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Dialysis Facility Profit Status and Access to Early Steps in Kidney Transplantation in the Southeastern United States

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An abstract of a thesis submitted to the
Faculty of the James T. Laney School of Graduate Studies of Emory University
in partial fulfillment of the requirements for the degree of
Master of Science in Clinical Research in 2020.

ABSTRACT

Dialysis Facility Profit Status and Access to Early Steps in Kidney Transplantation in the Southeastern United States

By Elizabeth Rebecca Walker, MS

Dialysis facilities in the United States play a key role in end-stage renal disease (ESRD) patient access to kidney transplantation, the optimal treatment for ESRD patients. Patients require a referral from a dialysis facility to begin evaluation at a transplant center. Previous studies reported patients treated at for-profit facilities are less likely to be waitlisted and less likely to receive kidney transplants, but the impact of for-profit status on early steps in the transplant process is unknown as completion of these steps is not documented in national surveillance data. Though the Southeastern United States has the highest burden of ESRD, it is the region with the lowest rate of kidney transplantation. It is critical to understand and address barriers to access to transplantation in this region. This study collected referral data from all nine transplant centers in Georgia, North Carolina, and South Carolina to determine the association between dialysis facility profit status and access to two critical steps early in the transplantation process: referral for transplant and start of evaluation at a transplant center. Cumulative incidence differences and multivariable Cox models were used to examine the association between dialysis facility profit status and completion of each of these two steps. Of the 33,659 incident ESRD patients initiating dialysis from January 1, 2012 to August 31, 2016 in these states, most received dialysis care at a for-profit facility (n=29,599, 85.0%) compared to a non-profit facility (n=5,060, 15.0%). There were significantly more for-profit facilities (n=590, 15.1%) in the region than non-profit facilities (n=105, 84.9%), which is consistent with national trends. For-profit facilities had lower cumulative incidence differences for referral within 1 year of initiation of dialysis compared to non-profit facilities (-4.6% [95% confidence interval (CI): -8.7% to -0.1%]). In both crude and adjusted Cox analyses, for-profit facilities demonstrated lower rates of referral for transplant relative to non-profit facilities (Crude Hazard Ratio (HR) = 0.87 [95%CI: 0.78 to 0.97]; Adjusted HR = 0.85 [95%CI: 0.77 to 0.95]). Start of evaluation at a transplant center did not differ significantly between groups. For ESRD patients living in the Southeast, receiving dialysis at a for-profit facility was associated with a lower likelihood of receiving a referral for kidney transplantation, a key step early in the transplantation process. This study emphasizes the importance of studying earlier steps, prior to waitlisting, to understand and address barriers to transplantation in this population.

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INTRODUCTION

End-stage renal disease (ESRD), defined as total and permanent kidney failure, affects more than 700,000 adults in the United States.[1] Kidney transplantation is the optimal treatment for patients with ESRD as it improves patient survival and quality of life compared with dialysis and a reduced total cost of care.[2-4] Despite the demonstrated long-term benefits of transplantation over chronic dialysis, less than 15% of all ESRD patients have completed the necessary steps to be waitlisted for a kidney transplant.[5] To determine why the vast majority of ESRD patients fail to be waitlisted, it is important to understand earlier steps in the kidney transplantation process require investigation.

There are several distinct steps to transplantation that must be navigated by patients and their healthcare providers in order to access a kidney transplant. Prior to waitlisting, ESRD patients must (1) be educated about kidney transplantation, (2) demonstrate interest in kidney transplantation, (3) receive a referral for evaluation at a transplant center, (4) initiate transplant evaluation at a transplant center by attending a first appointment. Only after the evaluation is complete can a patient be considered for transplant eligibility and move on to later steps, (5) waitlisting and (6) transplantation.

Following ESRD diagnosis, the vast majority of incident ESRD patients (nearly 90% between 2010-2016) initiate treatment in a dialysis facility. For these patients, the early steps in transplantation (steps 1-3) occur at the level of a dialysis facility.[6] Following education about transplantation, patients require a referral from their dialysis facility to a transplant center in order to begin evaluation. There are no requirements for dialysis facilities to refer patients for evaluation, but national guidelines from the Organ Procurement and Transplantation Network

(OPTN) recommend referring patients for evaluation, even if a clinician is uncertain of eligibility.[4]

Previous studies have reported that patients treated at for-profit facilities are less likely to be waitlisted for transplant and less likely to receive transplants. However, the impact of for-profit status on early steps in the transplantation process remains unknown.[7,8] This is largely attributable to the fact that national surveillance databases such as the United States Renal Data System (USRDS) and United Network for Organ Sharing (UNOS) do not routinely collect data on early transplant steps such as referral and evaluation. However, In order to design equitable interventions that improve access to transplantation, it is necessary to understand barriers at all steps of the transplant process, including those that occur at the level of the dialysis facility.

Therefore, in this study we examine the association between dialysis facility profit status and rate of referral (from a dialysis facility to a transplant center) and evaluation (at a transplant center). To do this, we will a novel data set of referrals received by all transplant centers in Georgia, South Carolina, and North Carolina. This research can inform ongoing efforts by policy makers, such as the Southeastern Kidney Transplant Coalition, and others to address disparities in access to kidney transplantation in the Southeast, the region with the greatest burden of kidney disease and lowest rates of transplantation in the nation.

BACKGROUND

Dialysis treatment is increasingly provided by for-profit facilities. Between 2000-2016, 88.3% of all incident ESRD patients initiated treatment in a for-profit dialysis facility.[8] The industry continues to undergo massive consolidation with one 2020 economic study estimating large for-profit dialysis chains have made over 1,200 acquisitions of independent dialysis facilities in the last 12 years.[9] As the growth and financial success of large for-profit dialysis providers promotes further consolidation, and the number of incident ESRD patients continue to rise, it is important to assess how profit status impacts ESRD patient care.

Dialysis facilities become coordinating centers for ESRD patients as critical early steps in the kidney transplantation process occur at the level of the dialysis facility. The growth and financial success of for-profit dialysis companies have many concerned that dialysis facility profit status may impact patient access to transplant. Several studies have shown that patients treated in for-profit facilities have reduced access to waitlisting and kidney transplantation.[7,8,10-12] In one of the first studies to examine the impact of facility profit status, a study by Garg et al. in 1999 demonstrated that for-profit ownership of dialysis facilities was associated with reduced access to the deceased donor kidney transplantation waitlist as well as with increased mortality.[11] Expounding upon this research, Zhang et al. examined the role of dialysis facility size, chain affiliation, and ownership on waitlisting of ESRD patients between 2006 and 2009. This study demonstrated that for-profit chain facilities, compared to non-profit chain facilities, were significantly less likely to waitlist patients while facility profit status did not influence waitlisting among non-chain facilities.[12] Since this study, dialysis has increasingly been provided by large-chain organizations.[9]

Expanding upon the research of Garg et al. and Zhang et al., a recent study by Gander et. al. reported receiving dialysis at for-profit facilities compared to non-profit facilities was associated with a lower likelihood of placement on the deceased donor kidney transplantation waitlist and receipt of a deceased donor kidney transplant. The Gander et al. study also found that patients in for-profit facilities were less likely to receive a living donor transplant, suggesting that patients in for-profit facilities may not be fully informed of all of their transplantation options.[8]

Recognizing the important role of the dialysis facility in early steps in the transplantation process, the Centers for Medicare & Medicaid Services (CMS) have instituted a number of requirements for dialysis facilities in attempts to improve access in the last 20 years. In 2005, CMS introduced a requirement that dialysis facilities inform and educate patients about their option for transplant within 45 days of dialysis initiation and document this compliance using Form CMS-2728.[13] CMS reinforced this policy in the 2008 CMS Conditions for Coverage for ESRD Facilities, though the content of this education is not standardized.[14]

Without standardized guidelines, the quality and content of transplant education patients receive can vary significantly between facilities. It was demonstrated by Kucirka et al. in 2012 that, despite the CMS education requirement, almost one-third of patients initiating dialysis reported they were not informed of their options for kidney transplantation and that patients receiving treatment in for-profit dialysis facilities were less likely to be informed of transplant compared to patients treated in non-profit facilities. They also found that educators at for-profit facilities were less likely to engage in “high-quality” transplant educational strategies (such as one-on-one discussions with patients about transplant) than educators at non-profit facilities[10]. In 2015, Waterman et al. reported that patients with access to high-quality, one-on-one discussions

with educators and patients with access to multiple educational platforms at their dialysis facility had increased access to transplant, including higher rates of waitlisting. This study also found that educators at for-profit dialysis centers were less likely to engage in one-on-one discussions about transplant compared to educators at non-profit dialysis facilities.[15]

Results from these investigations support findings from others suggesting that for-profit facilities may be incentivized against educating patients about transplant as an option in order to guarantee consistent revenue streams and better performance ratings.[16] Others have proposed that for-profit dialysis facilities are more likely to commit time and resources toward profit-generating services rather than commit time and resources towards lengthy transplant educational discussions.[17-19] For similar reasons, for-profit facilities may be less likely to refer patients for transplantation, though this has not previously been studied as referral information is not collected in national surveillance data.

Previous investigations of disparities in access to transplantation have been restricted to using waitlisting and transplantation as primary outcomes because national surveillance data does not report information on steps preceding waitlisting. In a study by Patzer et. al. in the state of Georgia, receiving dialysis treatment in a for-profit dialysis facility was associated with reduced access to transplantation at early steps in the transplantation process, specifically reduces access to receiving a referral for transplant evaluation at transplant center in Georgia. This was the largest study investigating disparities in access to referral for transplantation. Importantly, this study found that barriers to access to referral for transplantation differed from barriers to access to waitlisting and transplant. This was the first study to demonstrate the importance of studying referral for transplantation as a separate metric from waitlisting or receipt of a kidney transplant in order to design impactful interventions to improve equitable access for

all incident ESRD patients.[20] Clearly, further investigation is indicated into barriers to access in the steps preceding waitlisting, such as referral for transplantation (occurring at the level of the dialysis facility) and initiation of transplant evaluation at the transplant center.

In addition to its educational requirements for dialysis facilities, CMS has proposed new transplant access measures in its quality incentive program in order to encourage dialysis facilities to increase the proportion prevalent patients waitlisted (PPPW). This metric will be implemented in 2022 and seeks to target dialysis facilities with historically low levels of patients reaching the transplantation waitlist.[21] In order to increase the proportion of prevalent patients waitlisted, however, the proportion of patients referred for transplantation must also be increased. As demonstrated in previous studies, factors impacting earlier steps in kidney transplantation my differ significantly from factors impacting waitlisting and transplantation.[20]

Currently, less than 15% of all ESRD patients complete the necessary steps to be waitlisted for kidney transplant.[5] While it is unknown what proportion of ESRD patients are medically eligible for transplant, it is likely that 15% is too low. Dialysis facility healthcare providers are advised that, if there is any question of eligibility, that patient should be referred for evaluation. Recognizing the significant current discrepancy between referred patients and patients that are likely eligible for transplantation, CMS has set a target goal of 30% of all ESRD patients should be waitlisted for kidney transplantation by 2023.[22] Barriers to access to earlier steps in the transplantation process must be examined in order to understand what is blocking so many from reaching the waitlist.

The Southeastern United States has the highest burden of ESRD in the United States. Unfortunately, it is also the region with the lowest standardized transplantation rates.[23] It is therefore critical to understand barriers to access in this region in order to improve access to

transplantation. Though there exists a scarcity of available organs, profit status of the patient's dialysis facility should not be included in the many barriers to access to transplant.

METHODS

Hypothesis

This investigation hypothesized that dialysis facility profit status would be associated with differences in referral for transplantation and start of evaluation at a transplant center.

Data Sources

Patient-level clinical and demographic data was obtained from the United State Renal Data System (USRDS) database. USRDS data is a publicly available national database managed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) that contains information on nearly all U.S. patients with ESRD (cite). USRDS patient-level clinical and demographic data is collected at the initiation of dialysis using the CMS-2728 form. USRDS data is also linked to the United Network for Organ Sharing (UNOS) database on kidney waitlist and transplant events, but it does not contain information on early transplant steps such as referral.

Dialysis facility-level data was obtained from Dialysis Facility Compare (2016) and Dialysis Facility Report (2013-2016). Both Dialysis Facility Compare (DFC) and Dialysis Facility Report (DFR) data are commissioned by CMS and managed by the University of Michigan Kidney Epidemiology and Cost Center (cite). DFC reports information on dialysis facility profit status and corporate ownership (cite). DFR captures information on facility-level patient characteristics (mean age, percentage of males, race), mortality, treatment patterns, and transplantation rates. Dialysis facility-level data from DFC and DFR was linked to patient-level USRDS data using the dialysis facility's CMS certification number. Neighborhood factors, such as rurality of the facility and ZIP code, was determined using US Census Data and poverty status of a neighborhood was determined from the American Community Survey.

Patient-level referral and start of evaluation data was collected from all transplant centers in Georgia, North Carolina, and South Carolina by the ESRD Network 6 coordinating center. There are nine transplant centers in this service area: Augusta University Medical Center, Carolinas Medical Center, Duke University Hospital, Emory Transplant Center, Medical University of South Carolina, Piedmont Hospital, University of North Carolina, Vidant Medical Center, and Wake Forest Baptist Hospital Medical Center (**Figure 2**). Referral and start of evaluation data was linked to USRDS data by social security number and then de-identified by the ESRD Network 6 coordinating center. This study was approved by the institutional review board at Emory University (IRB00079596).

Study Population

All incident ESRD patients registered within the United States Renal Data System (USRDS) database in Georgia, North Carolina, and South Carolina who initiated dialysis between January 1, 2012 and August 31, 2016 were considered for inclusion (**Figure 2**). Patients were excluded if they were not within 18 years to 80 years of age when initiating dialysis or if they had been waitlisted or transplanted "preemptively" (prior to initiating dialysis) or had multiple referrals. Patients were excluded if they were treated in dialysis facilities within a transplant center, affiliated with a VA medical center, or treated fewer than 10 patients in one year. Referrals were excluded if they lacked a USRDS identifier or if they represented a duplicate referral for a patient, as we only wished to assess unique, first-time referrals for each patient within the cohort. Additionally, 5 patients missing information for the primary exposure (profit status) were excluded from analysis (**Figure 3**).

Outcomes and Study Variables

The primary exposure was dialysis facility profit status. Facility profit status was defined as for-profit or non-profit within the USRDS database. The primary outcome was access to early steps in kidney transplantation, defined as referral for transplant evaluation at a transplant center. Referral to a transplant center was considered complete at the time a referral order is received at a transplant center. Patients were censored for event (date of referral), death, or end of study period (August 31, 2017 for referral). The secondary outcome was initiation of transplant evaluation at a transplant center. Start of the transplant evaluation was considered complete at the time a patient attended a required component of the transplant evaluation (defined as first visit to a transplant center, satellite clinic, or required education class). For the secondary outcome, patients were censored for event, death, or end of study period (March 1, 2018 for evaluation), whichever came first.

Patient-level demographics as well as clinical and socioeconomic characteristics were obtained from USRDS as reported on the CMS-2728 form. Demographics assessed included age at start of dialysis, race/ethnicity, and attributed cause of ESRD (diabetes, hypertension, glomerulonephritis, and other). Clinical characteristics assessed comorbidities (presence of BMI greater than 35kg/m_2, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, tobacco use, and active malignancy) and whether or not a patient received nephrology care prior to ESRD diagnosis.

Socioeconomic factors considered included patient insurance provider (Medicare, Medicaid, employer coverage, other coverage, no coverage) and neighborhood socioeconomic indicators (percentage of residents living below the poverty line, percentage of African American

residents, and high school graduation rates). Dialysis facility-level characteristics including facility size and patient-to-social worker ratio were obtained from DFR.

Missing Data

There were 545 (1.6%) patients with incomplete CMS-2728 forms (missing all information on race/ethnicity, insurance, and comorbidities). As this was a small proportion of the total sample, we chose to conduct a complete case analysis, rather than conduct multiple imputations, which have known shortcomings.[24] These cases represented 1.6% of the final cohort. A secondary analysis was performed with these patients included and it did not impact final results.

Statistical Analysis

Descriptive statistics for patient-level characteristics (demographic factors, clinical characteristics, and socioeconomic factors) and facility-level characteristics were calculated and used to evaluate differences between patients treated in for-profit and non-profit dialysis facilities. The X^2 test was used to compare categorical variables, the Kruskal-Wallis test was used to assess non-parametric continuous variables, and the Wilcoxon rank sum test was used to assess parametric continuous variables between for-profit and non-profit groups.

The cumulative incidence function was used to estimate probability of outcomes as a function of time from the initiation of dialysis, with death considered as a competing risk. Cumulative incidence differences and 95% CIs between for-profit and non-profit groups were determined at follow-up times of 6 months, 1 year, 2 years, and 3 years for referral (and 6 months, 1 year, and 2 years for start of evaluation). Number at risk for each time point was calculated. Bootstrapping (a method of randomly resampling the effect size) was used to perform

10,000 resamples of the event in order to accurately assess 95% confidence intervals (CI) for these cumulative incidence differences.

For the main analysis, time to each event (referral or start of evaluation, censored for end of study period) was calculated using cause-specific hazard ratios and 95% CI, with death treated as a competing risk. End of study period was August 31, 2017 for referral and March 1, 2018 for evaluation (to give each referred patient at least 6 months to start evaluation). Bivariable Cox proportional hazard models were used to determine the crude association between covariates and access to transplantation.

