator of the focal relationship. As this construct cannot be directly observed in this dataset, it is italicized (Fig 1). These practices are activities undertaken by the facility that might include proper sanitation of dialysis machines and associated equipment, heightened infection surveillance, staff and patient education, and the activities of dedicated infection preventionists.<sup>47</sup> For patients, infection control practices involve aseptic care of the hemodialysis access site and lumen, and hygiene observation.

In implementing infection control measures, dialysis providers face a financial tradeoff between treating larger numbers of patients, representing increased revenue, and maintaining highquality care.<sup>18</sup> Racial and ethnic minorities and low-income individuals are less likely to be covered under private or employer-sponsored insurance,<sup>27</sup> which reimburses dialysis centers at higher rates than Medicare and Medicaid. Dialysis centers serving these groups are incentivized to offset their revenue loss through measures that decrease dialysis quality and increase infection risk.<sup>18,38</sup>

#### Mediator: Patient-to-staff ratio

Staffing, represented by the *patient-to-staff ratio*, refers to patient volume in relation to the number of full-time equivalent registered nurses and dialysis technicians employed at a facility. Increasing the number of nurses improves dialysis adequacy,<sup>76</sup> and by extension, this association is hypothesized to extend to other quality measures such as infection control. Although the relationship between staffing and infection risk in dialysis centers has not been reported, increased staffing results in fewer healthcare-associated infections in hospitals due to an increased capacity for infection surveillance and prevention strategies.<sup>77-80</sup> Infections can also be reduced by properly

sanitizing dialysis equipment,<sup>81</sup> which increases labor costs.<sup>18</sup> 70-75% of a dialysis center's variable costs are paid in nurse and technician wages.<sup>82</sup> Facilities that serve low-income patients and racial and ethnic minorities are hypothesized to increase the patient-to-staff ratio in order to reduce costs per patient.<sup>38</sup>

#### Confounders to the focal relationship

Facility, patient, and community characteristics associated with patient race and socioeconomic status that may influence infection control quality are identified as possible confounders of the focal relationship.

## Facility characteristics:

The facility characteristics examined as confounders in this model are patient volume and profit status.

*Patient volume* is defined as the annual number of hemodialysis patients treated in a dialysis center and is constrained by facility infrastructure: hemodialysis stations and staffing. Although the association of dialysis center patient volume with infection control quality has not been examined, a negative association is hypothesized by analogy with hospitals, in which greater bed occupancy, which translates to higher patient volumes, increases the risk of healthcare-associated infections due to an increased transmission risk between patients.<sup>83.85</sup> Black dialysis patients are more likely to receive care in urban dialysis centers which tend to have higher patient volumes than rural facilities,<sup>86</sup> while low-income communities are slightly more likely to receive care at smaller rural facilities compared to high-income communities.<sup>87</sup>

The overwhelming majority of US dialysis centers are operated *for profit*. For-profit facilities tend to be owned by chains that operate between 10 and  $\sim$ 2700 freestanding centers. On the other

hand, non-profit centers are more likely to be hospital-associated, though some are freestanding and chain-owned. For-profit centers belonging to large chains may benefit from standardized procedures, economies of scale, and more centralized coordination and administration. Although these factors might indicate better infection control quality, these centers are also likely to use cost-saving measures that lower infection control quality.<sup>38,88</sup> While Black patients are more likely to initiate dialysis at non-profit centers, they tend to receive maintenance dialysis treatment at for-profit facilities.<sup>27,89</sup> Patients in low-income communities are more likely to receive both initial and maintenance dialysis treatment at non-profit centers.<sup>89</sup>

Dialysis centers may be located in rural or *urban* areas, the latter defined by the Census Bureau as areas of 50,000 or more people or clusters of 2,500-50,000 people.<sup>90</sup> Urban areas have larger proportions of racial and ethnic minorities, while low-income groups are somewhat more represented in rural areas.<sup>91</sup> The relative difference in infection control quality between urban and rural dialysis centers is unknown but is hypothesized to be lower for urban centers as observed in urban versus rural hospital infections<sup>92</sup>.

# Characteristics of facility patient mix:

The confounders at the level of facility patient mix examined here are age and health status.

In general, individuals of older *age* are at greater risk of contracting healthcare-associated infections.<sup>93,94</sup> This may be due to a decreased immune response to infection, increased severity of illness, and a higher likelihood of comorbid conditions. However, in the dialysis setting, increasing age was associated with decreasing risk of access-related infections, potentially due to decreased sweat output which reduces bacterial skin colonization, and lower levels of activity in elderly

patients, which reduces contamination at the vascular access site.<sup>95,96</sup> Black and low-income dialysis patients are on average younger than white and high-income patients, respectively, partly due to the earlier development of hypertension and diabetes, major risk factors for ESRD.<sup>97,98</sup>

Patients of lower *health status* have other diseases or adverse health conditions in addition to End Stage Renal Disease<sup>99</sup> and require complex individual care management. Low-income patients and patients belonging to a racial minority are at higher risk of lower health status after adjusting for age.<sup>100-102</sup> Low health status also contributes to infection risk due to a weakened immune response, the need for frequent inpatient and emergency department visits, and the difficulty of administering appropriate antibiotics to sicker individuals in conjunction with other treatments.<sup>103-106</sup>

#### Community-level characteristics:

The community characteristics examined as confounders in this model are rurality, health literacy, and primary care access.

*Health literacy* is defined by the Institute of Medicine as "the degree to which individuals have the capacity to obtain, process, and understand basic information and services needed to make appropriate decisions regarding their health." <sup>107</sup> Racial minorities and low-income communities are disproportionately vulnerable to low health literacy, a phenomenon rooted in systemic barriers against access to resources needed to obtain and understand medical information. These barriers include racism, mistrust of medical providers, fewer opportunities for education, and a paucity of culturally appropriate health information and services.<sup>108-110</sup> Lower health literacy is associated with increased infection risk due to reduced adoption of protective practices.<sup>111</sup> Infection prevention through health literacy is bolstered by social relationships and support.<sup>112</sup> This construct could not be measured with available data.

*Primary care access* refers to the availability of services for the purpose of diagnosis, preventing and treating health problems, and promoting maintenance of health and well-being.<sup>113</sup> Dialysis patients belonging to racial minorities and low-income communities are less likely to have access to a primary care provider due to gaps in care coverage.<sup>27,114</sup> Consequent overutilization of emergency care results in a greater risk of infection from cross-transmission.<sup>115</sup> This construct cannot be measured with available data.

#### Other factors:

*Access type* refers to the port of access between the dialyzer and circulatory system, and includes three major types: (1) arteriovenous fistula, (2) arteriovenous graft, and (3) central venous catheter. Fistulas are the preferred vascular access type with the fewest complications in the nonelderly.<sup>116</sup> Fistulas and grafts are associated with a significantly lower risk of bloodstream infections in hemodialysis patients compared to central venous catheters.<sup>47,117</sup> This construct is not included in the model as the primary outcome measure is already adjusted for access type.

