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Center-Level Variation in the Development of Delayed Graft Function Following Deceased Donor Kidney Transplantation

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Abstract

Background—Patient-level risk factors for delayed graft function (DGF) have been well-described. However, the OPTN definition of DGF is based on dialysis in the first week, which is subject to center-level practice patterns. It remains unclear if there are center-level differences in DGF, and if measurable center characteristics can explain these differences.

Methods—Using 2003-2012 SRTR data, we developed a hierarchical (multilevel) model to determine the association between center characteristics and DGF incidence after adjusting for known patient risk factors, and to quantify residual variability across centers after adjustment for these factors.

Results—Of 82,143 deceased donor kidney transplant recipients, 27.0% developed DGF, with a range across centers of 3.2-63.3%. A center's proportion of preemptive transplants (OR 0.83, per 5% increment; 95%CI:0.74-0.93;P=0.001) and kidneys with >30 hours of cold ischemia time (OR 0.95, per 5% increment; 95%CI:0.92-0.98;P=0.001) were associated with less DGF. A center's proportion of donation after cardiac death donors (OR 1.12, per 5% increment; 95%CI:1.03-1.17; P<0.001) and imported kidneys (OR 1.06, per 5% increment; 95%CI:1.03-1.10; P<0.001) were associated with more DGF. After patient- and center-level adjustment, only 41.8% of centers had DGF incidences consistent with the national median and 28.2% had incidences above the national median.

Conclusions—Significant heterogeneity in DGF incidences across centers, even after adjusting for patient and center-level characteristics, calls into question the generalizability and validity of the current DGF definition. Enhanced understanding of center-level variability and improving the

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definition of DGF accordingly may improve DGF's utility in clinical care and as a surrogate endpoint in clinical trials.

Keywords

delayed graft function; kidney transplantation; Scientific Registry of Transplant Recipients

INTRODUCTION

Delayed graft function (DGF), as defined by the need for dialysis in the first seven days post-transplant, is collected on every kidney transplant recipient in the United States through the Organ Procurement and Transplantation Network (OPTN). Many studies have explored the role of DGF in directing clinical care and predicting post-transplant outcomes [1-6]. In fact, the U.S. Food & Drug Administration (FDA) has explored DGF as a potential surrogate endpoint in trials to test agents in a more rapid, cost-effective manner than using long-term graft outcomes as an endpoint [7]; FDA approval of DGF as a surrogate endpoint would certainly have profound effects on drug development in transplantation.

However, there is substantial heterogeneity in the reported associations between DGF and transplant outcomes [8-17]. For example, some have reported that DGF is an independent predictor of graft loss [18-20], while others have suggested that its effects are neutral except when associated with acute rejection [12, 21, 22]. Butala and colleagues reported a 5-fold increase in the relative risk of 1-year graft loss in DGF patients, and Shoske and colleagues reported a reduction in 1-year graft survival from 91% to 75% in DGF patients who did not have a rejection episode during their index transplant hospitalization [8, 23]. In a study with longer follow-up for rejection, Troppmann and colleagues reported 1- and 5-year actuarial graft survival of 99% and 89% for transplant recipients with neither DGF nor rejection, compared to 100% and 88% for DGF patients without rejection [22]. However, those patients that developed rejection and DGF had graft survival of 84% and 63%. Others have found that DGF is associated with poorer graft function, but not lower graft survival [24]. This heterogeneity renders the use of DGF as a surrogate endpoint challenging, yet the sources of this heterogeneity remain unclear.

Since DGF involves a subjective decision to treat a patient with dialysis in the first week following a transplant, one explanation for the heterogeneity of DGF's effects between single-center reports could be heterogeneity in center-level post-transplant dialysis practice patterns. Those centers that have a low threshold for dialysis, such as for minor perturbations of fluid status or minor elevations of potassium, will necessarily have a higher rate of DGF, independent of patient factors. The goal of this study was to explore and quantify the center-level heterogeneity of DGF following kidney transplantation, to determine whether or not center-level factors that can be ascertained from OPTN data are associated with DGF beyond patient factors, and to examine the residual variability in DGF incidences across centers after accounting for patient and center level factors.

RESULTS

DGF Incidence

Of 82,143 patients undergoing deceased donor kidney transplants (DDKT), 22,185 (27.0%) developed DGF. The incidence of DGF varied widely across 177 centers, from 3.2%-63.3% (median 27.3%, IQR:18.7-33.8%).