Confounding variables were included in the final adjusted model if they were (1) associated with exposure and with outcome on bivariable analysis or if (2) known clinical associations had been previously reported. Variables associated with exposure and outcome were considered for inclusion using backward selection; if excluding the variable did not significantly change the association between profit status and outcome (by greater than 10%), then the variable was not included in the model. Demographic variables (age, gender, and race/ethnicity) were included because of longstanding associations of these variables with both exposure and outcome (**Table 3**). Both crude and adjusted used robust sandwich variance estimator to account for potential clustering within dialysis facilities. The proportional hazard assumption was tested for both outcomes.

SAS version 9.4 (SAS Institute, Cary, NC) and R (version 3.6.1) were used for cohort development and data management. R was used for statistical analysis. Two-sided p-values were used for all analyses, and $p<0.05$ was considered statistically significant.

RESULTS

Baseline Characteristics

We included 33,659 ESRD patients from Georgia, South Carolina, and North Carolina (**Figure 3**). Among included patients, most received dialysis care at a for-profit facility (n=29,599, 85.0%) compared to a non-profit facility (n=5,060, 15.0%). There were significantly more for-profit facilities (n=590, 15.1%) in the region than non-profit facilities (n=105, 84.9%), which is consistent with trends observed nationally.[8] In the overall population, the mean age was 59.6 years (SD: 13.2 years), the patients were 55.0% male, and 56.0% were of non-Hispanic black race/ethnicity **(Table 1)**.

Patient demographics were similar across for-profit and non-profit facilities; there were no significant differences in age, sex distribution, or race/ethnicity between groups. Compared with patients treated in for-profit facilities, patients treated in non-profit facilities had significantly higher rates of ten of eleven comorbidities assessed. Differences were observed in attributable cause of ESRD, with more disease attributed to hypertension in for-profit facilities compared to non-profit facilities (37.8% vs. 32.6%) and less to diabetes (46.1% vs. 46.5%). There were no differences in proportion of patients receiving nephrology care prior to diagnosis. Patients treated in for-profit facilities were more likely to have have employer-based insurance, Medicare, or Medicaid, while patients in non-profit facilities were more likely to lack coverage. More for-profit facilities treated greater than 55 patients compared to non-profit facilities (**Table 1**).

For all patients, the median follow-up time (to referral, death, or censor) was 12.88 months (IQR 4.14-27.43 months). Median follow-up time was significantly longer for patients treated at for-profit facilities (13.08 months, [IQR 4.30-27.70 months]) compared to patients

treated at non-profit facilities (11.65 months, [IQR 3.45-26.18 months], p<0.001). Among those referred, median time from ESRD diagnosis to referral was 4.44 months (IQR 2.08-10.25 months). This time to referral was longer for patients treated at for-profit facilities (4.57 months [IQR 2.10-10.45 months]) compared to patients treated at non-profit facilities (3.81 months [IQR 2.04-9.13 months], p<0.001). Patients who were referred and started evaluation had a median time to evaluation of 5.36 months (IQR 2.10-23.75 months); this did not differ between groups.

Referral for transplantation evaluation following initiation of dialysis

A total of 14,737 patients (43.8%) were referred for transplant during the study period. There was a lower percentage of patients referred from for-profit dialysis facilities (43.2%, n=12,350) compared to patients referred from non-profit dialysis facilities (47.2%, n=2,387, p<0.001). There were 11,649 patients (34.6%) referred within one year of initiating dialysis. For-profit facilities also had lower percentages of referrals within one year compared to non-profit facilities (33.9% vs 38.5%; p<0.001).

In bivariable Cox hazard models, female patients were less likely to be referred for transplant compared to male patients (HR 0.82, 0.79-0.84). Patients younger than 60 years old and patients of non-white race were more likely to receive a referral. Compared to patients with ESRD attributed to diabetes, patients were more likely to receive a referral with ESRD attributed to glomerulonephritis (HR 0.83, 95%CI: 0.78-0.88) or hypertension (HR 1.08, 95%CI: 1.05-1.12). Patients with comorbidities such as cancer (HR 0.50, 95%CI: 0.46-0.55), COPD (HR 0.51, 95%CI: 0.48-0.55), peripheral vascular disease (HR 0.63, 95%CI: 0.59-0.67), atherosclerotic heart disease (HR 0.63, 95%CI: 0.60-0.67), cerebrovascular disease (HR 0.64, 95%CI: 0.60-0.69), other cardiac disease (HR 0.65, 95%CI: 0.62-0.69), or congestive heart failure (HR 0.71,

95%CI: 0.68-0.74) were less likely to be referred for transplant. Employer-based insurance was also associated with increased probability of referral for transplant (**Table 2**).

In the cumulative incidence analysis, with death treated as a competing risk, patients treated in for-profit facilities had significantly longer time to referral compared to patients treated in non-profit facilities. Patients treated in for-profit facilities had lower cumulative incidence of referral at 6 months and 1 year compared to patients treated in non-profit facilities (cumulative incidence difference -5.1% [95%CI: -9.1%, -1.2%] and -4.6% [95%CI: -8.7%, -0.1%] respectively). Cumulative incidence of referral for both groups, as well as cumulative incidence differences, 95% CI, and number at risk for follow-up times of 6 months, 1 year, 2 years, and 3 years are described in **Table 3**. A cumulative incidence plot illustrates that the reduced incidence of referral among patients treated in for-profit facilities persists over time as number at risk declines for each time point (**Figure 4**).

In bivariable competing-risk regression, female patients were less likely to be referred for transplant compared to male patients (HR: 0.82; 95% CI: 0.79-0.84). Younger patients were more likely to be referred compared to older patients, with likelihood decreasing with age: patients ages 18-29 were the most likely (HR: 2.30; 95% CI: 2.12-2.50), followed by patients ages 30-39 (HR: 2.24; 95% CI: 2.11-2.37), patients ages 40-49 (HR: 1.90; 95% CI: 1.81-1.99), and patients 50-59 (HR: 1.35; 95% CI: 1.29-1.41). Compared to patients ages 60-69, patients older than 70 years of age were very unlikely to receive a referral (HR: 0.40; 95% CI: 0.38-0.43). Compared to white non-Hispanic patients, non-white patients (black, white Hispanic, and patients of "Other" race/ethnicity) were more likely to be referred for transplant. Compared to patients with ESRD attributed to diabetes, patients with ESRD attributed to hypertension and glomerulonephritis were more likely to be referred (HR=1.08; 95%CI: 1.05-1.12 and HR=1.10;

95%CI: 1.03-1.19, respectively) and patients with disease attributed to “other” processes (not diabetes, hypertension, or glomerulonephritis) were less likely to be referred (HR=0.83; 95%CI: 0.78-0.83).

Comorbidities associated with significantly decreased likelihood of referral included congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, chronic obstructive pulmonary disease, smoking, and cancer. Among socioeconomic factors, only patient insurance status was associated with referral for transplant (patient neighborhood factors were not significantly associated with outcomes). Compared to patients insured by an employer, patients were less likely to be referred if they were insured by Medicare (HR=0.48; 95%CI: 0.46-0.50), Medicaid (HR=0.61; 95%CI: 0.58-0.64), or other coverage (HR=0.78; 95%CI: 0.73-0.83). Compared to large facilities (more than 79 patients), facilities with 26-78 patients were more likely to refer patients within one year (**Table 2**).

On unadjusted analysis, patients treated at for-profit facilities were less likely to receive a referral for transplant evaluation compared to patients treated at non-profit facilities (HR: 0.87; 95%CI: 0.78-0.97). The notably wide confidence interval in crude analysis is secondary to the application of the robust sandwich variance estimator, which was used to account for potential clustering within dialysis facilities. In multivariable analysis, after adjusting for confounding factors associated with exposure and outcome (age, gender, race/ethnicity, primary cause of ESRD, the presence of certain comorbidities (congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, and cancer), and insurance status, it was demonstrated that patients treated at a for-profit facility were significantly less likely to receive a

referral compared to patients treated at a non-profit facility (HR: 0.85; 95%CI: 0.76-0.95) as outlined in **Table 5**.

Profit status and evaluation at a transplant center

Among patients referred for evaluation at a transplant center (n=14,737), a total of 7,780 patients initiated evaluation at a transplant center (52.8% of referred patients). Of these, only 37.8% started evaluation within six months of the referral (n=5,575). Of the 12,350 patients referred for transplant from for-profit facilities, 52.5% started transplant evaluation compared to 54.6% of the 2,387 patients referred from non-profit facilities.

Patients receiving dialysis in for-profit facilities had lower 6-month cumulative incidence compared to patients receiving treatment in non-profit facilities (cumulative incidence difference -1.0%, 95% CI: -7.3% to 5.3%) though results do not reach significance. Trends remained consistent on 1-year cumulative incidence analysis (cumulative incidence difference -1.3%, 95% CI: -7.4% to 5.7%) as well as 2- and 3-year cumulative incidence analysis. Cumulative incidences for both groups, as well as cumulative incidence differences, 95% CI, and number at risk for follow-up times of 6 months, 1 year, and 2 years are described in **Table 6**. A cumulative incidence plot illustrates that the reduced incidence of referral among patients treated in for-profit facilities persists over time (**Figure 5**).

Bivariable competing-risk regression demonstrated that male patients younger than 60 years old were more likely to initiate evaluation. Though black patients were more likely to be referred for transplant than non-Hispanic white patients, this was not observed in evaluation analysis. Following referral, Hispanic white patients and patients of “other” race/ethnicity were more likely to initiate evaluation compared to non-Hispanic white patients (HR: 1.43; 95%CI: 1.26-1.63 and HR: 1.32; 95%CI: 1.14-1.53, respectively). Compared to patients with ESRD

attributed to diabetes, patients with ESRD attributed to glomerulonephritis, hypertension, and "other" causes were more likely to initiate evaluation. Among patients who were already referred, the presence of all comorbidities except for hypertension and cancer were associated with significantly decreased likelihood of starting evaluation at a transplant center. Among socioeconomic and facility-level factors, only insurance status was associated with initiation of evaluation following referral: patients with employer-based insurance plans were more likely to initiate evaluation than all other types of insurance plans (**Table 2**).

Crude and adjusted associations between dialysis facility profit status and initiation of evaluation following referral differed. On unadjusted analysis, results did not differ significantly between for-profit and non-profit groups (HR: 0.95; 95%CI: 0.90-1.01). On multivariable analysis after adjusting for demographics known to be associated with the outcome (age, gender, race/ethnicity) and confounding factors associated with exposure and outcome (primary cause of ESRD, the presence of certain comorbidities (a BMI greater than or equal to 35kg/m_2, congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, diabetes, chronic obstructive pulmonary disease, smoking, and cancer), insurance status, and size of the facility, it was demonstrated that patients treated at a for-profit facility and patients treated in a non-profit facility did not differ significantly in their likelihood to initiate evaluation at a transplant center once referred (HR: 0.93; 95%CI: 0.83-1.04) as outlined in **Table 6.**

Analysis of patients censored for death

Among the 33,659 patients in the final cohort, there were 18,922 patients (56.2%) who were not referred for transplant evaluation within one year of initiating dialysis. Of these, 9,449 patients (50.0%) died within one year of initiating dialysis prior to receiving a referral for

transplant. These patients were censored for death in the primary analysis, but the cohort was also examined for differences between for-profit and non-profit groups. Of the 5,060 patients treated in a non-profit facility, 1,347 patients (26.6%) died within one year of initiating dialysis without receiving a referral. Of the 28,599 patients treated in a for-profit facility, 8,102 patients (28.3%) died within one year of initiating dialysis without receiving a referral. Compared to patients treated in non-profit facilities, patients treated in for-profit facilities were not significantly more likely to die within one year of initiating dialysis (HR: 0.99; 95%CI: 0.94-1.05) on bivariable analysis.

DISCUSSION

Among adult ESRD patients treated in dialysis facilities within Georgia, North Carolina, and South Carolina (ESRD Network 6), patients treated in for-profit dialysis facilities were 13% less likely to receive a referral for transplant within one year of initiating dialysis compared to patients treated in non-profit dialysis facilities (HR: 0.87; 95%CI: 0.78-0.97). Additionally, patients receiving dialysis at for-profit facilities versus patients receiving dialysis at non-profit facilities had significantly lower cumulative incidence of referral at 6-months (cumulative incidence difference: -5.1; 95%CI: -9.1 to -1.0) and at one year (cumulative incidence difference: -4.6; 95%CI: -8.7 to -0.1). This study is the first to examine the relationship between dialysis facility profit status and early steps in the transplantation process (referral and start of evaluation at a transplant center) in a large population, expanding upon the previous work of Patzer et al. in the state of Georgia.[20]

In order to better understand why for-profit dialysis facilities refer fewer patients compared to non-profit facilities, further research is needed. It has been suggested that for-profit facilities' financial incentives may differ from patient-centered care incentives.[10,11,25] Compared to non-profit facilities, for-profit facilities may experience pressure to generate revenue and thus may be incentivized against referring patients in order to maintain higher treatment numbers and consistent revenue streams.[16] Additionally, as healthier patients tend to have fewer complications, a key metric in the performance rating for a dialysis facility, for-profit facilities may be incentivized to keep these patients in their treatment centers.[19] Further research is required to better understand this association. As the for-profit dialysis sector continues to grow, it is pertinent to continue and expand upon research into the differences in access to transplantation between for- and non-profit dialysis facilities.

Despite the clear survival and cost benefits of transplantation over dialysis, our findings demonstrate that less than half of all patients (43.8% of all patients; 47.2% of patients treated in non-profit facilities and 43.2% of patients treated in for-profit facilities) were referred for transplant evaluation overall. Though it is difficult to assess who should be referred for transplant evaluation, these rates of referral are likely too low. As CMS has targeted a goal to increase the number of waitlisted ESRD patients to 30% by 2023, increasing rates of referral become more important.[22]

Though it is difficult to determine which patients should be referred for transplant evaluation, our study demonstrates that for-profit dialysis facilities should be referring more patients. Patients treated in for-profit facilities were less likely to have 10 of the 11 comorbidities assessed at initiation of dialysis and more likely to have employer-based insurance. Despite the presence of these factors associated with increased waitlisting and transplantation, patients treated at a for-profit facility were less likely to receive a referral within one year of initiating dialysis compared to patients treated in a non-profit facility and had lower cumulative incidences of referral at both 6-month and one year.

Once referred, our study did not find significant differences between for- and non-profit facilities in rates of patients initiating evaluation at a transplant center. However, it is notable that only about half of referred patients initiated evaluation at a transplant center (52.8% of all patients; 54.6% of patients treated in non-profit facilities and 52.5% of patients treated in for-profit facilities). As CMS introduces policies in the 2020 ESRD Quality Incentive Program, such as the PPPW to increase waitlisting, it will become increasingly important to understand why approximately half of referred patients do not start the transplant evaluation.

Our findings suggest that targeted interventions encouraging dialysis centers, particularly for-profit facilities, to increase referral may lead to improved access to transplantation. A recent study by McPherson et al. reported substantial variation in referral practices in Georgia, North Carolina, and South Carolina, with referral rates ranging from 0% to 100%.[8] This strikingly wide variation in referral practices, coupled with our findings of lower referral numbers at for-profit facilities, further indicates a need for consistent and enforced guidelines on referral. The new CMS PPPW proposal seeks to encourage dialysis facilities to increase the proportion of prevalent patients waitlisted. While this metric may lead to increased referral rates in facilities with extremely low or 0% rates, our research suggests that it may be more impactful to target earlier steps in transplantation, such as referral for transplant.[21]

This study also found that different factors were associated with referral for transplant than waitlisting and transplantation. For example, black patients were more likely to be referred for transplant than white patients, but were less likely to initiate evaluation at a transplant center. This is notable as many prior studies have demonstrated lower rates of waitlisting and transplantation for black patients compared to white patients.[26] The different factors associated with referral compared to waitlisting and transplantation further suggest the need to collect data and study earlier steps in transplantation on a national level.

Limitations

This study has several limitations. First, given the nature of the data, this study was limited to the Southeastern states of Georgia, North Carolina, and South Carolina (ESRD Network 6) and could not assess patterns on a national scale. This region has both the highest burden of disease and lowest rates of kidney transplantation in the United States. As this data is not collected nationally, we can only capture referrals to transplant centers in these states.

Although it is likely not a common occurrence, if a patient treated in Georgia, North Carolina, or South Carolina was referred for evaluation to a transplant center in a different state (such as Tennessee), this would not be reflected in the data. For these reasons, generalizability to other areas may not be possible. Our findings demonstrate the need for national surveillance data to be collected on early transplant steps (prior to waitlisting) in order to better understand and address barriers to access to transplantation.

This study is limited to patients with ESRD who require dialysis treatment and are likely in later stages of disease. Patients with earlier stages of the disease (not requiring dialysis) were not included, so selection bias for late-stage ESRD patients must be considered. Confounding variables, such as comorbidities and insurance status, are assessed using the CMS-2728 form, which is completed at the initiation of dialysis. If these factors change over time, there may be unmeasured confounding that we cannot account for due to the nature of the data collection.

Finally, transplant centers differ in their criteria for transplant eligibility (such as cutoff age or specific comorbidity). Although the majority of the criteria are similar across centers, they are not identical and these criteria may impact the dialysis facility choice to refer. As the data-sharing agreement blinds this study from transplant center identifiers, differences in criteria of individual transplant centers cannot be assessed.