# 3B: Hypotheses

H1: Facilities with a high proportion of Black patients are associated with decreased dialysis center infection control quality after controlling for patient and facility-level confounders



H2: Facilities located in low-income communities are associated with decreased dialysis center infection control quality after controlling for patient and facility-level confounders



# 3C: Data sources

This analysis used data from Dialysis Facility Reports from payment years 2016-2021, ESRD-QIP reports from payment years 2016-2021, and the American Community Survey (five-year estimates spanning 2014-2019).

*Dialysis Facility Reports* have been produced annually since 1996 by the University of Michigan's Kidney Epidemiology and Cost Center (UM-KECC) using funding from the Centers for Medicare and Medicaid Services.<sup>118</sup> Reports are available for all dialysis centers except transplant-

only facilities and Department of Veterans Affairs facilities. For a given payment year (PY), these reports summarize facility and patient data from each Medicare-certified dialysis center between 2 and 6 calendar years prior. For example, the PY2021 report aggregates data from 2016-2019. This study uses data from PY2016-2021 to obtain measures for calendar years 2014-2019. Summaries are compiled from UM-KECC's ESRD patient database and are derived from dialysis facility survey data reported to CMS, Medicare dialysis and hospital payment records, transplant data, nursing home patient records, and the Social Security Death Master File. Data acquired from payment records are only available for Medicare patients in a given facility. Sample sizes varied from 6207 facilities in 2014 to 7920 facilities in 2019.

Data were merged with ESRD-QIP reports, published annually by the Centers for Medicare and Medicaid Services since 2010.<sup>119</sup> These reports summarize quality measures directly reported by all dialysis centers receiving Medicare payments to Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) and the National Healthcare Safety Network (NHSN). For a given payment year, measures are reported for a performance year two calendar years prior and a baseline year three years prior. For example, for PY2021, the performance year is 2019 and the baseline year is 2018. In 2019, thirteen measures were reported in four domains: (1) Clinical Care, (2) Care Coordination, (3) Safety, and (4) Patient and Family Engagement. Bloodstream Standardized Infection Ratios (SIRs) were included in the Safety domain starting from calendar year 2014. An improvement score is calculated by comparing a facility's performance to its own performance in the baseline year for each measure. An achievement score is also computed by comparing a facility's performance to the national average performance for a measure in the baseline year. SIRs were obtained from the achievement score portion of the Safety domain. Sample sizes ranged from 5571 facilities in 2014 to 7625 facilities in 2019. Zip code tabulation area (ZCTA) level measures of household median income were obtained from the American Community Survey (ACS), a housing survey conducted by the US Census Bureau sent to about 3.5 million households per year in the 50 US states, District of Columbia, and Puerto Rico.<sup>120</sup> First-stage data are collected by phone, mail and internet. Non-respondents to firststage survey methods are randomly selected for computer-assisted personal interviews. The ACS uses information collected to produce annual estimates based on geographic units stratified by census tract or block group. Data is available in five-year estimates for the block group and census tract level. Response rates ranged from 95-97% in 2014 to 86-91% in 2019. Facility records in ESRD-QIP and Dialysis Facility reports were linked by CMS certified provider number and to zip code tabulation areas (ZCTAs) in the ACS reports by crosswalking ZCTAs to facility zip code.

#### 3D: Analytic sample

Dialysis center annual bloodstream standardized infection ratios (SIRs) were obtained from the End Stage Renal Disease Quality Incentive Program Performance Score Summary Reports (ESRD-QIP PSSR) from calendar years 2014-2019 (41,958 facility-years). Facility-level characteristics were obtained by merging PSSR records with dialysis facility reports from calendar years 2014-2019. ZCTA-level measures were obtained from the American Community Survey fiveyear estimates ending in years 2014-2019. Area rurality was derived from the Center for Medicare and Medicaid Services carrier files for each year of the study period. After merging datasets, excluding 5592 facility-years that did not report infections, 618 facility-years not matched to dialysis facility records, 384 facility-years with fewer than 20 prevalent patients per year, and 641 facilityyears missing ZCTA-level measures and other model covariates, (see Figure 2 for details), a total of 34,723 facility-year records were included in the study sample.



Fig 2: Inclusion/Exclusion criteria for analytic sample. Abbreviations: ESRD-QIP – End Stage Renal Disease Quality Incentive Program UM-KECC – University of Michigan Kidney Epidemiology and Cost Center ACS – American Community Survey ZCTA – Zip Code Tabulation Area

# **3E: Constructs and Measures**

*Dialysis center infection control quality*. Quality of dialysis center infection control was assessed for each facility using the annual bloodstream standardized infection ratio (SIR), a continuous measure ranging from 0 to 11.03 in the sample. The SIR is derived from the total number of positive blood cultures self-reported by dialysis facilities, adjusted for eligible patient count and relative proportions of vascular access type (catheters, grafts, and fistulas), and normalized to the national average from

the previous year. An SIR of 1.0 indicates an infection risk equivalent to the national average calculated from the previous year.

Patient volume. Patient volume is a semi-continuous measure referring to the number of patients treated at a facility in a given year. Profit status. Profit status is a dichotomous variable coded as 0 for for-profit facilities and 1 for non-profit facilities. Urban vs. rural. Facilities were categorized as either in an urban or rural geographic area, coded as 0 and 1, respectively, based on the CMS fee-forservice rurality assignment for the facility zip code. Age. Patient age was assessed in a continuous measure; facility mean patient age. Race/ethnicity. The racial/ethnic mix of patients treated at a facility was assessed as a categorical measure representing the three tertiles of the facility proportion of Black patients from Dialysis Facility Reports. Socioeconomic status. Socioeconomic status is measured in a categorical variable for the three tertiles of median household income for the facility zip code tabulation area, derived from the American Community Survey. Health status was measured in the average number of comorbidities per prevalent Medicare patient from Dialysis Facility Reports. Comorbidities counted in this measure were alcohol dependence, anemias, cancer, cardiac arrest, cardiac dysrhythmias, cerebrovascular disease, congestive obstructive pulmonary disease, congestive heart failure, diabetes, drug dependence, gastrointestinal tract bleeding, hepatitis, HIV/AIDS, hyperparathyroidism, infections, ischemic heart disease, myocardial infarction, peripheral vascular disease, pneumonia, and tuberculosis.