Patient-Level Factors

Males were more likely to experience DGF (29.5% vs. 23.0%; P<0.001), as were African American patients (32.1% vs. 23.6% in Caucasians vs. 26.3% in Hispanic/Latinos; P<0.001) (Table 1). Recipients of grafts from donors with elevated serum creatinine (>1.5 mg/dL) (38.1% vs. 24.8%; P<0.001), diabetes (32.7% vs. 26.6%; P<0.001), and hypertension (34.0% vs. 24.3%; P<0.001) were more likely to experience DGF, as were recipients of imported grafts (30.5% vs. 25.8%; P<0.001) and recipients of grafts from donation after cardiac death (DCD) donors (43.0% vs. 24.5%; P<0.001) and expanded criteria donors (ECD) (33.2% vs. 25.6%; P<0.001).

Transplant Center Factors

Center-level kidney transplant volume during the 10-year study period ranged from 151-1,797 (median 421, IQR: 275-633) (Table 2). Of total transplant volume at a given center, the median proportion from deceased donors was 64.6% (IQR: 57.0-74.1%). Of total DDKT volume at a given center, the median proportion from DCD donors was 11.5% (IQR: 6.1%-16.0%), hypertensive donors was 26.7% (IQR: 22.2-31.8%), diabetic donors was 6.4% (IQR: 4.6-8.3%), African-American donors was 11.9% (IQR: 6.8-17.6%), African-American recipients was 29.9% (IQR: 14.0-43.5%), donors over the age of 65 was 2.4% (IQR: 1.2-4.6%), and recipients over the age of 65 was 15.3% (IQR: 12.1-19.1%). Kidneys with over 30 hours of cold ischemia time (CIT) represented over 50% of transplants in a handful of centers, but a much smaller proportion in most (median 6.5%, IQR:3.2-17.6%).

Patient-Level Model

After adjusting for patient-level factors, only 38.4% of centers had predicted incidences of DGF that would have put them in a category consistent with the national median (Figure 1A). 28.8% of centers had predicted incidences of DGF above the national median. The remaining 32.7% of centers had predicted incidences of DGF below the national median. The adjusted relative odds of DGF across centers ranged from 0.11 to 3.02 (IQR: 0.64-1.37).

Multilevel (Combined Patient and Center-Level) Logistic Model

After adjusting for patient-level factors, there were a number of factors at the center-level that were statistically significantly associated with DGF (Table 3). For every 5% increase in a center's use of preemptive transplants, there was a 17.0% decrease in the odds of DGF (OR 0.83; 95% CI: 0.74-0.93; P=0.001). Holding all other factors constant, the proportion of preemptive transplants would be associated with a 19.7% absolute decrease in the odds of DGF between centers at the 25th percentile of preemptive transplant use (4.8%) and those at the 75th percentile (10.6%). For every 5% increase in a center's use of DCD donors, there

was an 11.9% increase in the odds of DGF (OR 1.12; 95% CI: 1.03-1.17; P<0.001). Holding all other factors constant, the proportion of DCD donors would be associated with a 23.6% absolute increase in the odds of DGF between centers at the 25th percentile of DCD donor use (6.1%) and those at the 75th percentile (16.0%). For every 5% increase in a center's use of imported kidneys, there was a 6.1% increase in the odds of DGF (OR 1.06; 95% CI: 1.03-1.10; P<0.001). Holding all other factors constant, the proportion of imported kidneys would be associated with a 16.1% absolute increase in the odds of DGF between centers at the 25th percentile of imported kidney use (16.4%) and those at the 75th percentile (29.5%). For every 5% increase in a center's use of kidneys with cold ischemia time >30 hours, there was a 5.0% decrease in the odds of DGF (OR 0.95; 95% CI: 0.92-0.98; P=0.001). Holding all other factors constant, the proportion of kidneys with cold ischemia time >30 hours would be associated with a 14.4% absolute decrease in the odds of DGF between centers at the 25th percentile of use of kidneys with cold ischemia time >30 hours (3.2%) and those at the 75th percentile (17.6%). In other words, independent of an individual's kidney length of CIT, being transplanted at a center with increased experience transplanting kidneys with CIT>30 is associated with a lower likelihood of DGF.

Center volume and the proportions of deceased donor transplants, ECD transplants, donors with elevated serum creatinine, diabetic donors, hypertensive donors, donors >65 years of age, recipients >65 years of age, African-American donors, and African-American recipients were not statistically significantly associated with DGF and were therefore excluded from the final model.