CONCLUSION

Among US patients with ESRD in the Southeastern United States, receiving dialysis in for profit facilities was associated with lower access to referral for kidney transplantation. This study emphasizes the importance of studying earlier steps, prior to waitlisting, to understand and address barriers to transplantation in this population. Further research is needed to understand the mechanisms behind this association and to determine potential health system incentives that may be applied to reduce this disparity.

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Tables and Figures

Table 1. Characteristics of patients with incident ESRD initiating dialysis between January 1, 2012 and August 31, 2016 in Georgia, North Carolina, and South Carolina followed through February 28, 2018; overall and stratified by dialysis facility profit status

Population Characteristics	Overall population	Patients initiating dialysis at a for-profit facility	Patients initiating dialysis at a non-profit facility	p-value
Facilities, n (%)	686 (100)	582 (84.8)	104 (15.2)	**<.001**
Total patients, n (%)	33,659 (100)	28,599 (85.0)	5,060 (15.0)	**<.001**
Patient Demographics				
Age in years, mean (SD);	59.6 (13.2)	59.6 (13.2)	59.4 (13.3)	0.215
Age category, n (%)				
18-29	916 (2.7)	771 (2.7)	145 (2.9)	
30-39	2,014 (6.0)	1,702 (6.0)	312 (6.2)	
40-49	4,325 (12.8)	3,667 (12.8)	658 (13.0)	0.685
50-59	7,547 (22.4)	6,409 (22.4)	1,138 (22.5)	
60-69	10,121 (30.1)	8,581 (30.0)	1,540 (30.4)	
≥70	8,736 (26.0)	7,469 (26,1)	1,267 (25.0)	
Sex, n (%)				
Male	18,504 (55.0)	15,709 (54.9)	2,795 (55.2)	0.695
Female	15,155 (45.0)	12,890 (45.1)	2,265 (44.8)	
Race/ethnicity, n (%)				
White, non-Hispanic	13,453 (40.0)	11,460 (40.1)	1,993 (39.4)	
Black, non-Hispanic	18,859 (56.0)	15,996 (55.9)	2,863 (56.6)	0.789
White, Hispanic	713 (2.1)	602 (2.1)	111 (2.2)	
Other race/ethnicity	634 (1.9)	541 (1.9)	93 (1.8)	
Patient Clinical Characteristics				
Attributed cause of ESRD, n (%)[a]				
Diabetes	15,351 (46.5)	13,030 (46.5)	2,321 (46.7)	
Hypertension	12,219 (37.0)	10,594 (37.8)	1,625 (32.7)	<0.001
Glomerulonephritis	2,225 (6.7)	1,811 (6.5)	414 (8.3)	
Other	3,218 (9.8)	2,613 (9.3)	605 (12.2)	
Comorbidities, n (%)[b]				
BMI ≥ 35 kg/m2	8,519 (25.5)	7,255 (25.6)	1,264 (25.1)	0.464
Congestive heart failure	9,406 (27.9)	7,831 (27.4)	1,575 (31.1)	<0.001
Atherosclerotic heart disease	3,347 (9.9)	2,782 (9.7)	565 (11.2)	0.002
Other cardiac disease	5,894 (17.5)	4,937 (17.3)	957 (18.9)	0.005
Cerebrovascular disease (stroke)	3,156 (9.4)	2,590 (9.1)	566 (11.2)	<0.001
Peripheral vascular disease	3,007 (8.9)	2,456 (8.6)	551 (10.9)	<0.001
Hypertension	30,084 (89.4)	25,453 (84.6)	4,631 (15.4)	<0.001
Diabetes	20,324 (60.4)	17,195 (60.1)	3,129 (61.8)	0.023
Chronic Obstructive Pulmonary Disease	3,097 (9.2)	2,538 (8.9)	559 (11.0)	<0.001
Tobacco use	3,120 (9.3)	2,467 (8.6)	653 (12.9)	<0.001
Cancer	2,081 (6.2)	1,698 (5.9)	383 (7.6)	<0.001

Pre-ESRD nephrology care, n (%)[c]				
Received	21,095 (71.2)	17,909 (71.2)	3,186 (71.3)	0.907
Did not receive	8,530 (28.8)	7,247 (28.8)	1,283 (28.7)	
Patient Socioeconomic Characteristics				
Primary health insurance provider, n (%)				
Medicare	13,776 (40.9)	2,134 (42.2)	11,642 (40.7)	
Medicaid	8,335 (24.8)	7,141 (25.0)	1,194 (23.6)	<0.001
Employer group	5,903 (17.5)	5,144 (18.0)	759 (15.0)	
Other coverage	2,142 (6.4)	1,794 (6.3)	348 (6.9)	
No coverage	3,503 (10.4)	2,878 (10.1)	625 (12.4)	
Patient neighborhood (zip code) factors				
Number of patients living in a zip code where ≥20% of residents live below the poverty line, n(%)	10.585 (31.4)	8,996 (31.5)	1,589 (31.4)	0.954
% African American population in patient zip code, mean (SD)[d]	34.8 (23.7)	34.9 (23.2)	34.5 (26.7)	0.100
% High school graduates in patient zip code, mean (SD)[e]	82.8 (7.2)	82.9 (7.2)	82.2 (7.4)	0.210
Patient Dialysis Facility Characteristics				
Number of patients per facility, mean (SD)	85.0 (49.4)	83.9 (45.0)	91.2 (68.9)	0.232
Number of patients per facility by category, n (%)				
Very Small (11-25)	545 (1.6)	465 (1.6)	77 (1.5)	
Small (26-54)	6,474 (19.2)	5,116 (17.9)	1,358 (26.8)	<0.001
Medium (55-78)	8,097 (24.1)	7,210 (25.2)	8,097 (24.1)	
Large (>79)	18,546 (55.1)	15,808 (55.3)	2,738 (54.1)	
Number of social workers per facility, mean (SD);	0.9 (0.7)	0.9 (0.7)	0.9 (0.6)	0.943
Ratio of patients to social workers per facility, mean (SD)[f]	96.9 (40.1)	97.1 (39.5)	95.1 (43.4)	<0.001

Abbreviations: BMI: Body Mass Index; CI: Confidence Interval; SD: Standard Deviation

[a] Attributable cause information missing for 646 patients (1.9%)

[b] Patient BMI information missing for 243 patients (0.7%); removed patients missing all comorbidities.

[c] Information on patients who received nephrology before ESRD diagnosis missing for 4,064 patients (11.9%).

[d] Average percentage of African Americans in zip code of patient neighborhood was missing for 455 patients (1.4%).

[e] Average percentage of high school graduates in zip code of patient neighborhood was missing for 461 patients (1.4%).

[f] Number of patients for every 1 social worker. Calculated only for patients (n=31,127) that had at least 1 social worker at their home facility and not for patients with 0 social workers at their home facility (n=2,532).

Table 2. Characteristics and bivariable cause-specific hazard ratios of patients with incident ESRD who initiated dialysis between January 1, 2012 and August 31, 2016 in Georgia, North Carolina, and South Carolina who were referred for transplant and who initiated evaluation at a transplant center during follow-up (to August 31, 2017 for referral, to March 1, 2018 for evaluation).

Characteristics	**Overall population**	**Referred for evaluation at a transplant center (n, % of total)**		**Initiated evaluation at a transplant center following referral (n, % of those referred)**	
Patients, n (%)	**33,659 (100)**	**14,737 (43.8)**		**7,780 (52.8)**	
	n (% of total)	**n (row %)**	**HR[b] (95% CI)**	**n (row %)**	**HR[b] (95% CI)**
Dialysis Facility Profit Status					
Patients treated in non-profit facilities	5,060 (15.0)	2,387 (47.2)	[Ref]	1,302 (54.6)	[Ref]
Patients treated in for-profit facilities	28,599 (85.0)	12,350 (43.2)	**0.87 (0.78, 0.97)**	6,478 (52.5)	**0.95 (0.85, 1.07)**
Patient Demographics					
Age category					
18-29	916 (2.7)	677 (73.9)	2.30 (2.12, 2.50)	438 (64.7)	1.47 (1.33, 1.63)
30-39	2,014 (6.0)	1,466 (72.8)	2.24 (2.11, 2.37)	884 (60.3)	1.30 (1.20, 1.41)
40-49	4,325 (12.9)	2,864 (66.2)	1.90 (1.81, 1.99)	1,604 (56.0)	1.14 (1.07, 1.22)
50-59	7,547 (22.4)	3,970 (52.6)	1.35 (1.29, 1.41)	2,139 (53.9)	1.09 (1.03, 1.16)
60-69	10,121 (30.1)	4,153 (41.0)	[Ref]	2,098 (50.5)	[Ref]
≥70	8,736 (26.0)	1,607 (18.4)	0.40 (0.38, 0.43)	617 (38.4)	0.70 (0.64, 0.77)
Sex					
Male	18,504 (55.0)	8,637 (46.7)	[Ref]	4,628 (53.6)	[Ref]
Female	15,155 (45.0)	6,100 (40.3)	0.82 (0.79, 0.84)	3,152 (51.7)	0.94 (0.90, 0.98)
Race/ethnicity					
White, non-Hispanic	13,453 (40.0)	4,677 (34.8)	[Ref]	2,422 (51.8)	[Ref]
Black, non-Hispanic	18,859 (56.0)	9,343 (49.5)	1.46 (1.41, 1.51)	4,905 (52.5)	0.98 (0.93, 1.03)
White, Hispanic	713 (2.1)	391 (54.8)	1.61 (1.45, 1.78)	252 (64.5)	1.43 (1.26, 1.63)
Other race/Ethnicity	634 (1.9)	326 (51.4)	1.55 (1.39, 1.74)	201 (61.7)	1.32 (1.14, 1.53)
Patient Clinical Characteristics					
Attributed cause of ESRD [a]					
Diabetes	15,351 (46.5)	6,515 (42.4)	[Ref]	3,297 (50.6)	[Ref]
Hypertension	12,219 (37.0)	5,566 (45.6)	1.08 (1.05, 1.12)	2,927 (52.6)	1.07 (1.01, 1.12)
Glomerulonephritis	2,225 (6.7)	1,284 (57.7)	1.50	782 (60.9)	1.29

			(1.41, 1.60)		(1.20, 1.40)
Other	3,218 (9.8)	1,125 (35.0)	0.83 (0.78, 0.88)	627 (55.7)	1.20 (1.10, 1.31)
Comorbidities [b]					
BMI ≥ 35 kg/m2	8,519 (25.5)	3,894 (45.7)	1.05 (1.01, 1.09)	1,900 (48.8)	0.85 (0.81, 0.89)
Congestive heart failure	9,406 (27.9)	3,290 (35.0)	0.71 (0.68, 0.74)	1,529 (46.5)	0.80 (0.76, 0.85)
Atherosclerotic heart disease	3,347 (9.9)	1,035 (30.9)	0.63 (0.60, 0.67)	466 (45.0)	0.78 (0.71, 0.86)
Other cardiac disease	5,894 (17.5)	1,882 (31.9)	0.65 (0.62, 0.69)	881 (46.8)	0.83 (0.77, 0.89)
Cerebrovascular disease (stroke)	3,156 (9.4)	986 (31.2)	0.64 (0.60, 0.69)	442 (44.8)	0.77 (0.70, 0.85)
Peripheral vascular disease	3,007 (8.9)	903 (30.0)	0.63 (0.59, 0.67)	377 (41.8)	0.70 (0.63, 0.78)
Hypertension	30,084 (89.4)	13,353 (44.4)	1.13 (1.07, 1.19)	7,049 (52.8)	0.98 (0.91, 1.06)
Diabetes	20,324 (60.4)	8,515 (41.9)	0.87 (0.84, 0.89)	4,353 (51.1)	0.89 (0.85, 0.93)
Chronic Obstructive Pulmonary Disease	3,097 (9.2)	787 (25.4)	0.51 (0.48, 0.55)	297 (37.7)	0.63 (0.56, 0.71)
Tobacco use	3,120 (9.3)	1,309 (42.0)	0.93 (0.88, 0.99)	600 (45.8)	0.78 (0.72, 0.85)
Cancer	2,081 (6.2)	505 (24.3)	0.50 (0.46, 0.55)	251 (49.7)	0.93 (0.82, 1.06)
Pre-ESRD nephrology care [c]					
Received	21,095 (71.2)	9,277 (44.0)	[Ref]	4,915 (53.0)	[Ref]
Did not receive	8,530 (28.8)	3,773 (44.2)	1.03 (0.99, 1.07)	2,008 (53.2)	1.02 (0.97, 1.08)
Patient Socioeconomic Characteristics					
Primary health insurance provider					
Medicare	13,776 (40.9)	4,551 (33.0)	0.48 (0.46, 0.50)	2,180 (47.9)	0.69 (0.65, 0.74)
Medicaid	8,335 (24.8)	3,467 (41.6)	0.61 (0.58, 0.64)	1,660 (47.9)	0.68 (0.64, 0.72)
Employer group	5,903 (17.5)	3,433 (58.2)	[Ref]	2,109 (61.4)	[Ref]
Other coverage	2,142 (6.4)	1,065 (49.7)	0.78 (0.73, 0.83)	563 (53.0)	0.80 (0.73, 0.88)
No coverage	3,503 (10.4)	2,221 (63.4)	1.00 (0.94, 1.05)	1,267 (57.1)	0.87 (0.81, 0.93)
Patient Dialysis facility characteristics					
Number of patients per facility by category, n (%)					
Very Small (11-25)	545 (1.6)	235 (43.4)	1.07 (0.94, 1.22)	129 (54.9)	1.16 (0.90, 1.38)
Small (26-54)	6,474 (19.2)	2,864 (44.2)	1.07 (1.02, 1.11)	1,563 (54.6)	1.07 (1.02, 1.14)

Medium (55-78)	8,097 (24.1)	3,669 (45.3)	1.11 (1.07, 1.16)	1,922 (52.4)	1.02 (0.97, 1.08)
Large (>79)	18,546 (55.1)	7,969 (43.0)	[Ref]	4,166 (52.3)	[Ref]

[a] Attributable cause missing for 247 patients (1.7%) who were referred for transplant and 147 patients (1.9%) of patients who initiated evaluation.
[b] Patient BMI missing for 74 patients (0.5%) who were referred for transplant and 34 patients (0.4%) who initiated evaluation.
[c] Information on nephrology care before ESRD diagnosis missing for 1,687 patients (11.5%) who were referred for transplant and 857 patients (11.0%) who initiated evaluation.

Table 3. Cumulative incidence and cumulative incidence differences between dialysis facility profit status and referral for kidney transplantation among incident ESRD patients who initiated dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina between January 1, 2012 and August 31, 2016 followed through August 31, 2017

	Cumulative incidence % (95% CI)[a]			
Referral for transplant	**At 6 months**	**At 1 year**	**At 2 years**	**At 3 years**
Non-profit facility	30.4 (26.8, 34.0)	38.5 (34.5, 42.2)	44.3 (40.3, 48.0)	47.4 (43.2, 51.0)
For-profit facility	25.3 (24.1, 26.4)	33.9 (32.8, 35.0)	40.7 (39.8, 41.6)	43.5 (42.6, 44.3)
Incidence Difference	-5.1 (-9.1, -1.0)	-4.6 (-8.7, -0.1)	-3.6 (-8.0, 1.1)	-3.9 (-8.2, 0.8)
	Number of patients at risk (n, % of row)			
Overall population (n=33,659)	22,531 (66.9)	17,603 (52.3)	9,857 (29.3)	5,574 (16.6)
Non-profit facility (n=5,060)	3,174 (62.7)	2,498 (49.4)	1,408 (27.8)	769 (15.2)
For-profit facility (n=28,599)	19,357 (67.7)	15,105 (52.8)	8,449 (29.5)	5,574 (19.5)

[a] *Calculated using cumulative incidence function and adjusted for competing risk of death (logrank <0.0001). Confidence intervals estimated by bootstrap methods.*

Table 4. Cumulative incidence and cumulative incidence differences between dialysis facility profit status and initiation of evaluation at a transplant center among incident ESRD patients who initiated dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina between January 1, 2012 and August 31, 2016 and who were referred for transplant evaluation between January 1, 2012 and August 31, 2017 followed through February 28, 2018

	Cumulative incidence % (95% CI)[a]		
Initiation of evaluation	**At 6 months**	**At 1 year**	**At 2 years**
Non-profit facility	48.5 (42.4, 54.0)	52.6 (46.4, 57.8)	54.9 (46.4, 57.8)
For-profit facility	47.5 (45.8, 49.0)	51.3 (49.7, 52.7)	52.8 (49.7, 52.7)
Incidence Difference	-1.0 (-7.3, 6.0)	-1.3 (-7.4, 5.7)	-2.1 (-8.1, 4.9)
	Number of patients at risk (n, % of row)		

Referred patients (n=14,737)	7,091(48.1)	5,664 (38.4)	3,066 (20.8)
Non-profit facility (n=2,387)	1,128 (47.3)	887 (37.2)	512 (21.4)
For-profit facility (n=12,350)	5,963 (48.3)	5,664 (45.9)	3,643 (29.5)

Table 5. Crude and adjusted cause-specific hazard ratios between dialysis facility profit status and referral for kidney transplantation during follow-up among incident ESRD patients who initiated dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina[a]

	Unadjusted Model	Adjusted for confounding variables[b]
	HR (95% CI)	HR (95% CI)
Referral for transplant		
Non-profit facility	[Ref]	[Ref]
For-profit facility	0.87 (0.78, 0.97)	0.85 (0.76, 0.95)

[a] Patients who initiated dialysis between January 1, 2012 and August 31, 2016 were followed for referral outcome through August 31, 2017.