Construct	Measure	Hypothesized Relationship
		to the DV
Dialysis center	Standardized infection ratio (SIR), a	Standardized infection ratio
infection control	continuous measure derived from annual	is the dependent variable
quality	bloodstream infections reported to NHSN,	_
	adjusted for patient volume and hemodialysis	
	access type, and normalized to annual SIR	
	average from the prior year	

Table 1: Constructs used and associated measures

Race	<b>Facility patient racial/ethnic mix</b> is measured as the facility's proportion of Black	SIR will be higher in facilities
	patients, divided into three tertiles:	Black patients
	High proportion	
	Mid proportion	
	Low proportion (reference)	
Socioeconomic	Area median household income. One	SIR will be higher in zip code
status	categorical measure for tertile of median	tabulation areas with lower
	household income for facility zip code	median household income
	tabulation area (ZCTA):	
	• High income (reference)	
	Mid income	
	Low income	
Patient volume	Patient volume, one semi-continuous	SIR will increase with
	measure for the annual number of patients	increasing patient volume
	treated by a facility	
Patient-to-staff	Patient-to-staff ratio, one continuous	SIR will increase with
ratio	measure, patient volume divided by total	increasing patient-to-staff
	number of staff	ratio
Profit status	Profit staus. One dichotomous variable	SIR will be greater at for-
	categorized as	profit facilities than non-
	• For-profit (0)	profit facilities
	• Non-profit (1)	
Urban vs rural	Urban vs rural. Facilities were assigned to one	SIR will be higher in rural
	of two categories based on CMS definition for	facilities
	zip code	
	• $Urban(0)$	
	• Rural (1)	
Age	Age. One continuous measure for facility	SIR will decrease with
TT 11	mean patient age	increasing age
Health status	One continuous measure for average number	SIR will increase with
	ot comorbidities per patient	increasing number of
		comorbidities per patient

# 3F: Analytic strategy

# **Regression models:**

The analysis was performed using three models:

#### Model 1

The first part tests H1 and H2, whether race and socioeconomic status were associated with dialysis infection control quality. Standardized infection ratios (SIR) were positively skewed with a log-normal distribution. Therefore a log-linear model was used with log-transformed SIR as the dependent variable:

$$\log(\text{SIR}) = \beta_0 + \beta_1 * \% \text{Black} + \beta_2 * \text{Income} + \beta_3 t + \sum_{i=4}^{11} \beta_i X_i + \varepsilon$$
(i)

In the model above, SIR represents the mean Standardized Infection Ratio and the coefficients  $\beta_1$  and  $\beta_2$  are the parameters of interest, representing the association of the facility proportion of Black patients and ZCTA income, respectively, with infection control quality. It is a semi-continuous time trend, and its coefficient  $\beta_3$  represents annual changes affecting all dialysis centers.  $X_i$  represents all other facility, patient, and community-level control variables used.  $\varepsilon$  is the regression error term.

# Model 2

The second model assesses trends in racial and socioeconomic differences in infection control quality since the implementation of an infection quality measure under ESRD-QIP and includes an interaction term between time and (i) race and (ii) income

$$\log(\text{SIR}) = \beta_0 + \beta_1 * \% \text{Black} + \beta_2 * \text{Income} + \beta_3 * t + \beta_4 (\text{Race} * t) + \sum_{i=5}^{12} \beta_i X_i + \varepsilon$$
(ii)

$$\log(\text{SIR}) = \beta_0 + \beta_1 * \% \text{Black} + \beta_2 * \text{Income} + \beta_3 * t + \beta_4 (\% \text{Black} * t) + \sum_{i=5}^{12} \beta_i X_i + \varepsilon$$
(iii)

In this model, the parameter of interest is  $\beta_4$ , the coefficient of %Black \*t or Income\*t, and represents the change in the race and income difference in infection control quality over time. A positive coefficient indicates a widening difference over time, and a negative coefficient indicates a narrowing one.

# Model 3

The third model evaluates the contributions of each model predictor used above to racial and socioeconomic differences in infection control quality by Kitagawa-Blinder-Oaxaca decomposition, commonly referred to as Oaxaca-Blinder decomposition.<sup>121</sup> This is a statistical method often used to investigate inequalities in health outcomes between two comparison groups.<sup>122</sup> The procedure attempts to explain the difference in the means of an outcome between two groups by decomposing the difference into two parts: (i) the component due to differences in mean values of independent variables between the two groups, called the explained component or composition effect, and (ii) the component due to group differences in effects of independent variables on the outcome, called the unexplained component or relationship effect. In this study, the group comparisons are between facilities treating a disproportionately high proportion of Black patients vs. a disproportionately low proportion of Black patients and facilities located in relatively low-income areas vs. high-income areas. Oaxaca-Blinder decomposition was chosen in this study over alternative methods like e.g., first differences regression since it is applicable to cross-sectional variation; the primary explanatory variables (facility patient racial/ethnic mix and area income) exhibited little variation over time within facilities.

Dialysis centers were separated into two groups: those with a high proportion of Black patients (referred to hereafter as 'Black' dialysis centers) and those with a low Black patient proportion ('White' dialysis centers). As above, log(SIR) was used as the dependent variable. The difference in mean log SIR between the two dialysis center groups is given by

$$\overline{\log(SIR)}^{W} - \overline{\log(SIR)}^{B} = (\beta_{0}^{W} - \beta_{0}^{B}) + \sum_{i=1}^{n} (\beta_{i}^{W} \overline{X}_{i}^{W} - \beta_{i}^{B} \overline{X}_{i}^{B}) + (\varepsilon^{W} - \varepsilon^{B})$$
(iv)

Where X represents a set of n predictors, the superscripts W and B correspond to 'White' and 'Black' dialysis centers, respectively. The coefficients  $\beta^{W}$  and  $\beta^{B}$  are obtained from evaluating separate regressions of log(SIR) for 'Black' and 'White' dialysis centers and can take different values for the two groups. The error term  $\varepsilon$  is assumed to be normally distributed and equivalent for both groups, and is canceled by subtraction.

The Oaxaca-Blinder method decomposes the overall group difference into differences in the mean values of X and differences in  $\beta$  by creating a hypothetical counterfactual term with the mean X values of 'Black' dialysis centers but the  $\beta$  values of 'White' dialysis centers and adding and subtracting it from equation (iv):

$$\overline{\log (SIR)}^{W} - \overline{\log (SIR)}^{B} = (\beta_{0}^{W} - \beta_{0}^{B}) + \sum_{i=1}^{n} (\beta_{i}^{W} \overline{X}_{i}^{W} - \beta_{i}^{B} \overline{X}_{i}^{B})$$
$$+ \sum_{i=1}^{n} (\beta_{i}^{W} \overline{X}_{i}^{B} - \beta_{i}^{W} \overline{X}_{i}^{B})$$
(v)

This can be rearranged into the standard Oaxaca-Blinder linear decomposition:

$$\overline{\log (SIR)}^W - \overline{\log (SIR)}^B = \left[\sum_{i=1}^n (\bar{X}_i^W - \bar{X}_i^B)\beta_i^W\right] + \left[(\beta_0^W - \beta_0^B) + \sum_{i=1}^n (\beta_i^W - \beta_i^B)\bar{X}_i^B)\right]$$

(vi)

The first summation term on the right-hand side refers to the portion of the aggregate group difference attributable to differences in the mean X values between the two groups. This is the 'explained' portion or composition effect. The second term is the portion of the group difference attributed to the difference in  $\beta$  values between the two groups, called the 'unexplained' portion or relationship effect.

As shown above, for race, dialysis centers were also divided into groups based on ZCTAlevel income (high-income, H and low-income, L) and the contributions of predictors to the group mean difference assessed by the equation:

$$\overline{\log (SIR)}^{H} - \overline{\log (SIR)}^{L} = \left[\sum_{i=1}^{n} (\bar{X}_{i}^{H} - \bar{X}_{i}^{L})\beta_{i}^{H}\right] + \left[(\beta_{0}^{H} - \beta_{0}^{L}) + \sum_{i=1}^{n} (\beta_{i}^{H} - \beta_{i}^{L})\bar{X}_{i}^{L})\right]$$
(vii)

#### Statistical analysis:

All statistical analyses were conducted in StataSE 17 for Windows. I generated descriptive statistics for key predictors and confounders for the entire sample and for dialysis center groups divided into tertiles of standardized infection ratios (SIR) (Table 1). Bivariate analyses were conducted using Wald tests with the lowest infection tertile as the reference group.