After adjusting for patient and center-level factors, 41.8%of centers had predicted incidences of DGF that would have put them in a category consistent with the national median (Figure 1B). 28.2% had predicted incidences of DGF above the national median. The remaining 29.9% of centers had predicted incidences of DGF below the national median. The adjusted relative odds of DGF across centers ranged from 0.22 to 3.08 (IQR: 0.71-1.41).

DISCUSSION

In this national study of center-level factors and DGF, we found significant heterogeneity in a patient's likelihood of developing DGF based on the center at which the transplant is performed. While the median incidence of DGF was 27.3%, the range was 3.2-63.3%. Even after adjusting for patient and center-level characteristics, there remained significant heterogeneity in the predicted DGF incidences across centers. After patient-level adjustment, only 38.4% of centers had DGF incidences consistent with the national median. Adjusting for patient and center characteristics increased that, but only to 41.8%. Center-level characteristics associated with decreased DGF included a center's proportion of preemptive transplants (OR 0.83, per 5% increment; 95% CI: 0.74-0.93; P=0.001) and its proportion of kidneys with cold ischemia time >30 hours (OR 0.95 per 5% increment; 95% CI: 0.92-0.98; P=0.001). The increased use of DCD donors (OR 1.12, per 5% increment; 95% CI: 1.03-1.17; P<0.001) and imported kidneys (OR 1.06, per 5% increment; 95% CI: 1.03-1.10; P<0.001) were associated with increased DGF.

Our patient level-factors were consistent with the findings of Irish and colleagues [1, 2]. For example, they reported that donation after cardiac death was the factor most strongly associated with DGF. We also found that to be the case. Like them, we found similar associations and point estimates for male recipients, African-American recipients, and donors with hypertension. Donor age, but not recipient age, was associated with DGF in their studies as well as ours. These comparable findings lend face validity to the patient-level component of our model.

The etiology of the significant residual variability across centers is likely multifactorial, reflecting the complexity of perioperative care and practices across centers. For example, donor management [25, 26], anesthetic and perioperative fluid administration practices [28, 29], immunosuppression practices[3, 6, 30], which likely vary across centers, influence an individual transplant recipient's likelihood of developing DGF. Factors such as these may explain the significant residual variability of predicted DGF incidence after adjusting for patient- and center-level factors.

To our knowledge, this is the first study to report on center-level effects in the development of DGF. Notable strengths of this study include its large sample size and its inclusion of nearly all centers in the United States. Limitations of this study include its retrospective, observational nature and the difficulty in drawing causal inferences from studies using large, administrative databases. The center-level factors that we tested were ones that were simultaneously mechanistically plausible and *measurable*. However, it is quite possible that there are other patient- or center-level effects that are not captured by this database that might influence a patient's likelihood of developing DGF.

Many definitions of DGF are currently in use, though significant logistic and methodological challenges exist in utilizing a DGF definition based on serum creatinine levels, glomerular filtration rate, or urine output. The need for dialysis within the first seven days post-transplant is the most frequently used definition in the transplant literature [31]. However, we have demonstrated that DGF using this definition is subject to marked heterogeneity across transplant centers, even after accounting for patient- and center-level characteristics. For DGF to have clinical and research utility, a tenable definition of DGF would be resistant to such heterogeneity.

In conclusion, DGF, as defined by the need for dialysis in the first week after a kidney transplant, might not be biologically comparable from one center to another. While there are many patient-level factors associated with DGF, there are center-level factors, notably the proportion of preemptive transplants, DCD donors, imported transplants, and kidneys with cold ischemia time >30 hours, that are also associated with DGF. And even after adjustment for those patient and center-level factors, significant variability in the likelihood of DGF remains across centers, perhaps reflecting the subjective nature of the decision to dialyze a patient in the first week post-transplant. Ideally, a new definition should be designed and developed that is independent of these center-level treatment patterns. Care must be exercised in the use of the current DGF definition as an outcome in multi-center studies where post-transplant management is not standardized.

MATERIALS AND METHODS

Study Population

Patients 18 years of age and older undergoing non-preemptive, kidney-only DDKT between January 1, 2003 and December 31, 2012, as reported to the OPTN and distributed by the Scientific Registry of Transplant Recipients (SRTR), were selected for patient-level analysis. The SRTR includes information on all donors, wait-listed transplant candidates, and transplant recipients in the U.S. provided by members of the OPTN, and has been well-described elsewhere [32]. The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. Patients with missing DGF information were excluded from analysis (n=3). In addition, we excluded transplant centers that performed exceptionally few kidney transplants, defined as an average of 10 or fewer transplants per year, in order to maintain regression model stability.