[b] Model adjusted for the following variables: age, gender, race/ethnicity, primary cause of ESRD, the presence of certain comorbidities (congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, and cancer), and insurance status.

Table 6. Crude and adjusted cause-specific hazard ratios between dialysis facility profit status and referral for kidney transplantation during follow-up among incident ESRD patients who initiated dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina[a]

	Unadjusted Model	Adjusted for confounding variables[b]
	HR (95% CI)	HR (95% CI)
Referral for transplant		
Non-profit facility	[Ref]	[Ref]
For-profit facility	0.87 (0.78, 0.97)	0.85 (0.76, 0.96)

[a] Patients who initiated dialysis between January 1, 2012 and August 31, 2016 were referred (followed through August 31, 2017) were followed for evaluation outcome through March 1, 2018.

[b] Model adjusted for the following variables: age, gender, race/ethnicity, primary cause of ESRD, the presence of certain comorbidities (congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, and cancer), and insurance status.

Figures.

Figure 1. Transplant Centers in Georgia, North Carolina, and South Carolina

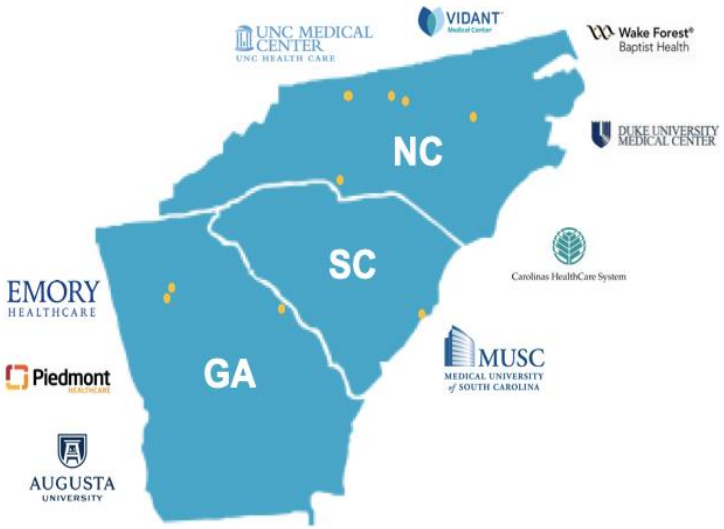


Figure 2. Inclusion and exclusion criteria

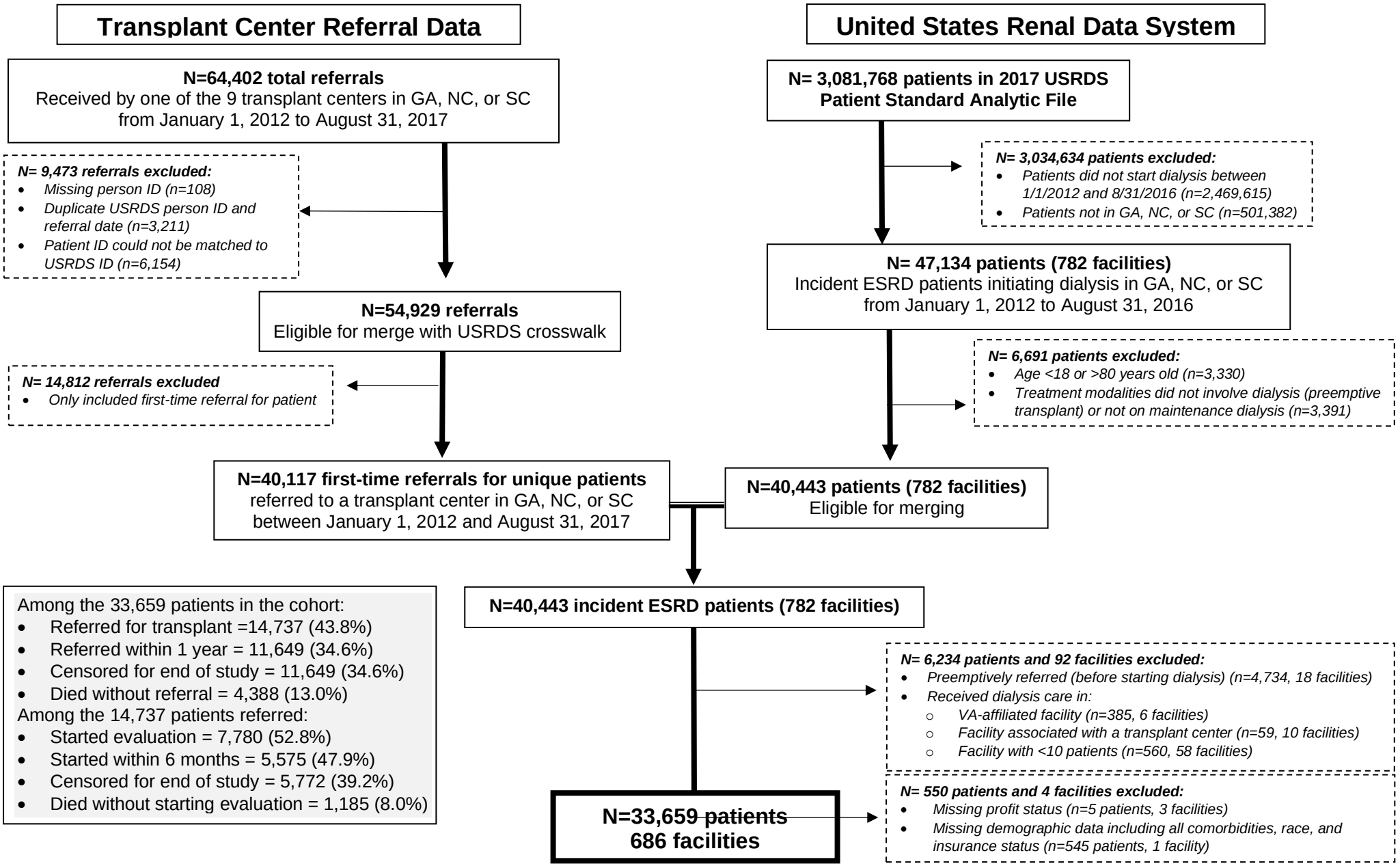


Figure 3. Follow-up timeline for included patients

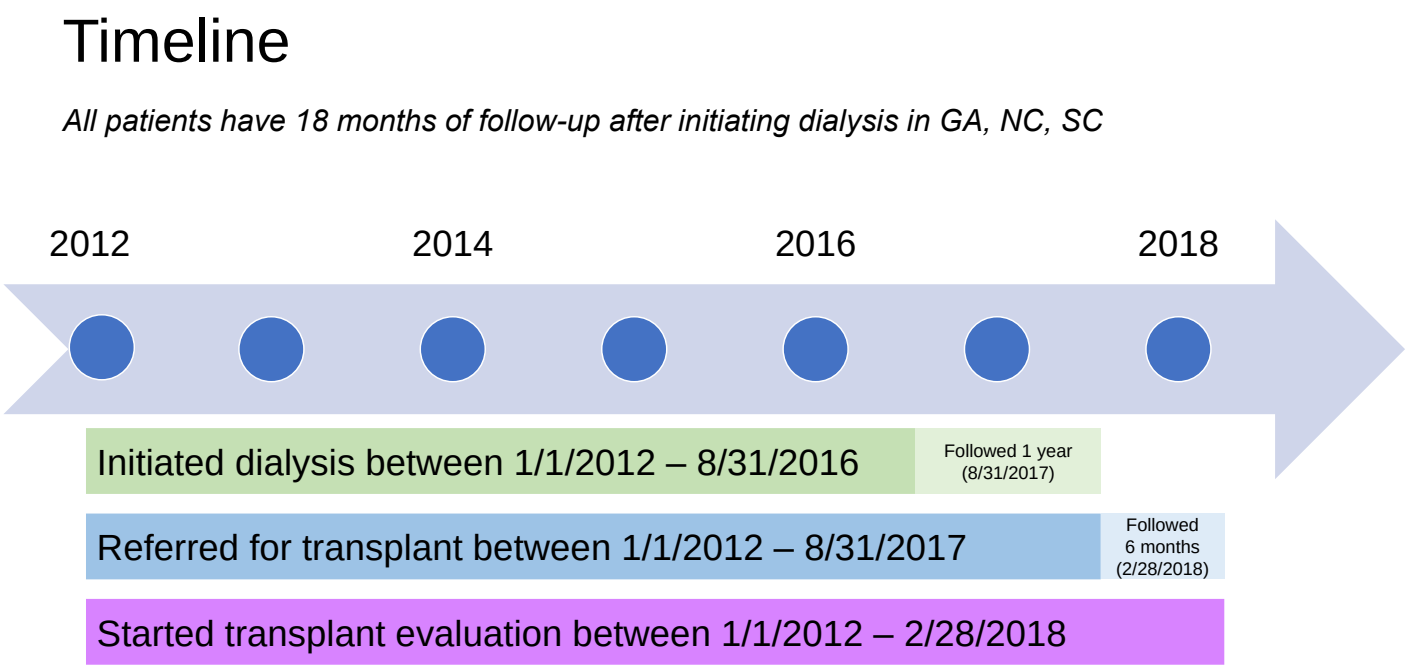
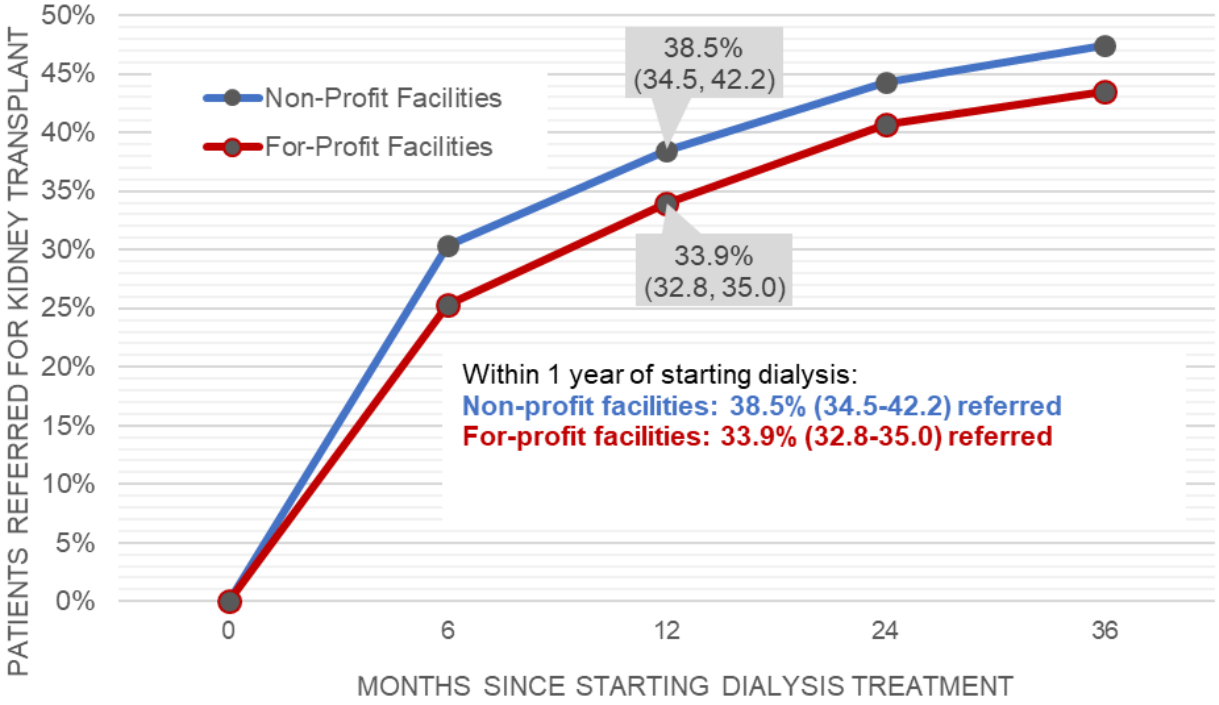
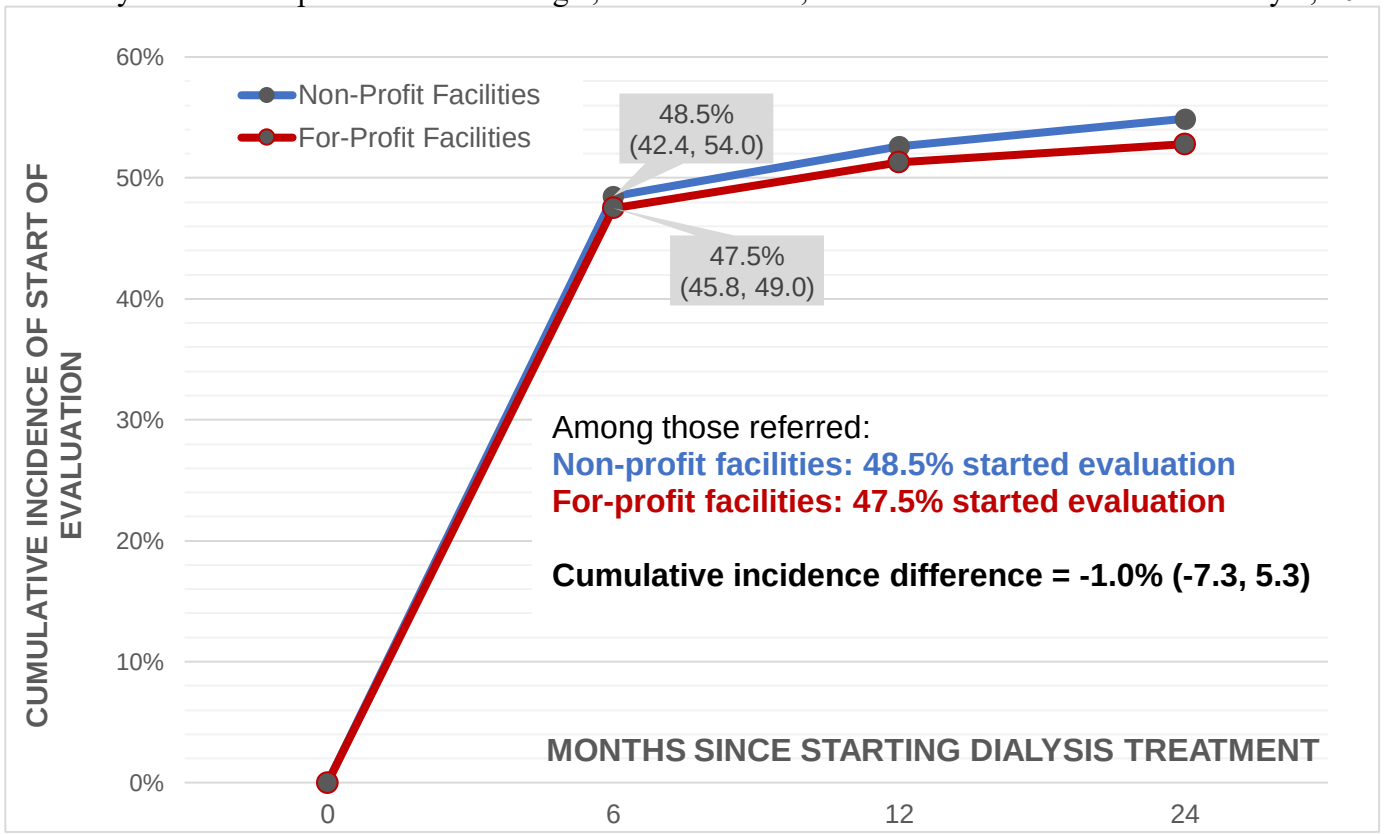


Figure 4. Cumulative incidence of referral for kidney transplantation among all incident ESRD patients initiating dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina between January 1, 2012 and December 31, 2016.



Cumulative incidence difference (95% CI)		**-5.1 (-9.1, -1.0)**	**-4.6 (-8.7, -0.1)**	**-3.6 (-8.0, 1.1)**	**-3.9 (-8.2, 0.8)**
Number at risk (row %)	33,659 (100)	22,531 (66.9)	17,603 (52.3)	9,857 (29.3)	5,574 (16.6)
Non-profit facility	5,060 (100)	3,174 (62.7)	2,498 (49.4)	1,408 (27.8)	769 (15.2)
For-profit facility	28,599 (100)	19,357 (67.7)	15,105 (52.8)	8,449 (29.5)	5,574 (19.5)

Figure 5. Cumulative incidence of starting evaluation at a transplant center among all incident ESRD patients referred within 1 year to a transplant center in Georgia, North Carolina, and South Carolina between January 1, 2012 and March 1, 2018.



Cumulative incidence difference (95% CI)		**-1.0 (-7.3, 5.3)**	-1.3 (-7.2, 5.2)	-2.1 (-8.1, 4.9)
Number at risk (row %)	14,737 (100)	7,091(48.1)	5,664 (38.4)	3,066 (20.8)
Non-profit facility	2,387 (100)	1,128 (47.3)	887 (37.2)	512 (21.4)
For-profit facility	12,350 (100)	5,963 (48.3)	5,664 (45.9)	3,643 (29.5)

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Dialysis Facility Profit Status and Access to Early Steps in Kidney Transplantation in the Southeastern United States

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Dialysis Facility Profit Status and Access to Early Steps in Kidney Transplantation in the Southeastern United States

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An abstract of a thesis submitted to the
Faculty of the James T. Laney School of Graduate Studies of Emory University
in partial fulfillment of the requirements for the degree of
Master of Science in Clinical Research in 2020.