In the analytic sample, 12.8% of facility-year records reported an SIR of zero. Facilities that reported zero SIRs in all years or in some years of the analysis tended to have lower patient volumes than facilities that consistently reported non-zero SIRs (mean 49.2, 81.2 and 123.7 patients/year in facilities reporting zero infections in all years, some years, and for facilities reporting nonzero SIRs

in all years, respectively, Table S1 in Appendix). Facility-years reporting zero SIRs were retained in the analysis on the grounds that they may have reported non-zero SIRs if they had larger patient volumes. Prior to conducting regression analyses, a small constant (0.023) equal to half the smallest non-zero SIR value, was added to all SIR values in the sample to enable the use of log-linear models. I used unadjusted and multivariable log-linear regression models to assess the relationship between key facility, demographic and area characteristics, and SIR. Model-predicted SIRs were generated using smearing retransformations in order to account for departures from parametric distribution assumptions.<sup>123</sup>

In Oaxaca-Blinder decomposition analysis, the sample was divided into tertiles based on (1) proportion of Black patients and (2) median ZCTA household income. The highest and lowest tertile for each category were used as comparison pairs, and the middle tertile was excluded. Decompositions used a log-linear specification. Results of all analyses are reported with standard errors clustered at the facility level.

This study was considered exempt from review by the Emory University Institutional Review Board due to the facility-year-level nature of the data.

# Chapter 4: Results

#### **4A: Sample Characteristics**

Facility, patient, and area-level characteristics of the analytical sample are shown in Table 2, presented as unweighted means and proportions. The overall mean annual bloodstream standardized infection ratio (SIR) was 0.839. Patients treated at facilities were more likely to be male (56.9%) and covered by Medicare (69.8%). Facilities had a racially and ethnically diverse patient mix (60.4% non-

Hispanic White, 33.6% non-Hispanic Black and 15.2% Hispanic). Facilities reported that patients had an average of 5.1 comorbidities, with 45.7% of patients diabetic and 16% living in nursing homes. With respect to facility characteristics, dialysis centers had an average of 18.7 hemodialysis stations, 112.5 patients per year, and 15.4 staff positions, with, on average, 5.2 nurses and 6.5 technicians. Centers predominantly served hemodialysis patients (91.7% of total patients) and operated as for-profit centers (89.9%). At the area level, Zip Code Tabulation Area (ZCTA) median household income was \$58,200. The average percentage of the adult population with at least a high school degree was 86%, while 15.2% were below the poverty level, and 7.9% of adults aged 25 years or older were unemployed. 76.7% of dialysis centers were in urban areas.

#### **4B: Results from Bivariate Analyses**

Average bloodstream standardized infection ratios ranged from 0.189 in the lowest infection tertile to 1.630 in the highest tertile. At the facility level, centers with higher infection control quality treated fewer patients per year (105.6, 121.9, and 110.1 for low, mid, and high-SIR tertiles, respectively, p < 0.001) and had fewer staff (14.5, 16.5, and 15.1 for low, mid, and high-SIR tertiles, respectively, p < 0.001) compared to centers with mid- and low-quality infection control.

Dialysis centers with mid- and low-infection control quality had, on average, a younger patient population (mean age 63.0, 62.7 and 62.4 for low, mid and high-infection tertiles, respectively, p < 0.001) and a greater proportion of Black patients (mean 32.5%, 33.6% and 34.6% for low, mid and high-SIR tertiles, respectively, p < 0.001) but fewer White patients (mean 61.5%, 59.9% and 59.9% for low, mid and high SIR tertiles, respectively, p < 0.001) than centers with highquality infection control. Mid-infection control quality dialysis centers had a larger proportion of Hispanic patients than either high or low-infection control quality centers (mean 15.3%, 16.2%, and 14.1% for low, mid, and high-SIR tertiles, respectively, p < 0.001). Patients at facilities with lowquality infection control were more likely to have any Medicare coverage (mean 71.1% vs 69% for high vs low SIR tertiles, respectively, p < 0.001) and live in nursing homes (mean 16.5% vs 15.8% for high vs low SIR tertiles respectively, p < 0.001), than centers with high-quality infection control.

At the ZCTA level, dialysis centers with low-quality infection control tended to be situated in regions with lower income (ZCTA median household income \$56500 vs \$59100 for high vs low SIR tertiles, respectively, p < 0.001) and more poverty (percentage below poverty limit 15.5% vs 14.8% for high vs. low SIR tertiles respectively, p < 0.001) than centers with mid- and high-quality infection control. Mid-quality infection control dialysis centers were more often present in urban locations compared to those with low and high-quality infection control (75.8%, 78.9% [p < 0.001] and 75.3% [n.s.] urban dialysis centers with low, mid and high-SIR tertiles, respectively).

	Dialysis facilities 2014-2019			
Characteristics	Total (N=34723)	Lowest SIR tertile (N=11541)	Middle SIR tertile (N=11622)	Highest SIR tertile (N=11560)
Standardized infection ratio SIR, mean (SD)	0.839 (0.742)	0.189 (0.173) <sup>Ref</sup>	0.698 (0.189)	1.630 (0.721)***
Facility characteristics				
# of stations, mean (SD)	18.7 (7.7)	18.1 (7.0) <sup>Ref</sup>	19.5 (8.0)***	18.5 (7.9)***
Patients/yr, mean (SD)	112.5 (64.0)	105.6 (60.5) <sup>Ref</sup>	121.9 (67.3)***	110.1 (63.0)***
% of HD patients	91.7 (11.3)	91.9 (11.4) <sup>Ref</sup>	91.8 (11.0)	91.4 (11.6)***
% of CAPD (PD) patients	1.0 (2.2)	0.9 (2.3) <sup>Ref</sup>	1.0 (2.1)	1.0 (2.3)
% of CCPD (PD) patients	5.7 (8.9)	$5.5 (8.9)^{\text{Ref}}$	5.6 (8.6)	6.0 (9.1)***
Staffing, mean (SD)				
Number of staff positions	15.4 (8.4)	14.5 (7.9) <sup>Ref</sup>	16.5 (9.0)***	15.1 (8.3)***
Full-time nurses	5.2 (3.7)	4.8 (3.3) <sup>Ref</sup>	5.5 (3.8)***	5.3 (3.9)***

**Table 2:** Summary descriptive statistics of dialysis facilities grouped by Standardized Infection Ratio (SIR) tertiles (2014-2019)