Patient-Level Logistic Model

Multivariable logistic regression exploring donor and recipient-level associations with the development of DGF was performed to ensure that our patient-level variables were consistent with previous DGF prediction models. Donor and graft variables included age, race, blood type, hypertension, diabetes mellitus, elevated serum creatinine, cause of death, DCD, ECD, import from another region, use of pulsatile perfusion, and CIT. Recipient variables included age, sex, race, peak panel reactive antibody (PRA), zero-HLA-mismatch, hypertension, and prior transplantation. These variables were included based on biological plausibility and published studies [1, 2]. Using a hierarchical (multi-level) model with a center-level random intercept, we calculated the expected and observed incidence of DGF across transplant centers in the United States, based on these identified patient-level predictors.

Multilevel (Combined Patient- and Center-Level) Logistic Model

To explore whether center-level characteristics were associated with DGF, above and beyond just patient-level characteristics, we fit a hierarchical model that incorporated plausible center-level characteristics that were measured in or could be calculated from SRTR data. Total DDKT volume was included in the model and was defined as the total number of transplants performed at the center that fit inclusion criteria for this study. Experience managing the patient-level risk factors known to be associated with DGF was also incorporated into the center-level model, as the proportion of total DDKT comprised of the following: DCD, ECD, imported kidneys, transplants with CIT>30 hours, donors with creatinine>1.5 mg/dL, diabetic donors, hypertensive donors, donors over age 65, recipients over age 65, African-American donors, and African-American recipients. Proportion of DDKT at a center (versus live donor KT) and the proportion of a center's transplants that were preemptive transplants were also included as center-level variables, as we hypothesized that a center's experience with these patients might inform their management of post-transplant dialysis. Center level variables that were not statistically significant in the multivariate model were not included in the final model for parsimony. The hierarchical model also included the following patient-level donor variables: age, race, blood type,

diabetes, hypertension, BMI, serum creatinine, cause of death, donation after cardiac death, CIT, need for inotropic support, cardiac arrest after the event leading to death, use of pulsatile perfusion, and transplant year. The following patient-level recipient variables were included as well: age, history of prior transplant, zero-HLA-mismatch, peak PRA, sex, and race.

Statistical Analysis

All analyses were performed using Stata 12.1 (StataCorp, College Station, TX), with a two-tailed alpha level of 0.05. Hierarchical modeling was performed with the xtmelogit command.

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Abbreviations

BMI	body-mass index
CIT	cold ischemia time
DCD	donation after cardiac death
DDKT	deceased donor kidney transplantation
DGF	delayed graft function
ECD	expanded criteria donor
IQR	interquartile range
OPTN	Organ Procurement and Transplantation Network
PRA	panel reactive antibody
SD	standard deviation
SRTR	Scientific Registry of Transplant Recipients