ABSTRACT

Dialysis Facility Profit Status and Access to Early Steps in Kidney Transplantation in the Southeastern United States

By Elizabeth Rebecca Walker, MS

Dialysis facilities in the United States play a key role in end-stage renal disease (ESRD) patient access to kidney transplantation, the optimal treatment for ESRD patients. Patients require a referral from a dialysis facility to begin evaluation at a transplant center. Previous studies reported patients treated at for-profit facilities are less likely to be waitlisted and less likely to receive kidney transplants, but the impact of for-profit status on early steps in the transplant process is unknown as completion of these steps is not documented in national surveillance data. Though the Southeastern United States has the highest burden of ESRD, it is the region with the lowest rate of kidney transplantation. It is critical to understand and address barriers to access to transplantation in this region. This study collected referral data from all nine transplant centers in Georgia, North Carolina, and South Carolina to determine the association between dialysis facility profit status and access to two critical steps early in the transplantation process: referral for transplant and start of evaluation at a transplant center. Cumulative incidence differences and multivariable Cox models were used to examine the association between dialysis facility profit status and completion of each of these two steps. Of the 33,659 incident ESRD patients initiating dialysis from January 1, 2012 to August 31, 2016 in these states, most received dialysis care at a for-profit facility (n=29,599, 85.0%) compared to a non-profit facility (n=5,060, 15.0%). There were significantly more for-profit facilities (n=590, 15.1%) in the region than non-profit facilities (n=105, 84.9%), which is consistent with national trends. For-profit facilities had lower cumulative incidence differences for referral within 1 year of initiation of dialysis compared to non-profit facilities (-4.6% [95% confidence interval (CI): -8.7% to -0.1%]). In both crude and adjusted Cox analyses, for-profit facilities demonstrated lower rates of referral for transplant relative to non-profit facilities (Crude Hazard Ratio (HR) = 0.87 [95%CI: 0.78 to 0.97]; Adjusted HR = 0.85 [95%CI: 0.77 to 0.95]). Start of evaluation at a transplant center did not differ significantly between groups. For ESRD patients living in the Southeast, receiving dialysis at a for-profit facility was associated with a lower likelihood of receiving a referral for kidney transplantation, a key step early in the transplantation process. This study emphasizes the importance of studying earlier steps, prior to waitlisting, to understand and address barriers to transplantation in this population.

Dialysis Facility Profit Status and Access to Early Steps in Kidney Transplantation in the Southeastern United States

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A thesis submitted to the
Faculty of the James T. Laney School of Graduate Studies of Emory University
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INTRODUCTION

End-stage renal disease (ESRD), defined as total and permanent kidney failure, affects more than 700,000 adults in the United States.[1] Kidney transplantation is the optimal treatment for patients with ESRD as it improves patient survival and quality of life compared with dialysis and a reduced total cost of care.[2-4] Despite the demonstrated long-term benefits of transplantation over chronic dialysis, less than 15% of all ESRD patients have completed the necessary steps to be waitlisted for a kidney transplant.[5] To determine why the vast majority of ESRD patients fail to be waitlisted, it is important to understand earlier steps in the kidney transplantation process require investigation.

There are several distinct steps to transplantation that must be navigated by patients and their healthcare providers in order to access a kidney transplant. Prior to waitlisting, ESRD patients must (1) be educated about kidney transplantation, (2) demonstrate interest in kidney transplantation, (3) receive a referral for evaluation at a transplant center, (4) initiate transplant evaluation at a transplant center by attending a first appointment. Only after the evaluation is complete can a patient be considered for transplant eligibility and move on to later steps, (5) waitlisting and (6) transplantation.

Following ESRD diagnosis, the vast majority of incident ESRD patients (nearly 90% between 2010-2016) initiate treatment in a dialysis facility. For these patients, the early steps in transplantation (steps 1-3) occur at the level of a dialysis facility.[6] Following education about transplantation, patients require a referral from their dialysis facility to a transplant center in order to begin evaluation. There are no requirements for dialysis facilities to refer patients for evaluation, but national guidelines from the Organ Procurement and Transplantation Network

(OPTN) recommend referring patients for evaluation, even if a clinician is uncertain of eligibility.[4]

Previous studies have reported that patients treated at for-profit facilities are less likely to be waitlisted for transplant and less likely to receive transplants. However, the impact of for-profit status on early steps in the transplantation process remains unknown.[7,8] This is largely attributable to the fact that national surveillance databases such as the United States Renal Data System (USRDS) and United Network for Organ Sharing (UNOS) do not routinely collect data on early transplant steps such as referral and evaluation. However, In order to design equitable interventions that improve access to transplantation, it is necessary to understand barriers at all steps of the transplant process, including those that occur at the level of the dialysis facility.

Therefore, in this study we examine the association between dialysis facility profit status and rate of referral (from a dialysis facility to a transplant center) and evaluation (at a transplant center). To do this, we will a novel data set of referrals received by all transplant centers in Georgia, South Carolina, and North Carolina. This research can inform ongoing efforts by policy makers, such as the Southeastern Kidney Transplant Coalition, and others to address disparities in access to kidney transplantation in the Southeast, the region with the greatest burden of kidney disease and lowest rates of transplantation in the nation.

BACKGROUND

Dialysis treatment is increasingly provided by for-profit facilities. Between 2000-2016, 88.3% of all incident ESRD patients initiated treatment in a for-profit dialysis facility.[8] The industry continues to undergo massive consolidation with one 2020 economic study estimating large for-profit dialysis chains have made over 1,200 acquisitions of independent dialysis facilities in the last 12 years.[9] As the growth and financial success of large for-profit dialysis providers promotes further consolidation, and the number of incident ESRD patients continue to rise, it is important to assess how profit status impacts ESRD patient care.

Dialysis facilities become coordinating centers for ESRD patients as critical early steps in the kidney transplantation process occur at the level of the dialysis facility. The growth and financial success of for-profit dialysis companies have many concerned that dialysis facility profit status may impact patient access to transplant. Several studies have shown that patients treated in for-profit facilities have reduced access to waitlisting and kidney transplantation.[7,8,10-12] In one of the first studies to examine the impact of facility profit status, a study by Garg et al. in 1999 demonstrated that for-profit ownership of dialysis facilities was associated with reduced access to the deceased donor kidney transplantation waitlist as well as with increased mortality.[11] Expounding upon this research, Zhang et al. examined the role of dialysis facility size, chain affiliation, and ownership on waitlisting of ESRD patients between 2006 and 2009. This study demonstrated that for-profit chain facilities, compared to non-profit chain facilities, were significantly less likely to waitlist patients while facility profit status did not influence waitlisting among non-chain facilities.[12] Since this study, dialysis has increasingly been provided by large-chain organizations.[9]

Expanding upon the research of Garg et al. and Zhang et al., a recent study by Gander et. al. reported receiving dialysis at for-profit facilities compared to non-profit facilities was associated with a lower likelihood of placement on the deceased donor kidney transplantation waitlist and receipt of a deceased donor kidney transplant. The Gander et al. study also found that patients in for-profit facilities were less likely to receive a living donor transplant, suggesting that patients in for-profit facilities may not be fully informed of all of their transplantation options.[8]

Recognizing the important role of the dialysis facility in early steps in the transplantation process, the Centers for Medicare & Medicaid Services (CMS) have instituted a number of requirements for dialysis facilities in attempts to improve access in the last 20 years. In 2005, CMS introduced a requirement that dialysis facilities inform and educate patients about their option for transplant within 45 days of dialysis initiation and document this compliance using Form CMS-2728.[13] CMS reinforced this policy in the 2008 CMS Conditions for Coverage for ESRD Facilities, though the content of this education is not standardized.[14]

Without standardized guidelines, the quality and content of transplant education patients receive can vary significantly between facilities. It was demonstrated by Kucirka et al. in 2012 that, despite the CMS education requirement, almost one-third of patients initiating dialysis reported they were not informed of their options for kidney transplantation and that patients receiving treatment in for-profit dialysis facilities were less likely to be informed of transplant compared to patients treated in non-profit facilities. They also found that educators at for-profit facilities were less likely to engage in “high-quality” transplant educational strategies (such as one-on-one discussions with patients about transplant) than educators at non-profit facilities[10]. In 2015, Waterman et al. reported that patients with access to high-quality, one-on-one discussions

with educators and patients with access to multiple educational platforms at their dialysis facility had increased access to transplant, including higher rates of waitlisting. This study also found that educators at for-profit dialysis centers were less likely to engage in one-on-one discussions about transplant compared to educators at non-profit dialysis facilities.[15]

Results from these investigations support findings from others suggesting that for-profit facilities may be incentivized against educating patients about transplant as an option in order to guarantee consistent revenue streams and better performance ratings.[16] Others have proposed that for-profit dialysis facilities are more likely to commit time and resources toward profit-generating services rather than commit time and resources towards lengthy transplant educational discussions.[17-19] For similar reasons, for-profit facilities may be less likely to refer patients for transplantation, though this has not previously been studied as referral information is not collected in national surveillance data.

Previous investigations of disparities in access to transplantation have been restricted to using waitlisting and transplantation as primary outcomes because national surveillance data does not report information on steps preceding waitlisting. In a study by Patzer et. al. in the state of Georgia, receiving dialysis treatment in a for-profit dialysis facility was associated with reduced access to transplantation at early steps in the transplantation process, specifically reduces access to receiving a referral for transplant evaluation at transplant center in Georgia. This was the largest study investigating disparities in access to referral for transplantation. Importantly, this study found that barriers to access to referral for transplantation differed from barriers to access to waitlisting and transplant. This was the first study to demonstrate the importance of studying referral for transplantation as a separate metric from waitlisting or receipt of a kidney transplant in order to design impactful interventions to improve equitable access for

all incident ESRD patients.[20] Clearly, further investigation is indicated into barriers to access in the steps preceding waitlisting, such as referral for transplantation (occurring at the level of the dialysis facility) and initiation of transplant evaluation at the transplant center.

In addition to its educational requirements for dialysis facilities, CMS has proposed new transplant access measures in its quality incentive program in order to encourage dialysis facilities to increase the proportion prevalent patients waitlisted (PPPW). This metric will be implemented in 2022 and seeks to target dialysis facilities with historically low levels of patients reaching the transplantation waitlist.[21] In order to increase the proportion of prevalent patients waitlisted, however, the proportion of patients referred for transplantation must also be increased. As demonstrated in previous studies, factors impacting earlier steps in kidney transplantation my differ significantly from factors impacting waitlisting and transplantation.[20]

Currently, less than 15% of all ESRD patients complete the necessary steps to be waitlisted for kidney transplant.[5] While it is unknown what proportion of ESRD patients are medically eligible for transplant, it is likely that 15% is too low. Dialysis facility healthcare providers are advised that, if there is any question of eligibility, that patient should be referred for evaluation. Recognizing the significant current discrepancy between referred patients and patients that are likely eligible for transplantation, CMS has set a target goal of 30% of all ESRD patients should be waitlisted for kidney transplantation by 2023.[22] Barriers to access to earlier steps in the transplantation process must be examined in order to understand what is blocking so many from reaching the waitlist.

The Southeastern United States has the highest burden of ESRD in the United States. Unfortunately, it is also the region with the lowest standardized transplantation rates.[23] It is therefore critical to understand barriers to access in this region in order to improve access to

transplantation. Though there exists a scarcity of available organs, profit status of the patient's dialysis facility should not be included in the many barriers to access to transplant.

METHODS

Hypothesis

This investigation hypothesized that dialysis facility profit status would be associated with differences in referral for transplantation and start of evaluation at a transplant center.

Data Sources

Patient-level clinical and demographic data was obtained from the United State Renal Data System (USRDS) database. USRDS data is a publicly available national database managed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) that contains information on nearly all U.S. patients with ESRD (cite). USRDS patient-level clinical and demographic data is collected at the initiation of dialysis using the CMS-2728 form. USRDS data is also linked to the United Network for Organ Sharing (UNOS) database on kidney waitlist and transplant events, but it does not contain information on early transplant steps such as referral.

Dialysis facility-level data was obtained from Dialysis Facility Compare (2016) and Dialysis Facility Report (2013-2016). Both Dialysis Facility Compare (DFC) and Dialysis Facility Report (DFR) data are commissioned by CMS and managed by the University of Michigan Kidney Epidemiology and Cost Center (cite). DFC reports information on dialysis facility profit status and corporate ownership (cite). DFR captures information on facility-level patient characteristics (mean age, percentage of males, race), mortality, treatment patterns, and transplantation rates. Dialysis facility-level data from DFC and DFR was linked to patient-level USRDS data using the dialysis facility's CMS certification number. Neighborhood factors, such as rurality of the facility and ZIP code, was determined using US Census Data and poverty status of a neighborhood was determined from the American Community Survey.

Patient-level referral and start of evaluation data was collected from all transplant centers in Georgia, North Carolina, and South Carolina by the ESRD Network 6 coordinating center. There are nine transplant centers in this service area: Augusta University Medical Center, Carolinas Medical Center, Duke University Hospital, Emory Transplant Center, Medical University of South Carolina, Piedmont Hospital, University of North Carolina, Vidant Medical Center, and Wake Forest Baptist Hospital Medical Center (**Figure 2**). Referral and start of evaluation data was linked to USRDS data by social security number and then de-identified by the ESRD Network 6 coordinating center. This study was approved by the institutional review board at Emory University (IRB00079596).

Study Population

All incident ESRD patients registered within the United States Renal Data System (USRDS) database in Georgia, North Carolina, and South Carolina who initiated dialysis between January 1, 2012 and August 31, 2016 were considered for inclusion (**Figure 2**). Patients were excluded if they were not within 18 years to 80 years of age when initiating dialysis or if they had been waitlisted or transplanted "preemptively" (prior to initiating dialysis) or had multiple referrals. Patients were excluded if they were treated in dialysis facilities within a transplant center, affiliated with a VA medical center, or treated fewer than 10 patients in one year. Referrals were excluded if they lacked a USRDS identifier or if they represented a duplicate referral for a patient, as we only wished to assess unique, first-time referrals for each patient within the cohort. Additionally, 5 patients missing information for the primary exposure (profit status) were excluded from analysis (**Figure 3**).

Outcomes and Study Variables

The primary exposure was dialysis facility profit status. Facility profit status was defined as for-profit or non-profit within the USRDS database. The primary outcome was access to early steps in kidney transplantation, defined as referral for transplant evaluation at a transplant center. Referral to a transplant center was considered complete at the time a referral order is received at a transplant center. Patients were censored for event (date of referral), death, or end of study period (August 31, 2017 for referral). The secondary outcome was initiation of transplant evaluation at a transplant center. Start of the transplant evaluation was considered complete at the time a patient attended a required component of the transplant evaluation (defined as first visit to a transplant center, satellite clinic, or required education class). For the secondary outcome, patients were censored for event, death, or end of study period (March 1, 2018 for evaluation), whichever came first.

Patient-level demographics as well as clinical and socioeconomic characteristics were obtained from USRDS as reported on the CMS-2728 form. Demographics assessed included age at start of dialysis, race/ethnicity, and attributed cause of ESRD (diabetes, hypertension, glomerulonephritis, and other). Clinical characteristics assessed comorbidities (presence of BMI greater than 35kg/m_2, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, tobacco use, and active malignancy) and whether or not a patient received nephrology care prior to ESRD diagnosis.

Socioeconomic factors considered included patient insurance provider (Medicare, Medicaid, employer coverage, other coverage, no coverage) and neighborhood socioeconomic indicators (percentage of residents living below the poverty line, percentage of African American

residents, and high school graduation rates). Dialysis facility-level characteristics including facility size and patient-to-social worker ratio were obtained from DFR.

Missing Data

There were 545 (1.6%) patients with incomplete CMS-2728 forms (missing all information on race/ethnicity, insurance, and comorbidities). As this was a small proportion of the total sample, we chose to conduct a complete case analysis, rather than conduct multiple imputations, which have known shortcomings.[24] These cases represented 1.6% of the final cohort. A secondary analysis was performed with these patients included and it did not impact final results.

Statistical Analysis

Descriptive statistics for patient-level characteristics (demographic factors, clinical characteristics, and socioeconomic factors) and facility-level characteristics were calculated and used to evaluate differences between patients treated in for-profit and non-profit dialysis facilities. The X^2 test was used to compare categorical variables, the Kruskal-Wallis test was used to assess non-parametric continuous variables, and the Wilcoxon rank sum test was used to assess parametric continuous variables between for-profit and non-profit groups.

The cumulative incidence function was used to estimate probability of outcomes as a function of time from the initiation of dialysis, with death considered as a competing risk. Cumulative incidence differences and 95% CIs between for-profit and non-profit groups were determined at follow-up times of 6 months, 1 year, 2 years, and 3 years for referral (and 6 months, 1 year, and 2 years for start of evaluation). Number at risk for each time point was calculated. Bootstrapping (a method of randomly resampling the effect size) was used to perform

10,000 resamples of the event in order to accurately assess 95% confidence intervals (CI) for these cumulative incidence differences.

For the main analysis, time to each event (referral or start of evaluation, censored for end of study period) was calculated using cause-specific hazard ratios and 95% CI, with death treated as a competing risk. End of study period was August 31, 2017 for referral and March 1, 2018 for evaluation (to give each referred patient at least 6 months to start evaluation). Bivariable Cox proportional hazard models were used to determine the crude association between covariates and access to transplantation.