Full time technicians	6.5 (4.4)	$6.2 (4.2)^{\text{Ref}}$	7.1 (4.7)***	6.2 (4.3)
Patient-to-staff ratio	7.3 (2.2)	7.3 (2.2) <sup>Ref</sup>	7.4 (2.1)***	7.3 (2.2)
Ownership type, %				
For profit	89.9	89.4 <sup>Ref</sup>	90.9***	89.3
Non-profit	10.1	10.6	9.1	10.7
Patient characteristics,				
mean (SD)				
Patient age	62.7 (3.9)	$63.0(3.8)^{\text{Ref}}$	62.7 (3.7)***	62.4 (4.2)***
% Female patients	43.1 (7.7)	$43.2 (8.0)^{\text{Ref}}$	43.1 (7.4)	43.0 (7.9)*
% White patients	60.4 (28.6)	$61.5(28.6)^{\text{Ref}}$	59.9 (28.4)***	59.9 (28.9)***
% Black patients	33.6 (29.2)	32.5 (29.1) <sup>Ref</sup>	33.6 (28.9)**	34.6 (29.6)***
% Hispanic patients	15.2 (21.6)	15.3 (21.8) <sup>Ref</sup>	16.2 (22.0)**	14.1 (21.0)***
% nursing home patients	16.0 (9.2)	$15.8 (9.3)^{\text{Ref}}$	15.8 (8.7)	16.5 (9.7)***
% diabetic patients	45.7 (11.6)	45.7 (11.8) <sup>Ref</sup>	45.7 (11.6)	45.6 (11.5)
# comorbidities/ patient	5.1 (0.7)	$5.0 (0.7)^{\text{Ref}}$	5.0 (0.6)**	5.1 (0.7)***
% Medicare patients	69.8 (15.3)	69.0 (15.8) <sup>Ref</sup>	69.1 (15.4)	71.1 (14.5)***
Area characteristics, mean				
(SD)				
Median HH income, \$K	58.2 (23.2)	59.1 (23.6) <sup>Ref</sup>	59.1 (23.7)	56.5 (22.2)***
% < high school	14.0 (8.7)	14 1 (8 8) <sup>Ref</sup>	141(89)	139 (84)
education	1 (0.7)		1 (0.7)	13.5 (0.1)
% below poverty limit	15.2 (8.5)	$14.8 (8.3)^{\text{Ref}}$	15.1 (8.7)**	15.5 (8.6)***
% Unemployed	7.9 (4.0)	$7.8 (4.0)^{\text{Ref}}$	7.9 (4.1)**	7.9 (4.2)***
Rurality, %				
Urban	76.7	$75.8^{\text{Ref}}$	78.9***	75.3
Rural	23.3	24.1	21.1	24.7

\* - *p* < 0.05, \*\* - *p* < 0.01, \*\*\* - *p* < 0.001

Infection ratios, facility and ZCTA-level characteristics were assessed across SIR tertiles by Wald tests using low infection tertile facilities as the reference group. Abbreviations: SIR – Standardized Infection Ratio

SIR – Standardized Infection Ratio
ZCTA – Zip Code Tabulation Area
SD – standard deviation
HD – Hemodialysis
PD – Peritoneal Dialysis
CAPD – Continuous Ambulatory Peritoneal Dialysis
CCPD – Continuous Cycler-assisted Peritoneal Dialysis
HH - Household

# 4C: Main Analysis

# **Results of Model 1 Log-Linear Regression Analysis**

In unadjusted regression models, standardized infection ratios (SIR) decreased overall over

time (-10.97% relative decrease per year; p < 0.001; Table 3). Infections were higher at dialysis

centers with high (+17.14% increase in SIR; p < 0.001) and mid (+13.43%; p < 0.001) proportions of Black patients as compared to those with low proportions of Black patients (Table 3). Infection control quality was also lower for dialysis centers located in low-income areas (+10.28% increase in SIR; p <0.001) and mid-income areas (+5.17%; p < 0.05), as compared to high-income areas (Table 3).

There were also differences in SIRs by other facility, patient, and area-level characteristics. Rural facilities reported fewer infections (-12.43%, p < 0.001) as compared to urban facilities. SIRs increased with increasing patient volume (+0.29% per additional patient, p < 0.001), increasing patient-to-staff ratios (+3.21% per unit increase, p < 0.001), and increasing mean comorbidities per patient (+8.91% per additional comorbidity, p < 0.001). An increase in mean patient age was associated with a lower SIR (-2.53% per year; p < 0.001).

In fully adjusted models, ZCTA-level income continued to be positively associated with infection control quality (Table 3): low- and middle-income areas had a higher SIR compared with high-income areas (low-income: +5.74%; p < 0.05; mid-income: = +5.52%; p < 0.05). After adjustment for covariates, the proportion of Black patients was no longer associated with SIR. As in the unadjusted model, an annual decrease in the overall SIR was observed (-11.04% per year; p < 0.001).

For calendar years 2015-2017, annual counts of bloodstream infections reported by dialysis centers were available in addition to SIRs. When regression analysis was performed on this sample (17,179 facility-year records), similar associations between patient racial mix and ZCTA-level income with infections per eligible patient were seen (Appendix, Table S2). Mean SIR increased with increasing proportions of hemodialysis (+0.32% per percentage point increase, p < 0.01), Medicare (+0.37% per percentage point increase, p < 0.001), and comorbidities per patient (+17.27% per additional comorbidity, p < 0.001) and decreased with increasing patient age (-2.39% per year, p < 0.001) and proportion of female patients (-0.32% per percentage point increase, p < 0.05). Patient-to-staff ratios and rurality were no longer significantly associated with infection control quality in adjusted models.

	Unadjusted model	Fully adjusted model
Characteristics	Relative change in SIR (%)	Relative change in SIR (%)
Time (per year)	-10.97***	-11.04***
Area-level characteristics ZCTA median income		
High income	Ref	Ref
Middle income	+5.17*	+5.52*
Low income	+10.28***	+5.74*
<u>Facility characteristics</u> Annual patient count Patient-to-staff ratio % Hemodialysis patients Profit status For profit Non-profit Rurality	+0.29*** +3.21*** +0.11 Ref -3.89	+0.30*** +0.32 +0.32** Ref -6.83
Urban	Ref	Ref
Rural	-12.43***	-1.69
Patient characteristics Mean Patient age % Black patients	-2.53***	-2.39***
Low	Ref	Ref
Middle	+13.43***	+3.42
High	+17.14***	+4.43
% Female patients	-0.01	-0.32*
% Medicare patients	+0.04	+0.37***
Mean comorbidities/pt	+8.91***	+17.27***

**Table 3**: Unadjusted and adjusted association of facility patient racial mix and area-level median household income with facility standardized infection ratios (SIR)

\* - *p* < 0.05, \*\* - *p* < 0.01, \*\*\* - *p* < 0.001

Data are reported as percent changes in the geometric mean of bloodstream standardized infection ratios. Estimates were derived from log-linear regressions using standard errors clustered at the facility level. Unadjusted estimates are presented alongside a fully adjusted model including all covariates listed.

### **Results of Model 2 Log-Linear Regression Analysis**

To determine whether the differences in infection control quality between dialysis centers in low- and mid- versus high-income areas changed over time, additional models were analyzed that included interaction terms between a continuous time trend and facility proportion of Black patients or ZCTA-level median household income (Table 4). In both the time and patient racial mix- or income-adjusted models and the fully adjusted models, no significant interaction was observed between the time trend and facility proportion of Black patients or ZCTA-level income. This suggests that the adjusted difference in standardized infection ratios between facilities serving low or high proportions of Black patients or located in low- and high-income areas did not change over the study period (Fig 3).