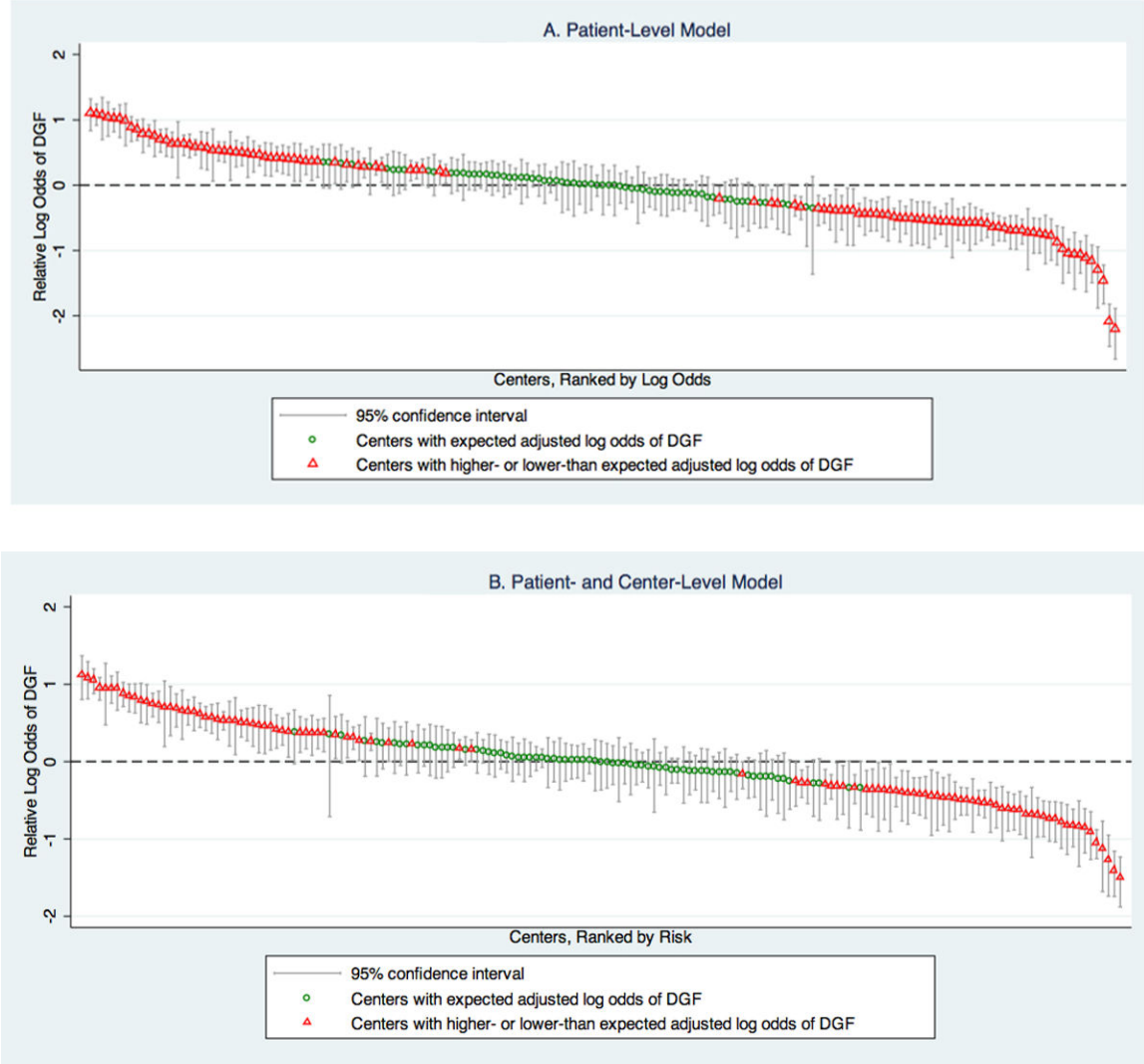

Figure 1.

Relative likelihood of DGF, based on (A) a model that only includes patient-level characteristics and (B) a model that combines patient and center-level characteristics, by center.

A displays the log odds of DGF at a center relative to the national median based on adjustment for patient-level characteristics. Based on this model, 38.4% (68/177) of centers have 95% confidence intervals that encompass the national median log odds of DGF. The relative log odds ranged from -2.20-1.11 (IQR:-0.44-0.31), which corresponds to a relative odds of DGF range across centers of 0.11-3.02 (IQR: 0.64-1.37).

B displays the log odds of DGF at a center relative to the national median based on adjustment for patient and center-level characteristics. Based on this model, 41.8% (74/177) of centers have 95% confidence intervals that encompass the national median log odds of DGF. The relative log odds ranged from -1.50-1.12 (IQR: -0.34-0.34), which corresponds to a relative odds of DGF range across centers of 0.22-3.08 (IQR: 0.71-1.41).

DGF=delayed graft function, IQR=interquartile range

Table 1

Patient-level characteristics, by the development of DGF.

	DGF (N=22,185)	No DGF (N=59,958)	P-value
Donor Characteristics			
Mean Age (SD)	41.9 (15.8)	37.7 (16.8)	<0.001
African-American	3,007 (26.3%)	8,440 (73.7%)	0.055
Hypertension	7,694 (34.0%)	14,961 (66.0%)	<0.001
Diabetes Mellitus	1,859 (32.7%)	3,826 (67.3%)	<0.001
Creatinine > 1.5mg/dL	5,111 (38.1%)	8,307 (61.9%)	<0.001
Donation After Cardiac Death	4,202 (43.8%)	5,389 (56.2%)	<0.001
Expanded Criteria Donor	5,002 (33.2%)	10,042 (66.7%)	<0.001
Imported Kidney	6,577 (30.5%)	15,002 (69.5%)	<0.001
Median CIT (IQR)	19 (13.3-24.6)	16.4 (11.2-22.0)	<0.001
Recipient Characteristics			
Mean Age (SD)	52.7 (12.7)	51.7 (13.2)	<0.001
Male	14,854 (29.5%)	35,444 (70.5%)	<0.001
African-American	8,888 (32.1%)	18,775 (67.9%)	<0.001
Median Peak PRA (IQR)	4 (0-36)	3 (0-37)	0.7
Zero-HLA-Mismatch	1,738 (20.8%)	6,597 (79.1%)	<0.001
Prior Transplant	3,113 (27.3%)	8,298 (72.7%)	0.5