Confounding variables were included in the final adjusted model if they were (1) associated with exposure and with outcome on bivariable analysis or if (2) known clinical associations had been previously reported. Variables associated with exposure and outcome were considered for inclusion using backward selection; if excluding the variable did not significantly change the association between profit status and outcome (by greater than 10%), then the variable was not included in the model. Demographic variables (age, gender, and race/ethnicity) were included because of longstanding associations of these variables with both exposure and outcome (**Table 3**). Both crude and adjusted used robust sandwich variance estimator to account for potential clustering within dialysis facilities. The proportional hazard assumption was tested for both outcomes.

SAS version 9.4 (SAS Institute, Cary, NC) and R (version 3.6.1) were used for cohort development and data management. R was used for statistical analysis. Two-sided p-values were used for all analyses, and $p<0.05$ was considered statistically significant.

RESULTS

Baseline Characteristics

We included 33,659 ESRD patients from Georgia, South Carolina, and North Carolina (**Figure 3**). Among included patients, most received dialysis care at a for-profit facility (n=29,599, 85.0%) compared to a non-profit facility (n=5,060, 15.0%). There were significantly more for-profit facilities (n=590, 15.1%) in the region than non-profit facilities (n=105, 84.9%), which is consistent with trends observed nationally.[8] In the overall population, the mean age was 59.6 years (SD: 13.2 years), the patients were 55.0% male, and 56.0% were of non-Hispanic black race/ethnicity **(Table 1)**.

Patient demographics were similar across for-profit and non-profit facilities; there were no significant differences in age, sex distribution, or race/ethnicity between groups. Compared with patients treated in for-profit facilities, patients treated in non-profit facilities had significantly higher rates of ten of eleven comorbidities assessed. Differences were observed in attributable cause of ESRD, with more disease attributed to hypertension in for-profit facilities compared to non-profit facilities (37.8% vs. 32.6%) and less to diabetes (46.1% vs. 46.5%). There were no differences in proportion of patients receiving nephrology care prior to diagnosis. Patients treated in for-profit facilities were more likely to have have employer-based insurance, Medicare, or Medicaid, while patients in non-profit facilities were more likely to lack coverage. More for-profit facilities treated greater than 55 patients compared to non-profit facilities (**Table 1**).

For all patients, the median follow-up time (to referral, death, or censor) was 12.88 months (IQR 4.14-27.43 months). Median follow-up time was significantly longer for patients treated at for-profit facilities (13.08 months, [IQR 4.30-27.70 months]) compared to patients

treated at non-profit facilities (11.65 months, [IQR 3.45-26.18 months], p<0.001). Among those referred, median time from ESRD diagnosis to referral was 4.44 months (IQR 2.08-10.25 months). This time to referral was longer for patients treated at for-profit facilities (4.57 months [IQR 2.10-10.45 months]) compared to patients treated at non-profit facilities (3.81 months [IQR 2.04-9.13 months], p<0.001). Patients who were referred and started evaluation had a median time to evaluation of 5.36 months (IQR 2.10-23.75 months); this did not differ between groups.

Referral for transplantation evaluation following initiation of dialysis

A total of 14,737 patients (43.8%) were referred for transplant during the study period. There was a lower percentage of patients referred from for-profit dialysis facilities (43.2%, n=12,350) compared to patients referred from non-profit dialysis facilities (47.2%, n=2,387, p<0.001). There were 11,649 patients (34.6%) referred within one year of initiating dialysis. For-profit facilities also had lower percentages of referrals within one year compared to non-profit facilities (33.9% vs 38.5%; p<0.001).

In bivariable Cox hazard models, female patients were less likely to be referred for transplant compared to male patients (HR 0.82, 0.79-0.84). Patients younger than 60 years old and patients of non-white race were more likely to receive a referral. Compared to patients with ESRD attributed to diabetes, patients were more likely to receive a referral with ESRD attributed to glomerulonephritis (HR 0.83, 95%CI: 0.78-0.88) or hypertension (HR 1.08, 95%CI: 1.05-1.12). Patients with comorbidities such as cancer (HR 0.50, 95%CI: 0.46-0.55), COPD (HR 0.51, 95%CI: 0.48-0.55), peripheral vascular disease (HR 0.63, 95%CI: 0.59-0.67), atherosclerotic heart disease (HR 0.63, 95%CI: 0.60-0.67), cerebrovascular disease (HR 0.64, 95%CI: 0.60-0.69), other cardiac disease (HR 0.65, 95%CI: 0.62-0.69), or congestive heart failure (HR 0.71,

95%CI: 0.68-0.74) were less likely to be referred for transplant. Employer-based insurance was also associated with increased probability of referral for transplant (**Table 2**).

In the cumulative incidence analysis, with death treated as a competing risk, patients treated in for-profit facilities had significantly longer time to referral compared to patients treated in non-profit facilities. Patients treated in for-profit facilities had lower cumulative incidence of referral at 6 months and 1 year compared to patients treated in non-profit facilities (cumulative incidence difference -5.1% [95%CI: -9.1%, -1.2%] and -4.6% [95%CI: -8.7%, -0.1%] respectively). Cumulative incidence of referral for both groups, as well as cumulative incidence differences, 95% CI, and number at risk for follow-up times of 6 months, 1 year, 2 years, and 3 years are described in **Table 3**. A cumulative incidence plot illustrates that the reduced incidence of referral among patients treated in for-profit facilities persists over time as number at risk declines for each time point (**Figure 4**).

In bivariable competing-risk regression, female patients were less likely to be referred for transplant compared to male patients (HR: 0.82; 95% CI: 0.79-0.84). Younger patients were more likely to be referred compared to older patients, with likelihood decreasing with age: patients ages 18-29 were the most likely (HR: 2.30; 95% CI: 2.12-2.50), followed by patients ages 30-39 (HR: 2.24; 95% CI: 2.11-2.37), patients ages 40-49 (HR: 1.90; 95% CI: 1.81-1.99), and patients 50-59 (HR: 1.35; 95% CI: 1.29-1.41). Compared to patients ages 60-69, patients older than 70 years of age were very unlikely to receive a referral (HR: 0.40; 95% CI: 0.38-0.43). Compared to white non-Hispanic patients, non-white patients (black, white Hispanic, and patients of "Other" race/ethnicity) were more likely to be referred for transplant. Compared to patients with ESRD attributed to diabetes, patients with ESRD attributed to hypertension and glomerulonephritis were more likely to be referred (HR=1.08; 95%CI: 1.05-1.12 and HR=1.10;

95%CI: 1.03-1.19, respectively) and patients with disease attributed to “other” processes (not diabetes, hypertension, or glomerulonephritis) were less likely to be referred (HR=0.83; 95%CI: 0.78-0.83).

Comorbidities associated with significantly decreased likelihood of referral included congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, chronic obstructive pulmonary disease, smoking, and cancer. Among socioeconomic factors, only patient insurance status was associated with referral for transplant (patient neighborhood factors were not significantly associated with outcomes). Compared to patients insured by an employer, patients were less likely to be referred if they were insured by Medicare (HR=0.48; 95%CI: 0.46-0.50), Medicaid (HR=0.61; 95%CI: 0.58-0.64), or other coverage (HR=0.78; 95%CI: 0.73-0.83). Compared to large facilities (more than 79 patients), facilities with 26-78 patients were more likely to refer patients within one year (**Table 2**).

On unadjusted analysis, patients treated at for-profit facilities were less likely to receive a referral for transplant evaluation compared to patients treated at non-profit facilities (HR: 0.87; 95%CI: 0.78-0.97). The notably wide confidence interval in crude analysis is secondary to the application of the robust sandwich variance estimator, which was used to account for potential clustering within dialysis facilities. In multivariable analysis, after adjusting for confounding factors associated with exposure and outcome (age, gender, race/ethnicity, primary cause of ESRD, the presence of certain comorbidities (congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, and cancer), and insurance status, it was demonstrated that patients treated at a for-profit facility were significantly less likely to receive a

referral compared to patients treated at a non-profit facility (HR: 0.85; 95%CI: 0.76-0.95) as outlined in **Table 5**.

Profit status and evaluation at a transplant center

Among patients referred for evaluation at a transplant center (n=14,737), a total of 7,780 patients initiated evaluation at a transplant center (52.8% of referred patients). Of these, only 37.8% started evaluation within six months of the referral (n=5,575). Of the 12,350 patients referred for transplant from for-profit facilities, 52.5% started transplant evaluation compared to 54.6% of the 2,387 patients referred from non-profit facilities.

Patients receiving dialysis in for-profit facilities had lower 6-month cumulative incidence compared to patients receiving treatment in non-profit facilities (cumulative incidence difference -1.0%, 95% CI: -7.3% to 5.3%) though results do not reach significance. Trends remained consistent on 1-year cumulative incidence analysis (cumulative incidence difference -1.3%, 95% CI: -7.4% to 5.7%) as well as 2- and 3-year cumulative incidence analysis. Cumulative incidences for both groups, as well as cumulative incidence differences, 95% CI, and number at risk for follow-up times of 6 months, 1 year, and 2 years are described in **Table 6**. A cumulative incidence plot illustrates that the reduced incidence of referral among patients treated in for-profit facilities persists over time (**Figure 5**).

Bivariable competing-risk regression demonstrated that male patients younger than 60 years old were more likely to initiate evaluation. Though black patients were more likely to be referred for transplant than non-Hispanic white patients, this was not observed in evaluation analysis. Following referral, Hispanic white patients and patients of “other” race/ethnicity were more likely to initiate evaluation compared to non-Hispanic white patients (HR: 1.43; 95%CI: 1.26-1.63 and HR: 1.32; 95%CI: 1.14-1.53, respectively). Compared to patients with ESRD

attributed to diabetes, patients with ESRD attributed to glomerulonephritis, hypertension, and "other" causes were more likely to initiate evaluation. Among patients who were already referred, the presence of all comorbidities except for hypertension and cancer were associated with significantly decreased likelihood of starting evaluation at a transplant center. Among socioeconomic and facility-level factors, only insurance status was associated with initiation of evaluation following referral: patients with employer-based insurance plans were more likely to initiate evaluation than all other types of insurance plans (**Table 2**).

Crude and adjusted associations between dialysis facility profit status and initiation of evaluation following referral differed. On unadjusted analysis, results did not differ significantly between for-profit and non-profit groups (HR: 0.95; 95%CI: 0.90-1.01). On multivariable analysis after adjusting for demographics known to be associated with the outcome (age, gender, race/ethnicity) and confounding factors associated with exposure and outcome (primary cause of ESRD, the presence of certain comorbidities (a BMI greater than or equal to 35kg/m_2, congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, diabetes, chronic obstructive pulmonary disease, smoking, and cancer), insurance status, and size of the facility, it was demonstrated that patients treated at a for-profit facility and patients treated in a non-profit facility did not differ significantly in their likelihood to initiate evaluation at a transplant center once referred (HR: 0.93; 95%CI: 0.83-1.04) as outlined in **Table 6.**

Analysis of patients censored for death

Among the 33,659 patients in the final cohort, there were 18,922 patients (56.2%) who were not referred for transplant evaluation within one year of initiating dialysis. Of these, 9,449 patients (50.0%) died within one year of initiating dialysis prior to receiving a referral for

transplant. These patients were censored for death in the primary analysis, but the cohort was also examined for differences between for-profit and non-profit groups. Of the 5,060 patients treated in a non-profit facility, 1,347 patients (26.6%) died within one year of initiating dialysis without receiving a referral. Of the 28,599 patients treated in a for-profit facility, 8,102 patients (28.3%) died within one year of initiating dialysis without receiving a referral. Compared to patients treated in non-profit facilities, patients treated in for-profit facilities were not significantly more likely to die within one year of initiating dialysis (HR: 0.99; 95%CI: 0.94-1.05) on bivariable analysis.

DISCUSSION

Among adult ESRD patients treated in dialysis facilities within Georgia, North Carolina, and South Carolina (ESRD Network 6), patients treated in for-profit dialysis facilities were 13% less likely to receive a referral for transplant within one year of initiating dialysis compared to patients treated in non-profit dialysis facilities (HR: 0.87; 95%CI: 0.78-0.97). Additionally, patients receiving dialysis at for-profit facilities versus patients receiving dialysis at non-profit facilities had significantly lower cumulative incidence of referral at 6-months (cumulative incidence difference: -5.1; 95%CI: -9.1 to -1.0) and at one year (cumulative incidence difference: -4.6; 95%CI: -8.7 to -0.1). This study is the first to examine the relationship between dialysis facility profit status and early steps in the transplantation process (referral and start of evaluation at a transplant center) in a large population, expanding upon the previous work of Patzer et al. in the state of Georgia.[20]

In order to better understand why for-profit dialysis facilities refer fewer patients compared to non-profit facilities, further research is needed. It has been suggested that for-profit facilities' financial incentives may differ from patient-centered care incentives.[10,11,25] Compared to non-profit facilities, for-profit facilities may experience pressure to generate revenue and thus may be incentivized against referring patients in order to maintain higher treatment numbers and consistent revenue streams.[16] Additionally, as healthier patients tend to have fewer complications, a key metric in the performance rating for a dialysis facility, for-profit facilities may be incentivized to keep these patients in their treatment centers.[19] Further research is required to better understand this association. As the for-profit dialysis sector continues to grow, it is pertinent to continue and expand upon research into the differences in access to transplantation between for- and non-profit dialysis facilities.

Despite the clear survival and cost benefits of transplantation over dialysis, our findings demonstrate that less than half of all patients (43.8% of all patients; 47.2% of patients treated in non-profit facilities and 43.2% of patients treated in for-profit facilities) were referred for transplant evaluation overall. Though it is difficult to assess who should be referred for transplant evaluation, these rates of referral are likely too low. As CMS has targeted a goal to increase the number of waitlisted ESRD patients to 30% by 2023, increasing rates of referral become more important.[22]

Though it is difficult to determine which patients should be referred for transplant evaluation, our study demonstrates that for-profit dialysis facilities should be referring more patients. Patients treated in for-profit facilities were less likely to have 10 of the 11 comorbidities assessed at initiation of dialysis and more likely to have employer-based insurance. Despite the presence of these factors associated with increased waitlisting and transplantation, patients treated at a for-profit facility were less likely to receive a referral within one year of initiating dialysis compared to patients treated in a non-profit facility and had lower cumulative incidences of referral at both 6-month and one year.

Once referred, our study did not find significant differences between for- and non-profit facilities in rates of patients initiating evaluation at a transplant center. However, it is notable that only about half of referred patients initiated evaluation at a transplant center (52.8% of all patients; 54.6% of patients treated in non-profit facilities and 52.5% of patients treated in for-profit facilities). As CMS introduces policies in the 2020 ESRD Quality Incentive Program, such as the PPPW to increase waitlisting, it will become increasingly important to understand why approximately half of referred patients do not start the transplant evaluation.

Our findings suggest that targeted interventions encouraging dialysis centers, particularly for-profit facilities, to increase referral may lead to improved access to transplantation. A recent study by McPherson et al. reported substantial variation in referral practices in Georgia, North Carolina, and South Carolina, with referral rates ranging from 0% to 100%.[8] This strikingly wide variation in referral practices, coupled with our findings of lower referral numbers at for-profit facilities, further indicates a need for consistent and enforced guidelines on referral. The new CMS PPPW proposal seeks to encourage dialysis facilities to increase the proportion of prevalent patients waitlisted. While this metric may lead to increased referral rates in facilities with extremely low or 0% rates, our research suggests that it may be more impactful to target earlier steps in transplantation, such as referral for transplant.[21]

This study also found that different factors were associated with referral for transplant than waitlisting and transplantation. For example, black patients were more likely to be referred for transplant than white patients, but were less likely to initiate evaluation at a transplant center. This is notable as many prior studies have demonstrated lower rates of waitlisting and transplantation for black patients compared to white patients.[26] The different factors associated with referral compared to waitlisting and transplantation further suggest the need to collect data and study earlier steps in transplantation on a national level.

Limitations

This study has several limitations. First, given the nature of the data, this study was limited to the Southeastern states of Georgia, North Carolina, and South Carolina (ESRD Network 6) and could not assess patterns on a national scale. This region has both the highest burden of disease and lowest rates of kidney transplantation in the United States. As this data is not collected nationally, we can only capture referrals to transplant centers in these states.

Although it is likely not a common occurrence, if a patient treated in Georgia, North Carolina, or South Carolina was referred for evaluation to a transplant center in a different state (such as Tennessee), this would not be reflected in the data. For these reasons, generalizability to other areas may not be possible. Our findings demonstrate the need for national surveillance data to be collected on early transplant steps (prior to waitlisting) in order to better understand and address barriers to access to transplantation.

This study is limited to patients with ESRD who require dialysis treatment and are likely in later stages of disease. Patients with earlier stages of the disease (not requiring dialysis) were not included, so selection bias for late-stage ESRD patients must be considered. Confounding variables, such as comorbidities and insurance status, are assessed using the CMS-2728 form, which is completed at the initiation of dialysis. If these factors change over time, there may be unmeasured confounding that we cannot account for due to the nature of the data collection.

Finally, transplant centers differ in their criteria for transplant eligibility (such as cutoff age or specific comorbidity). Although the majority of the criteria are similar across centers, they are not identical and these criteria may impact the dialysis facility choice to refer. As the data-sharing agreement blinds this study from transplant center identifiers, differences in criteria of individual transplant centers cannot be assessed.