# **Table 4**: Unadjusted and adjusted association between bloodstream standardized infection ratios (SIRs) and patient racial mix or ZCTA-level median household income interacted with the time trend

	Time and race-adjusted model	Time, race and covariate adjusted model	Time and income- adjusted model (N=34721)	Time, income and covariate adjusted model
	(N=34721)	(N=34721)	(1. 0)	(N=34721)
	Relative	Relative	Relative	Relative
Characteristics	change in SIR	change in SIR	change in SIR	change in SIR
	(%)	(%)	(%)	(%)
<u>Time (year)</u>	-10.54***	-11.13***	-11.09***	-10.96***
Race-time interactions				
High %Black pts * time	-0.61	+0.00		
Mid %Black pts * time	-0.083	+0.00		
Income-time interactions				
Middle income * time			+0.28	-0.40
Low Income * time			+0.13	+0.13
Area-level characteristics				
ZCTA median income				
High income		Ref	Ref	Ref
Middle income		+5 52*	+4 16	+7.06
Low income		+5.74*	+9.80*	+5.24
Facility characteristics				
Patients/year		+0 30***		+0 30***
Patient-to-staff ratio		+0.32		+0.32
% Hemodialysis pts		+0.32**		+0.32**
Profit status		10.52		10.52
For profit		Ref		Ref
Non-profit		-6.83		-6.84
Rurality		0.05		0.01
Urban		Ref		Ref
Rural		-1 69		-1 71
Patient Characteristics		1.07		1.71
Mean Patient age		-2 40***		-2 40***
% Black patients		2.10		2.10
Low	Ref	Ref		Ref
Middle	+15 95**	+3.19		+3.42
High	+20 69***	+3 59		+4 44
% Female nationts	. 20.07	-0.32*		-0 32*
% Medicare patients		+0.38***		+0.38***
Mean comorbidities/pt		+17 27***		+17 28***

\* - p < 0.05, \*\* - p < 0.01, \*\*\* - p < 0.001

Data are reported as percent changes in the geometric mean of bloodstream standardized infection ratios. Estimates were derived from log-linear using standard errors clustered at the facility level. The unadjusted models use either facility proportion of Black patients or ZCTA-level median household income as the primary predictor and includes year and income-year interaction terms. Facilities with low proportions of Black patients or located in high-income areas were specified as the reference levels.



**Fig 3**: Model-predicted estimates for mean standardized infection ratio (SIR) over time, grouped by income tertile (only lowest and highest income tertile shown). Ribbons represent 95% confidence intervals around the mean, calculated using smearing retransformations<sup>123</sup> with standard errors clustered at the facility level.

#### **Results of Model 3 Oaxaca-Blinder Decomposition Analysis**

Oaxaca-Blinder decomposition analysis was conducted on the mean difference in the logtransformed SIR of dialysis centers divided into two pairs of comparison groups: (i) Facilities in the highest vs. lowest tertile for proportion of Black patients and (ii) facilities in the lowest vs. highest tertile for ZCTA median household income (Table 5). Dialysis centers treating disproportionately many Black patients had lower quality infection control than facilities treating disproportionately few Black patients (mean [SE] logSIR of -0.64 [0.02] vs -0.80 [0.02], p < 0.001). This corresponds to a 17.3% relatively higher SIR for facilities treating disproportionately many Black patients. The net difference of 0.16 was decomposed into an explained (mean [SE] logSIR difference of 0.07 [0.02], P < 0.01) representing the composition effect and unexplained components (mean [SE] logSIR difference of 0.09 [0.03], P < 0.01) representing the relationship effect. The explained component accounted for 45.9% and the unexplained component for 54.0% of the crude net difference in SIR between the comparison groups.

Dialysis centers in low-income areas were also associated with decreased infection control quality compared with those in high-income areas (mean [SE] logSIR of -0.65 [0.02] vs -0.75 [0.02], p < 0.05), corresponding to a 10.4% relative increase in SIR for low-income-area dialysis centers. The model could not decompose this difference into statistically unique explained differences (covariates) and unexplained differences (parameter estimates).

Dialysis Center Comparison group	Unadjusted Mean (SE) log(SIR)	Crude net difference (SE) in mean log(SIR)	Explained difference (SE)	Unexplained difference (SE)
High proportion of Black patients	-0.635 (0.017)***	0.159 (0.025)***	0.072 (0.022)**	0.088 (0.031)**
Low proportion of Black patients	-0.795 (0.018)***			
Located in area of				
Low-income	-0.650 (0.018)***	0.098 (0.025)***	0.057 (0.032)	0.042 (0.040)
High-income	-0.749 (0.017)***			

**Table 5**: Oaxaca-Blinder decomposition of differences in log-transformed Standardized Infection Ratio between dialysis center comparison groups

\* - *p* < 0.05, \*\* - *p* < 0.01, \*\*\* - *p* < 0.001

The analysis controlled for time, patient count, age, and sex, patient-staff ratio, proportion of hemodialysis patients and Medicare patients, mean comorbidities per patient, rurality and profit status. The race group comparison additionally controlled for area income and the income group comparison controlled for proportion of Black patients. Clustered standard errors at the facility level are reported in parentheses.

The explained difference in log(SIR) or composition effect between dialysis centers with high and low proportions of Black patients was further decomposed into contributions of individual predictors (Fig 4). Most of the explained SIR difference was associated with patient age (93.0% of the explained difference; p < 0.001), dialysis centers treating high proportions of Black patients having younger patients, a factor associated with increased infection risk. The facility group treating high proportions of Black patients also had larger patient volumes (71.1% of the explained difference; p < 0.001) and a larger proportion of hemodialysis patients (9.9% of the explained difference; p < 0.05) than the reference group, both factors associated with lower infection quality control. Finally, dialysis centers treating disproportionately many Black patients reported fewer comorbidities per patient (contributing -18.0% of explained difference; p < 0.001) and Medicare patients (contributing -5.1% of explained difference; p < 0.05). The negative sign indicates that since increasing comorbidities and Medicare patients are associated with greater standardized infection ratios, dialysis centers treating disproportionately many Black patients would have had an even greater SIR if they had contained as many Medicare patients or treated patients with as many comorbidities as the facility group treating a smaller proportion of Black patients.

After decomposition of the unexplained difference or relationship effect in log(SIR) between dialysis centers with high and low proportions of Black patients, the largest contribution was due to income. Low area-income was associated with lower infection control quality in the facility group treating high proportions of Black patients but not in the facility group treating low proportions of Black patients (contributing 103.0% of the unexplained difference, p < 0.01). Non-profit status was associated with higher infection control quality in facilities treating disproportionately many Black patients but not in facilities treating disproportionately few Black patients (contributing -30.3% of the unexplained difference, p < 0.01).



**Fig 4**: Explained difference or composition effect (panel A) and unexplained difference or relationship effect (panel B) of patient, facility and area-level factors associated with log-transformed Standardized Infection Ratios between dialysis centers with high vs low proportions of Black patients. Significant (a = 0.05) associations are represented as red bars, while nonsignificant associations are shown as grey bars. \* - p < 0.05, \*\* - p < 0.01, \*\*\* - p < 0.001

#### Chapter 5: Discussion

# 5A: Key Findings

This study examined the association of race and community average household income with dialysis center infection control quality (model 1), the trends in these associations over time (model 2), and decomposed the associations by the contributions of key predictors (model 3).