DGF=delayed graft function, CIT=cold ischemia time, IQR=interquartile range, SD=standard deviation, PRA=panel reactive antibody

Table 2

Characteristics of the 177 studied transplant centers. The percentages represent the proportion of transplants at a center that fit the corresponding characteristic.

	Minimum	25th Percentile	Median	75th Percentile	Maximum
DGF Incidence	3.2%	18.7%	27.3%	33.8%	63.3%
Center Volume (over 10 years)	151	275	421	633	1797
Proportion of Transplants that Are DDKT	18.1%	57.0%	64.6%	74.1%	97.5%
Proportion of Donation After Cardiac Death KT	0.0%	6.1%	11.5%	16.0%	40.4%
Proportion of Expanded Criteria Donors	1.7%	11.6%	17.0%	22.9%	47.8%
Proportion of Imported Kidneys	8.7%	16.4%	21.0%	29.5%	77.5%
Proportion of KT with CIT > 30 Hours	0.0%	3.2%	6.5%	17.6%	91.3%
Proportion of KT with Donor Creatinine >1.5 mg/dL	2.3%	10.6%	13.6%	18.7%	41.2%
Proportion of Preemptive KT	0.4%	4.8%	6.7%	10.6%	24.2%
Proportion of Diabetic Donors	1.7%	4.6%	6.4%	8.3%	14.5%
Proportion of Hypertensive Donors	11.4%	22.2%	26.7%	31.8%	52.6%
Proportion of KT with Donor Age > 65 Years	0.0%	1.2%	2.4%	4.6%	14.6%
Proportion of KT with Recipient Age > 65 Years	4.2%	12.1%	15.3%	19.1%	34.4%
Proportion of KT with African-American Donors	1.1%	6.8%	11.9%	17.6%	36.4%
Proportion of KT with African-American Recipients	0.4%	14.0%	29.9%	43.5%	91.6%

DGF = delayed graft function, DDKT = deceased donor kidney transplant, KT = kidney transplants, CIT = cold ischemia time

Table 3

Adjusted odds ratio for the development of DGF in a model combining patient- and center-level characteristics

	Adjusted Odds Ratio (95% Confidence Interval)	P-value
Donor Factors		
Age (5-year increments)	1.07 (1.07-1.08)	<0.001
Hypertension	1.40 (1.34-1.46)	<0.001
Donation After Cardiac Death	2.73 (2.57-2.91)	<0.001
Serum Creatinine >1.5 mg/dL	1.94 (1.85-2.02)	<0.001
Cold Ischemia Time (5 hour Increments)	1.18 (1.16-1.19)	<0.001
Recipient Factors		
Age (5-year increments)	1.00 (0.99-1.00)	0.2
Male	1.49 (1.43-1.55)	<0.001
Peak PRA (5% increments)	1.00 (1.00-1.00)	<0.001
Zero-HLA-Mismatch	0.73 (0.68-0.78)	<0.001
Prior Transplant	0.99 (0.93-1.05)	0.7
Center-Level Factors		
Proportion of Preemptive Transplants (5% increments)	0.83 (0.74-0.93)	0.001
Proportion of Donation After Cardiac Death Donors (5% increments)	1.12 (1.03-1.17)	<0.001
Proportion of Transplants with Cold Ischemia Time >30 Hours (5% increments)	0.95 (0.92-0.98)	0.001
Proportion of Imported Kidneys (5% increments)	1.06 (1.03-1.10)	<0.001

DGF = delayed graft function, BMI=body mass index, PRA = panel reactive antibody

Year of transplant, donor blood type, donor cause of death, donor creatinine, donor cardiac arrest after event leading to death, donor race, donor BMI, use of pulsatile perfusion, and recipient race were also included in the model.