CONCLUSION

Among US patients with ESRD in the Southeastern United States, receiving dialysis in for profit facilities was associated with lower access to referral for kidney transplantation. This study emphasizes the importance of studying earlier steps, prior to waitlisting, to understand and address barriers to transplantation in this population. Further research is needed to understand the mechanisms behind this association and to determine potential health system incentives that may be applied to reduce this disparity.

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Tables and Figures

Table 1. Characteristics of patients with incident ESRD initiating dialysis between January 1, 2012 and August 31, 2016 in Georgia, North Carolina, and South Carolina followed through February 28, 2018; overall and stratified by dialysis facility profit status

Population Characteristics	Overall population	Patients initiating dialysis at a for-profit facility	Patients initiating dialysis at a non-profit facility	p-value
Facilities, n (%)	686 (100)	582 (84.8)	104 (15.2)	**<.001**
Total patients, n (%)	33,659 (100)	28,599 (85.0)	5,060 (15.0)	**<.001**
Patient Demographics				
Age in years, mean (SD);	59.6 (13.2)	59.6 (13.2)	59.4 (13.3)	0.215
Age category, n (%)				
18-29	916 (2.7)	771 (2.7)	145 (2.9)	
30-39	2,014 (6.0)	1,702 (6.0)	312 (6.2)	
40-49	4,325 (12.8)	3,667 (12.8)	658 (13.0)	0.685
50-59	7,547 (22.4)	6,409 (22.4)	1,138 (22.5)	
60-69	10,121 (30.1)	8,581 (30.0)	1,540 (30.4)	
≥70	8,736 (26.0)	7,469 (26,1)	1,267 (25.0)	
Sex, n (%)				
Male	18,504 (55.0)	15,709 (54.9)	2,795 (55.2)	0.695
Female	15,155 (45.0)	12,890 (45.1)	2,265 (44.8)	
Race/ethnicity, n (%)				
White, non-Hispanic	13,453 (40.0)	11,460 (40.1)	1,993 (39.4)	
Black, non-Hispanic	18,859 (56.0)	15,996 (55.9)	2,863 (56.6)	0.789
White, Hispanic	713 (2.1)	602 (2.1)	111 (2.2)	
Other race/ethnicity	634 (1.9)	541 (1.9)	93 (1.8)	
Patient Clinical Characteristics				
Attributed cause of ESRD, n (%)[a]				
Diabetes	15,351 (46.5)	13,030 (46.5)	2,321 (46.7)	
Hypertension	12,219 (37.0)	10,594 (37.8)	1,625 (32.7)	<0.001
Glomerulonephritis	2,225 (6.7)	1,811 (6.5)	414 (8.3)	
Other	3,218 (9.8)	2,613 (9.3)	605 (12.2)	
Comorbidities, n (%)[b]				
BMI ≥ 35 kg/m2	8,519 (25.5)	7,255 (25.6)	1,264 (25.1)	0.464
Congestive heart failure	9,406 (27.9)	7,831 (27.4)	1,575 (31.1)	<0.001
Atherosclerotic heart disease	3,347 (9.9)	2,782 (9.7)	565 (11.2)	0.002
Other cardiac disease	5,894 (17.5)	4,937 (17.3)	957 (18.9)	0.005
Cerebrovascular disease (stroke)	3,156 (9.4)	2,590 (9.1)	566 (11.2)	<0.001
Peripheral vascular disease	3,007 (8.9)	2,456 (8.6)	551 (10.9)	<0.001
Hypertension	30,084 (89.4)	25,453 (84.6)	4,631 (15.4)	<0.001
Diabetes	20,324 (60.4)	17,195 (60.1)	3,129 (61.8)	0.023
Chronic Obstructive Pulmonary Disease	3,097 (9.2)	2,538 (8.9)	559 (11.0)	<0.001
Tobacco use	3,120 (9.3)	2,467 (8.6)	653 (12.9)	<0.001
Cancer	2,081 (6.2)	1,698 (5.9)	383 (7.6)	<0.001

Pre-ESRD nephrology care, n (%)[c]				
Received	21,095 (71.2)	17,909 (71.2)	3,186 (71.3)	0.907
Did not receive	8,530 (28.8)	7,247 (28.8)	1,283 (28.7)	
Patient Socioeconomic Characteristics				
Primary health insurance provider, n (%)				
Medicare	13,776 (40.9)	2,134 (42.2)	11,642 (40.7)	
Medicaid	8,335 (24.8)	7,141 (25.0)	1,194 (23.6)	<0.001
Employer group	5,903 (17.5)	5,144 (18.0)	759 (15.0)	
Other coverage	2,142 (6.4)	1,794 (6.3)	348 (6.9)	
No coverage	3,503 (10.4)	2,878 (10.1)	625 (12.4)	
Patient neighborhood (zip code) factors				
Number of patients living in a zip code where ≥20% of residents live below the poverty line, n(%)	10.585 (31.4)	8,996 (31.5)	1,589 (31.4)	0.954
% African American population in patient zip code, mean (SD)[d]	34.8 (23.7)	34.9 (23.2)	34.5 (26.7)	0.100
% High school graduates in patient zip code, mean (SD)[e]	82.8 (7.2)	82.9 (7.2)	82.2 (7.4)	0.210
Patient Dialysis Facility Characteristics				
Number of patients per facility, mean (SD)	85.0 (49.4)	83.9 (45.0)	91.2 (68.9)	0.232
Number of patients per facility by category, n (%)				
Very Small (11-25)	545 (1.6)	465 (1.6)	77 (1.5)	
Small (26-54)	6,474 (19.2)	5,116 (17.9)	1,358 (26.8)	<0.001
Medium (55-78)	8,097 (24.1)	7,210 (25.2)	8,097 (24.1)	
Large (>79)	18,546 (55.1)	15,808 (55.3)	2,738 (54.1)	
Number of social workers per facility, mean (SD);	0.9 (0.7)	0.9 (0.7)	0.9 (0.6)	0.943
Ratio of patients to social workers per facility, mean (SD)[f]	96.9 (40.1)	97.1 (39.5)	95.1 (43.4)	<0.001

Abbreviations: BMI: Body Mass Index; CI: Confidence Interval; SD: Standard Deviation

[a] Attributable cause information missing for 646 patients (1.9%)

[b] Patient BMI information missing for 243 patients (0.7%); removed patients missing all comorbidities.

[c] Information on patients who received nephrology before ESRD diagnosis missing for 4,064 patients (11.9%).

[d] Average percentage of African Americans in zip code of patient neighborhood was missing for 455 patients (1.4%).

[e] Average percentage of high school graduates in zip code of patient neighborhood was missing for 461 patients (1.4%).

[f] Number of patients for every 1 social worker. Calculated only for patients (n=31,127) that had at least 1 social worker at their home facility and not for patients with 0 social workers at their home facility (n=2,532).

Table 2. Characteristics and bivariable cause-specific hazard ratios of patients with incident ESRD who initiated dialysis between January 1, 2012 and August 31, 2016 in Georgia, North Carolina, and South Carolina who were referred for transplant and who initiated evaluation at a transplant center during follow-up (to August 31, 2017 for referral, to March 1, 2018 for evaluation).

Characteristics	**Overall population**	**Referred for evaluation at a transplant center (n, % of total)**		**Initiated evaluation at a transplant center following referral (n, % of those referred)**	
Patients, n (%)	**33,659 (100)**	**14,737 (43.8)**		**7,780 (52.8)**	
	n (% of total)	**n (row %)**	**HR[b] (95% CI)**	**n (row %)**	**HR[b] (95% CI)**
Dialysis Facility Profit Status					
Patients treated in non-profit facilities	5,060 (15.0)	2,387 (47.2)	[Ref]	1,302 (54.6)	[Ref]
Patients treated in for-profit facilities	28,599 (85.0)	12,350 (43.2)	**0.87 (0.78, 0.97)**	6,478 (52.5)	**0.95 (0.85, 1.07)**
Patient Demographics					
Age category					
18-29	916 (2.7)	677 (73.9)	2.30 (2.12, 2.50)	438 (64.7)	1.47 (1.33, 1.63)
30-39	2,014 (6.0)	1,466 (72.8)	2.24 (2.11, 2.37)	884 (60.3)	1.30 (1.20, 1.41)
40-49	4,325 (12.9)	2,864 (66.2)	1.90 (1.81, 1.99)	1,604 (56.0)	1.14 (1.07, 1.22)
50-59	7,547 (22.4)	3,970 (52.6)	1.35 (1.29, 1.41)	2,139 (53.9)	1.09 (1.03, 1.16)
60-69	10,121 (30.1)	4,153 (41.0)	[Ref]	2,098 (50.5)	[Ref]
≥70	8,736 (26.0)	1,607 (18.4)	0.40 (0.38, 0.43)	617 (38.4)	0.70 (0.64, 0.77)
Sex					
Male	18,504 (55.0)	8,637 (46.7)	[Ref]	4,628 (53.6)	[Ref]
Female	15,155 (45.0)	6,100 (40.3)	0.82 (0.79, 0.84)	3,152 (51.7)	0.94 (0.90, 0.98)
Race/ethnicity					
White, non-Hispanic	13,453 (40.0)	4,677 (34.8)	[Ref]	2,422 (51.8)	[Ref]
Black, non-Hispanic	18,859 (56.0)	9,343 (49.5)	1.46 (1.41, 1.51)	4,905 (52.5)	0.98 (0.93, 1.03)
White, Hispanic	713 (2.1)	391 (54.8)	1.61 (1.45, 1.78)	252 (64.5)	1.43 (1.26, 1.63)
Other race/Ethnicity	634 (1.9)	326 (51.4)	1.55 (1.39, 1.74)	201 (61.7)	1.32 (1.14, 1.53)
Patient Clinical Characteristics					
Attributed cause of ESRD [a]					
Diabetes	15,351 (46.5)	6,515 (42.4)	[Ref]	3,297 (50.6)	[Ref]
Hypertension	12,219 (37.0)	5,566 (45.6)	1.08 (1.05, 1.12)	2,927 (52.6)	1.07 (1.01, 1.12)
Glomerulonephritis	2,225 (6.7)	1,284 (57.7)	1.50	782 (60.9)	1.29

			(1.41, 1.60)		(1.20, 1.40)
Other	3,218 (9.8)	1,125 (35.0)	0.83 (0.78, 0.88)	627 (55.7)	1.20 (1.10, 1.31)
Comorbidities [b]					
BMI ≥ 35 kg/m2	8,519 (25.5)	3,894 (45.7)	1.05 (1.01, 1.09)	1,900 (48.8)	0.85 (0.81, 0.89)
Congestive heart failure	9,406 (27.9)	3,290 (35.0)	0.71 (0.68, 0.74)	1,529 (46.5)	0.80 (0.76, 0.85)
Atherosclerotic heart disease	3,347 (9.9)	1,035 (30.9)	0.63 (0.60, 0.67)	466 (45.0)	0.78 (0.71, 0.86)
Other cardiac disease	5,894 (17.5)	1,882 (31.9)	0.65 (0.62, 0.69)	881 (46.8)	0.83 (0.77, 0.89)
Cerebrovascular disease (stroke)	3,156 (9.4)	986 (31.2)	0.64 (0.60, 0.69)	442 (44.8)	0.77 (0.70, 0.85)
Peripheral vascular disease	3,007 (8.9)	903 (30.0)	0.63 (0.59, 0.67)	377 (41.8)	0.70 (0.63, 0.78)
Hypertension	30,084 (89.4)	13,353 (44.4)	1.13 (1.07, 1.19)	7,049 (52.8)	0.98 (0.91, 1.06)
Diabetes	20,324 (60.4)	8,515 (41.9)	0.87 (0.84, 0.89)	4,353 (51.1)	0.89 (0.85, 0.93)
Chronic Obstructive Pulmonary Disease	3,097 (9.2)	787 (25.4)	0.51 (0.48, 0.55)	297 (37.7)	0.63 (0.56, 0.71)
Tobacco use	3,120 (9.3)	1,309 (42.0)	0.93 (0.88, 0.99)	600 (45.8)	0.78 (0.72, 0.85)
Cancer	2,081 (6.2)	505 (24.3)	0.50 (0.46, 0.55)	251 (49.7)	0.93 (0.82, 1.06)
Pre-ESRD nephrology care [c]					
Received	21,095 (71.2)	9,277 (44.0)	[Ref]	4,915 (53.0)	[Ref]
Did not receive	8,530 (28.8)	3,773 (44.2)	1.03 (0.99, 1.07)	2,008 (53.2)	1.02 (0.97, 1.08)
Patient Socioeconomic Characteristics					
Primary health insurance provider					
Medicare	13,776 (40.9)	4,551 (33.0)	0.48 (0.46, 0.50)	2,180 (47.9)	0.69 (0.65, 0.74)
Medicaid	8,335 (24.8)	3,467 (41.6)	0.61 (0.58, 0.64)	1,660 (47.9)	0.68 (0.64, 0.72)
Employer group	5,903 (17.5)	3,433 (58.2)	[Ref]	2,109 (61.4)	[Ref]
Other coverage	2,142 (6.4)	1,065 (49.7)	0.78 (0.73, 0.83)	563 (53.0)	0.80 (0.73, 0.88)
No coverage	3,503 (10.4)	2,221 (63.4)	1.00 (0.94, 1.05)	1,267 (57.1)	0.87 (0.81, 0.93)
Patient Dialysis facility characteristics					
Number of patients per facility by category, n (%)					
Very Small (11-25)	545 (1.6)	235 (43.4)	1.07 (0.94, 1.22)	129 (54.9)	1.16 (0.90, 1.38)
Small (26-54)	6,474 (19.2)	2,864 (44.2)	1.07 (1.02, 1.11)	1,563 (54.6)	1.07 (1.02, 1.14)

Medium (55-78)	8,097 (24.1)	3,669 (45.3)	1.11 (1.07, 1.16)	1,922 (52.4)	1.02 (0.97, 1.08)
Large (>79)	18,546 (55.1)	7,969 (43.0)	[Ref]	4,166 (52.3)	[Ref]

[a] Attributable cause missing for 247 patients (1.7%) who were referred for transplant and 147 patients (1.9%) of patients who initiated evaluation.
[b] Patient BMI missing for 74 patients (0.5%) who were referred for transplant and 34 patients (0.4%) who initiated evaluation.
[c] Information on nephrology care before ESRD diagnosis missing for 1,687 patients (11.5%) who were referred for transplant and 857 patients (11.0%) who initiated evaluation.

Table 3. Cumulative incidence and cumulative incidence differences between dialysis facility profit status and referral for kidney transplantation among incident ESRD patients who initiated dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina between January 1, 2012 and August 31, 2016 followed through August 31, 2017

	Cumulative incidence % (95% CI)[a]			
Referral for transplant	**At 6 months**	**At 1 year**	**At 2 years**	**At 3 years**
Non-profit facility	30.4 (26.8, 34.0)	38.5 (34.5, 42.2)	44.3 (40.3, 48.0)	47.4 (43.2, 51.0)
For-profit facility	25.3 (24.1, 26.4)	33.9 (32.8, 35.0)	40.7 (39.8, 41.6)	43.5 (42.6, 44.3)
Incidence Difference	-5.1 (-9.1, -1.0)	-4.6 (-8.7, -0.1)	-3.6 (-8.0, 1.1)	-3.9 (-8.2, 0.8)
	Number of patients at risk (n, % of row)			
Overall population (n=33,659)	22,531 (66.9)	17,603 (52.3)	9,857 (29.3)	5,574 (16.6)
Non-profit facility (n=5,060)	3,174 (62.7)	2,498 (49.4)	1,408 (27.8)	769 (15.2)
For-profit facility (n=28,599)	19,357 (67.7)	15,105 (52.8)	8,449 (29.5)	5,574 (19.5)

[a] *Calculated using cumulative incidence function and adjusted for competing risk of death (logrank <0.0001). Confidence intervals estimated by bootstrap methods.*

Table 4. Cumulative incidence and cumulative incidence differences between dialysis facility profit status and initiation of evaluation at a transplant center among incident ESRD patients who initiated dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina between January 1, 2012 and August 31, 2016 and who were referred for transplant evaluation between January 1, 2012 and August 31, 2017 followed through February 28, 2018

	Cumulative incidence % (95% CI)[a]		
Initiation of evaluation	**At 6 months**	**At 1 year**	**At 2 years**
Non-profit facility	48.5 (42.4, 54.0)	52.6 (46.4, 57.8)	54.9 (46.4, 57.8)
For-profit facility	47.5 (45.8, 49.0)	51.3 (49.7, 52.7)	52.8 (49.7, 52.7)
Incidence Difference	-1.0 (-7.3, 6.0)	-1.3 (-7.4, 5.7)	-2.1 (-8.1, 4.9)
	Number of patients at risk (n, % of row)		

Referred patients (n=14,737)	7,091(48.1)	5,664 (38.4)	3,066 (20.8)
Non-profit facility (n=2,387)	1,128 (47.3)	887 (37.2)	512 (21.4)
For-profit facility (n=12,350)	5,963 (48.3)	5,664 (45.9)	3,643 (29.5)

Table 5. Crude and adjusted cause-specific hazard ratios between dialysis facility profit status and referral for kidney transplantation during follow-up among incident ESRD patients who initiated dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina[a]

	Unadjusted Model	Adjusted for confounding variables[b]
	HR (95% CI)	HR (95% CI)
Referral for transplant		
Non-profit facility	[Ref]	[Ref]
For-profit facility	0.87 (0.78, 0.97)	0.85 (0.76, 0.95)

[a] Patients who initiated dialysis between January 1, 2012 and August 31, 2016 were followed for referral outcome through August 31, 2017.