Model 1 found that dialysis centers with higher proportions of Black patients and facilities in low-income areas had lower quality infection control. This association is consistent with previous literature that found greater risks of peritoneal dialysis infections and sepsis after hospitalization in racial minorities and low-income patients.<sup>10-13,75</sup> After adjustment for facility, patient, and area-level characteristics, the association between race and infection control quality became nonsignificant, suggesting that the model covariates included mediators of this relationship. In the fully adjusted model, a difference in infection control quality between low- and mid-area income dialysis centers vs. those in high-income areas persisted. Contrary to hypotheses, patient-to-staff ratios were not associated with reported infections and may not mediate racial and socioeconomic infection differences.

Model 2 found that overall, standardized infection ratios decreased in all dialysis centers by approximately 11% per year. Contrary to hypotheses, the infection difference in dialysis centers in low-income neighborhoods (versus high-income neighborhoods) did not widen but remained constant over the six years of the study period (Figure 3). The lack of change in the racial and socioeconomic differences in infection control quality may reflect risk factors beyond the ability of dialysis facilities to control, such as lower patient literacy,<sup>108,111</sup> increased comorbidity burden<sup>103</sup>, and lack of access to primary care<sup>124</sup> in low-income patients. If this hypothesis holds true for infection

risk and for other dialysis quality measures, the excessive penalization of dialysis centers serving racial minorities and low-income groups under the ESRD-QIP is inappropriate, and the decreased revenue to these facilities may hinder their ability to deliver quality care.

The relatively consistent difference in dialysis infection control quality by area income over the study period suggests that penalization under ESRD-QIP may be a weak motivator for quality improvement: only a few dialysis centers are subject to the full penalty, and over 50% receive no penalty.<sup>125</sup> Quality improvement measures, e.g. infection control practices to reduce infections, are expensive; a 2% reimbursement penalty might not provide a sufficient financial incentive for improvement, especially for facilities that serve underinsured patients and operate with smaller profit margins. Future studies may examine changes in dialysis center quality over time stratified by the magnitude of penalty they face. Penalization of facilities with vulnerable patient groups may also incentivize the selection of patients with less risky profiles and fewer comorbidities, which may be investigated by examining changes in facility patient mix over time in relation to penalization under the ESRD-QIP.

Model 3 demonstrated that the difference in infection control quality by facility patient racial mix was driven primarily by patient volume and patient age (71% and 93% of the composition effect, respectively). Increasing patient volume can come at the cost of quality: Grieco and McDevitt found that a dialysis provider can increase its patient load by 1.6% without increasing productivity, labor, or capital if quality standards are relaxed such that infections increase by one percentage point.<sup>18</sup> For example, inadequate sanitation of a dialysis station<sup>81</sup> and reuse of dialyzers<sup>37</sup> may reduce labor and capital costs, respectively, but both measures increase infection risk.

The contribution of age to differences in infection control quality by patient racial mix may be explained by the observation that Black dialysis patients are on average, younger than white patients. This may be due, in part, to the earlier development of diabetes and hypertension in these patients, risk factors for chronic kidney disease.<sup>97,98</sup> Younger age is associated with a greater risk of dialysis infections, as older individuals exhibit decreased bacterial skin colonization and lower levels of physical activity. The younger age of the Black dialysis population is also reflected in the fact that dialysis centers treating high proportions of Black patients report fewer comorbidities per patient, as advancing age is accompanied by the development of chronic conditions and decreasing health status. The racial difference in infection control would be even greater if the facility comparison pair reported equivalent numbers of comorbidities per patient.

Area-level income accounted for most of the unexplained difference or relationship effect (+103%) between infection control quality in dialysis center groups categorized by proportion of Black patients, suggesting an interaction between race and income that deepens this difference. Prior research has found evidence of interaction between socioeconomic factors and race in the development of chronic kidney disease and its progression to end-stage renal disease.<sup>126,127</sup>

Non-profit facilities are associated with increased infection control quality in dialysis centers treating high proportions of Black patients but not in centers with low proportions of Black patients. Prior evidence is mixed on the association between dialysis quality and profit status: non-profit centers had decreased mortality rates compared to for-profit centers<sup>128</sup> but had poorer performance scores on quality measures.<sup>16,129</sup> However, these studies did not directly examine infections as a quality measure or their association with patient race. This finding suggests that racial minorities face decreases in dialysis quality as nonprofit facilities represent a decreasing proportion of the dialysis market over time. Further research assessing these impacts is warranted.

Finally, decomposition of the difference in facility infections grouped by area income did not identify statistically significant components, suggesting that this difference is driven by predictors not included in the model.

# 5B: Strengths and limitations:

This study has several limitations. First, bloodstream standardized infection ratios were derived from positive blood cultures taken after hospitalization and only captured infections that migrate to the bloodstream. They did not reflect infections treated in ambulatory settings that do not require blood cultures. Infections are also self-reported, and dialysis centers have a financial incentive to underreport them, which may result in measurement error. However, all dialysis centers potentially face this incentive, which may decrease the impact of this error on the analysis. Second, health literacy and primary care access could not be measured. Both factors are hypothesized to bias results away from the null and this may have resulted in estimates greater than the population parameter. Third, the study period (2014-2019) precluded direct evaluation of the impact of ESRD-QIP on hemodialysis infection risk. The program first included infections as a measure for assessing payment reductions in 2014, so the data do not include a pre-implementation period required for ESRD-QIP evaluation. Fourth, in the Oaxaca-Blinder decomposition analysis in model 3, facilities are grouped into comparison groups by their tertile ranking for proportion of Black patients or area income. This type of analysis is typically performed for distinct patient groups, separated on the basis of race or gender (among other characteristics). Separation by facility patient racial/ethnic mix or area income introduces a blurring of the distinction between groups. However, analyses were

robust to comparisons of dialysis center groups by highest to lowest quartile and pentile of the proportion of Black patients and area income. Finally, this study used facility ID as a unique identifier for dialysis centers. However, new facility IDs are assigned to centers when they change ownership. This may result in the same facility being counted twice in the analytic sample in a year of ownership transition.

Despite these limitations, the study has several strengths. It is the first to assess the association of race and socioeconomic status with hemodialysis infection control quality in recent years. Prior studies examining this relationship have been largely confined to the peritoneal dialysis setting in the early 2000s.<sup>10-13</sup> It is also the first to examine differences in infections at hemodialysis centers grouped by patient racial mix or area income over time. Finally, these results are generalizable as the study uses a national sample that includes 82% of US dialysis centers.