[b] Model adjusted for the following variables: age, gender, race/ethnicity, primary cause of ESRD, the presence of certain comorbidities (congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, and cancer), and insurance status.

Table 6. Crude and adjusted cause-specific hazard ratios between dialysis facility profit status and referral for kidney transplantation during follow-up among incident ESRD patients who initiated dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina[a]

	Unadjusted Model	Adjusted for confounding variables[b]
	HR (95% CI)	HR (95% CI)
Referral for transplant		
Non-profit facility	[Ref]	[Ref]
For-profit facility	0.87 (0.78, 0.97)	0.85 (0.76, 0.96)

[a] Patients who initiated dialysis between January 1, 2012 and August 31, 2016 were referred (followed through August 31, 2017) were followed for evaluation outcome through March 1, 2018.

[b] Model adjusted for the following variables: age, gender, race/ethnicity, primary cause of ESRD, the presence of certain comorbidities (congestive heart failure, atherosclerotic heart disease, other cardiac disease, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, and cancer), and insurance status.

Figures.

Figure 1. Transplant Centers in Georgia, North Carolina, and South Carolina

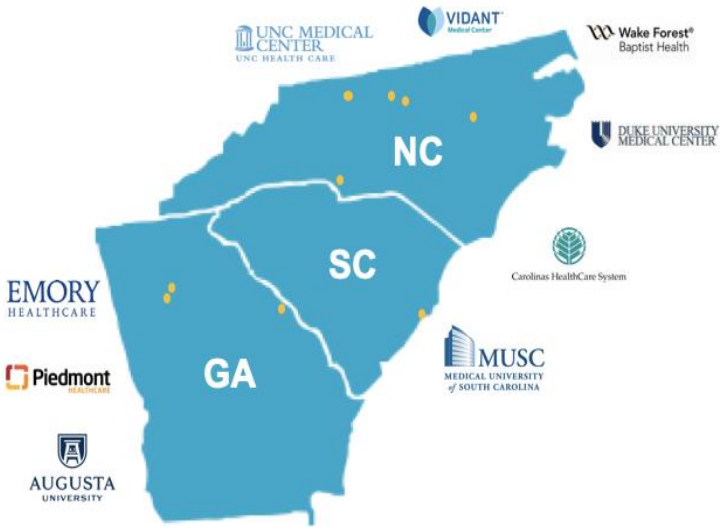


Figure 2. Inclusion and exclusion criteria

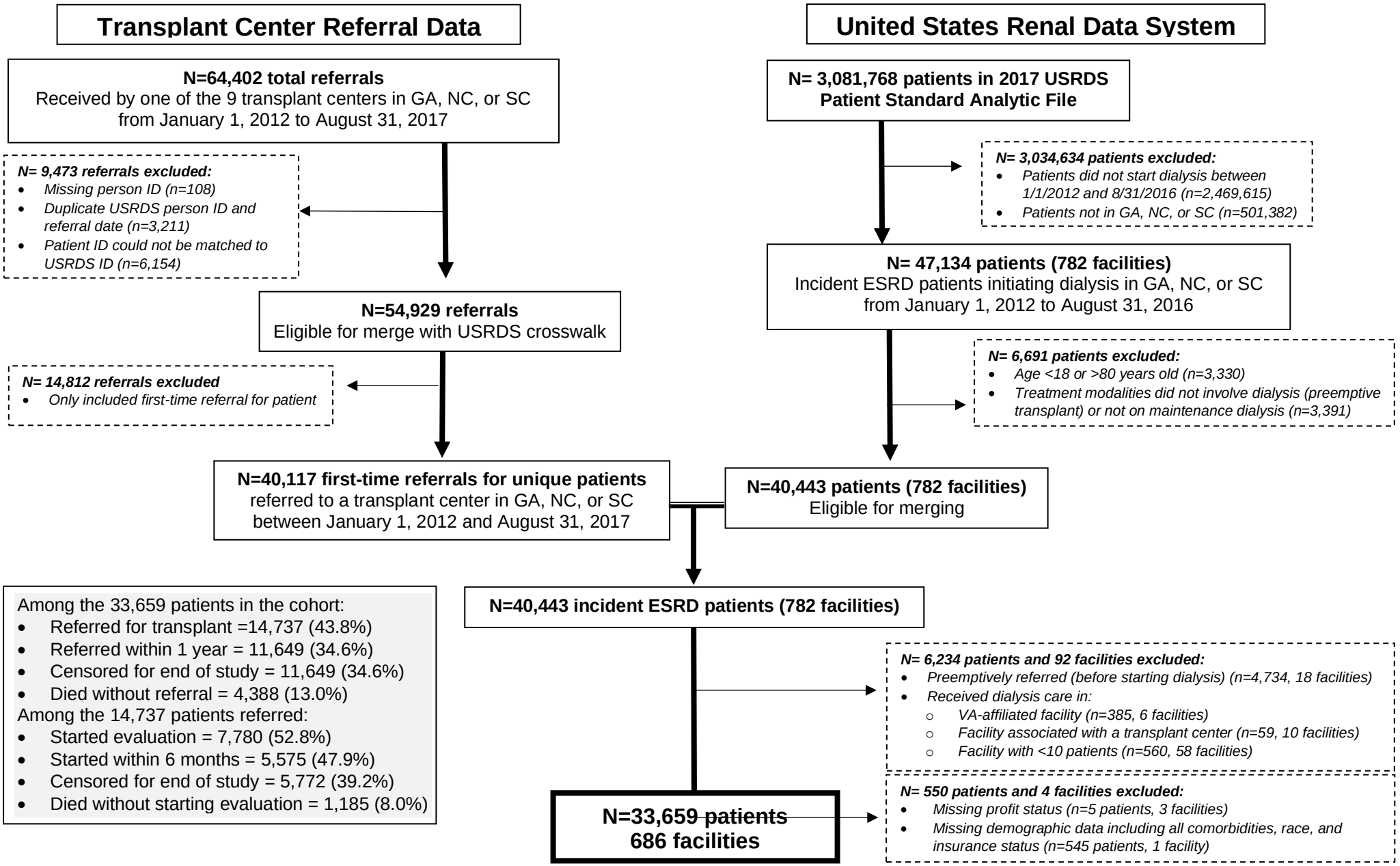


Figure 3. Follow-up timeline for included patients

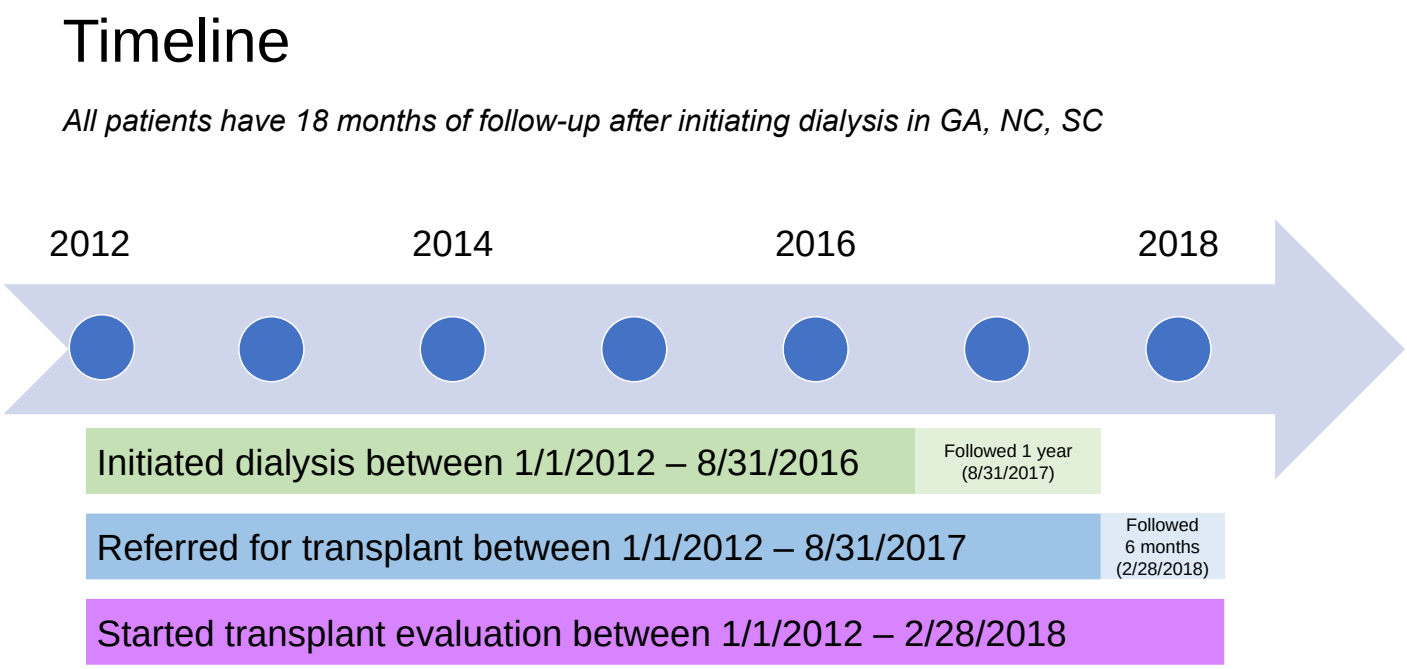
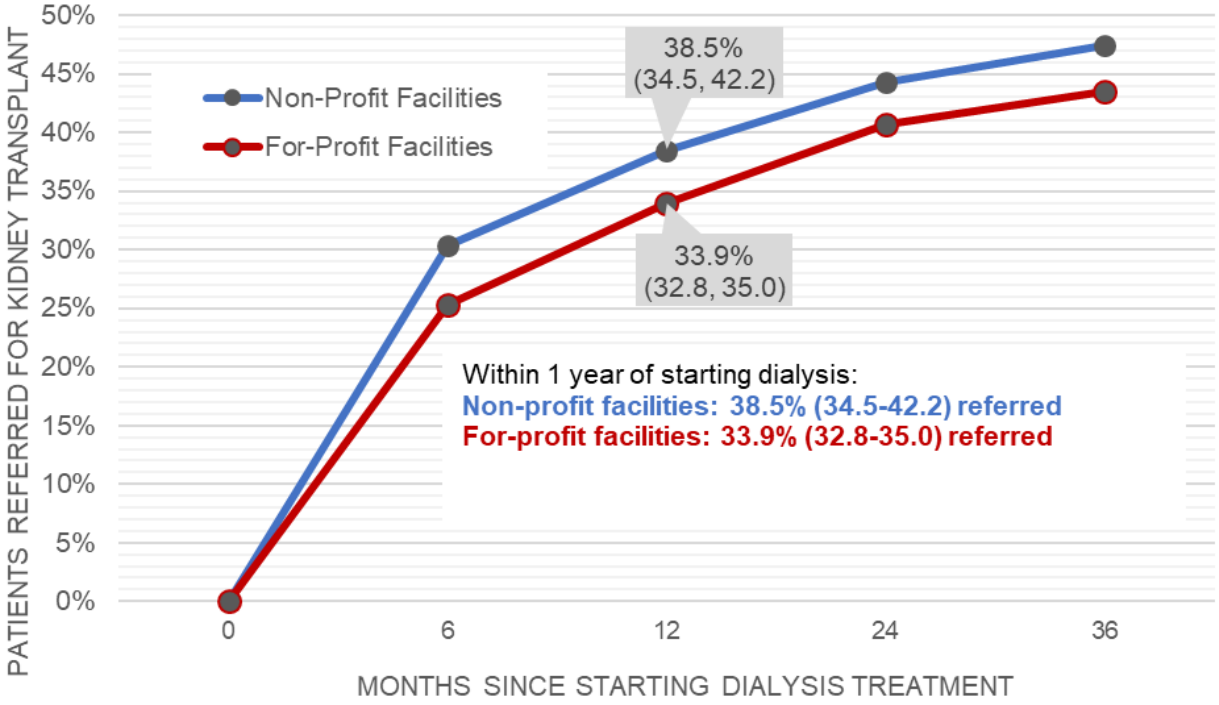
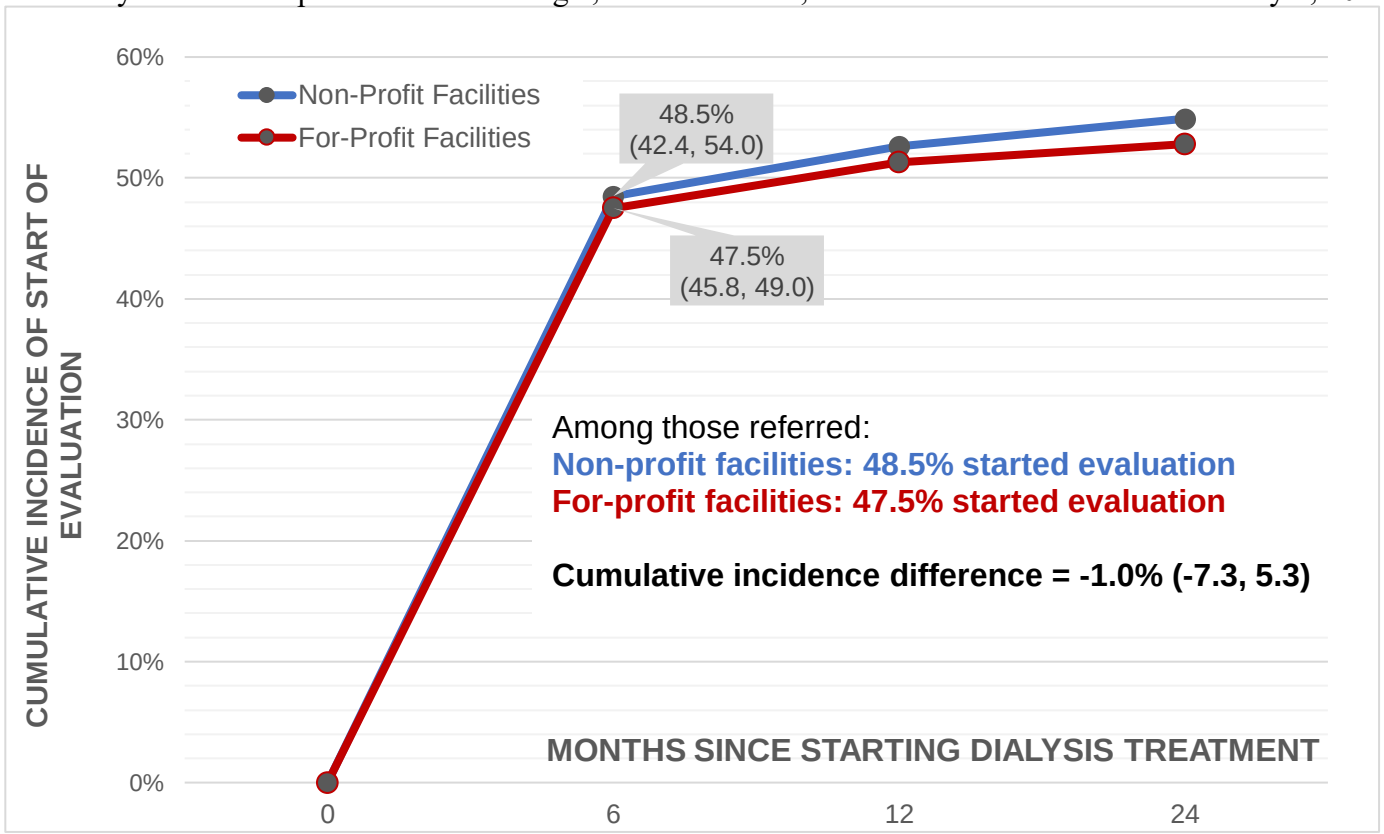


Figure 4. Cumulative incidence of referral for kidney transplantation among all incident ESRD patients initiating dialysis in dialysis facilities in Georgia, North Carolina, and South Carolina between January 1, 2012 and December 31, 2016.



Cumulative incidence difference (95% CI)		**-5.1 (-9.1, -1.0)**	**-4.6 (-8.7, -0.1)**	**-3.6 (-8.0, 1.1)**	**-3.9 (-8.2, 0.8)**
Number at risk (row %)	33,659 (100)	22,531 (66.9)	17,603 (52.3)	9,857 (29.3)	5,574 (16.6)
Non-profit facility	5,060 (100)	3,174 (62.7)	2,498 (49.4)	1,408 (27.8)	769 (15.2)
For-profit facility	28,599 (100)	19,357 (67.7)	15,105 (52.8)	8,449 (29.5)	5,574 (19.5)

Figure 5. Cumulative incidence of starting evaluation at a transplant center among all incident ESRD patients referred within 1 year to a transplant center in Georgia, North Carolina, and South Carolina between January 1, 2012 and March 1, 2018.



Cumulative incidence difference (95% CI)		**-1.0 (-7.3, 5.3)**	-1.3 (-7.2, 5.2)	-2.1 (-8.1, 4.9)
Number at risk (row %)	14,737 (100)	7,091(48.1)	5,664 (38.4)	3,066 (20.8)
Non-profit facility	2,387 (100)	1,128 (47.3)	887 (37.2)	512 (21.4)
For-profit facility	12,350 (100)	5,963 (48.3)	5,664 (45.9)	3,643 (29.5)