# 5C: Policy Implications

The findings of this work underscore the importance of additional strategies to reduce racial and socioeconomic inequalities in dialysis quality. This analysis indicates that reducing patient volume at dialysis centers may mitigate the racial difference in hemodialysis infections. This holds true for other healthcare settings: hospitals that mandated minimum nurse staffing ratios had improved patient outcomes in mortality, length of stay, and readmission ratios.<sup>130</sup> Other measures may include mandating infection control programs and dedicated infection preventionists, currently required in hospitals but not dialysis facilities.<sup>131</sup>

Preserving the informal safety net of non-profit dialysis centers may also prevent further widening of racial inequities in dialysis quality. In the hospital setting, racial minorities experience larger decreases in healthcare access after safety net hospital closure comapred to white patients.<sup>132</sup> If this extends to the dialysis setting, closure or acquisition of nonprofit facilities may result in decreases in both dialysis quality and access to care for racial minority patients since nonprofit facilities treating high proportions of Black patients are associated with lower infections. Finally, infection differences are likely rooted in social determinants of health, and elimination of these inequalities will require broad integrated approaches to patient care outside the scope of the dialysis setting.

# 5D: Directions for future research

This study suggests approaches for future research. Patient-level observations will permit a more granular examination of infection trends and differences than the facility-level data used in this analysis. These may be obtained from Medicare claims data held by the US Renal Data System (USRDS). USRDS infection data also span a time period preceding ESRD-QIP implementation of the infection quality measure and permit direct evaluation of the program's impact on dialysis infection control quality.

Policies that impact infections are also likely to change dramatically in the wake of COVID-19 pandemic in 2020. Mortality both due to COVID-19 and due to missed dialysis treatment has disproportionately impacted low-income and racial minority dialysis patients.<sup>133</sup> The Medicare program has begun incentivizing providers to move toward home dialysis and alter infection control protocols in dialysis centers; the effects of these policy changes will need to be assessed in future years.

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# <u>Appendix</u>

**Table S1:** Summary descriptive statistics of dialysis facilities grouped by whether they reported zero SIRs in all years in which they appeared in the analytic sample, a subset of years, or whether they reported non-zero SIRs in all years.

	Dialysis facilities 2014-2019			
Characteristics	Total (N=34723, 100%)	Zero SIR in all years (N=228, 0.7%)	Zero SIR in some years (N=8747, 25.2%)	Non-zero SIR in all years (N=25748, 74.1%)
Infection measure, mean (SD)	0.839 (0.742)	0 (0)	0.408 (0.593)	0.993 (0.728)
<u>Characteristics of</u> <u>facilities</u>				
# of stations, mean (SD)	18.7 (7.7)	13.8 (5.6)	15.8 (5.9)	19.8 (7.9)
Patients/yr, mean (SD) % of HD patients	112.5 (64.0) 91.7 (11.3)	49.2 (27.5) 90.6 (16.5)	81.2 (45.6) 91.7 (11.7)	123.7 (65.7) 91.7 (11.1)
% of CAPD (PD) patients	1.0 (2.2)	0.7 (2.1)	0.9 (2.2)	1.0 (2.2)
% of CCPD (PD) patients	5.7 (8.9)	6.4 (11.9)	5.8 (9.3)	5.7 (8.7)
Staffing, mean (SD)				
Number of staff positions	15.4 (8.4)	8.2 (3.5)	11.7 (5.7)	16.7 (8.8)
Full-time nurses Full time technicians	5.2 (3.7) 6.5 (4.4)	2.8 (2.1) 2.6 (1.7)	3.7 (2.4) 4.7 (3.1)	5.7 (3.9) 7.2 (4.6)
Ownership type, %	、 <i>´</i>	× ,		· · ·
For profit Non-profit	89.9 10.1	90.3 9.7	88.7 11.3	90.3 9.7
Characteristics of				
<u>patients treated in</u> <u>facilities</u> , mean (SD)				
Patient age % Female patients	62.7 (3.9) 43.1 (7.7)	62.9 (7.4) 43.2 (11.1)	63.3 (3.8) 42.9 (8.8)	62.5 (3.9) 43.2 (7.3)
% White patients % Black patients	60.4 (28.6) 33.6 (29.2)	64.2 (28.2) 29.9 (28.2)	64.7 (28.8) 29.7 (28.8)	58.9 (28.5) 34.9 (29.3)
% Hispanic patients	15.2 (21.6)	14.7 (0.6)	12.0 (18.7)	16.3 (22.4)
% nursing home patients	16.0 (9.2)	18.0 (14.8)	16.3 (9.5)	15.9 (9.1)
% diabetic patients	45.7 (11.6)	45.3 (13.4)	45.8 (12.0)	45.6 (11.5)
# comorbidities/	5.1 (0.7)	5.2 (1.0)	5.1 (0.7)	5.1 (0.7)
% Medicare patients	69.8 (15.3)	77.8 (13.6)	71.2 (15.2)	69.2 (15.3)

Area characteristics,				
mean (SD)				
Median HH income,	58.2(23.2)	631 (270)	59 3 (23 5)	57 8 (23 1)
\$K	50.2 (25.2)	0.0.1(27.0)	57.5 (25.5)	57.0 (25.1)
% < high school	14.0 (8.7)	13 () (8 2)	13.0.(7.9)	144(80)
education	14.0(0.7)	13.0 (0.2)	13.0 (7.7)	14.4(0.7)
% below poverty limit	15.2 (8.5)	13.2 (7.9)	14.1 (7.9)	15.5 (8.7)
% Unemployed	7.9 (4.0)	6.2 (3.5)	6.9 (3.7)	8.2 (4.2)
Rurality, %				
Urban	76.7	80.0	67.1	80.0
Rural	23.3	20.0	32.9	20.0

Abbreviations: SIR – Standardized Infection Ratio

ZCTA – Zip Code Tabulation Area SD – standard deviation HD – Hemodialysis CAPD – Continuous Ambulatory Peritoneal Dialysis CCPD – Continuous Cycler-assisted Peritoneal Dialysis HH - Household

**Table S2**: Unadjusted and adjusted association of patient racial mix and area-level median household income with infections/patient-year

	Unadjusted model (N = 17179)	Fully adjusted model (N= 17179)
Characteristics	Relative change in infections/patient-year (%)	Relative change in infections/patient-year (%)
Time (per year)	-11.85***	-13.47***
Area-level characteristics		
ZCTA median income		
High income	Ref	Ref
Middle income	+4.26	+4.74
Low income	+17.92***	+10.94**
Facility characteristics		
Annual patient count	+0.41***	+0.44***
Patient-to-staff ratio	+4.80***	+0.44
% Hemodialysis patients	+0.11	+0.74***
Profit status		
For profit	Ref	Ref
Non-profit	+1.22	-5.01
Rurality		
Urban	Ref	Ref
Rural	-17.63***	-0.80
Patient characteristics		
Mean Patient age	-2.40***	-2.06***
% Black patients		

Low	Ref	Ref	
Middle	+16.84***	+3.47	
High	+25.81***	+6.99	
% Female patients	+0.19	-0.16	
% Medicare patients	+0.18*	+0.52***	
# Comorbidities/patient	+15.04**	+18.42***	
% Catheters	+1.28***	+1.15***	
% Fistulas	-0.83***	-0.25	
* - $p < 0.05$ , ** - $p < 0.01$ , *** - $p < 0.001$			

Data are reported as percent changes in the geometric mean of infections per year per eligible patient. Estimates were derived from log-linear regressions using standard errors clustered at the facility level. Unadjusted estimates are presented alongside a fully adjusted model including all covariates listed.