American Journal of Transplantation

Variation in living donor evaluation and acceptance across the United States.

--Manuscript Draft--

Manuscript Number:	AMJT-D-25-00743
Full Title:	Variation in living donor evaluation and acceptance across the United States.
Article Type:	Original Article
Section/Category:	Clinical
Keywords:	living kidney donation; donor evaluation; risk assessment; health disparities
Manuscript Region of Origin:	UNITED STATES
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IRB Statement Does your manuscript involve human subjects?	No
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Clinical Trials Does your manuscript include a clinical trial?	No
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Word count: Main body - 2557 words (4000 word limit); Abstract - 199 words (200 word limit)

Abbreviations: blood pressure (BP), body mass index (BMI), End Stage Kidney Disease (ESKD), estimated glomerular filtration rate (eGFR), Kidney Donor Risk of ESKD (KDRE), Kidney Failure Risk Projection (KFRP)

Keywords: living kidney donation; donor evaluation; risk assessment; health disparities

Abstract:

Variability exists in rates of acceptance of living kidney donor candidates across transplant centers in the US, and there is lack of consensus on eligibility criteria for candidates. A multicenter retrospective cohort study was performed to understand variations in transplant-center and provider decisions surrounding living donor candidacy by donor ancestry and ethnicity. Among candidates who completed a donor evaluation at nine transplant centers, the Kidney Failure Risk Projection model was used as an objective metric to estimate donor risk of developing End-Stage Kidney Disease (ESKD) within 15 years after nephrectomy. Overall, candidates accepted for donation had extremely low risk of developing ESKD, but variations by donor ancestry/ethnicity were observed. The 15-year estimated donor risk for ESKD was lowest in Hispanic candidates (0.1%) who were accepted for donation, but this risk was 1.4 times higher for White candidates and 3.25 times higher for Black candidates who were accepted ($p<0.001$). No statistically significant variations were observed at the level of the transplant center or providers by donor ancestry/ethnicity. Similar patterns by ancestry/ethnicity were noted in candidates who were not accepted as donors. Standardization of living donor candidate evaluation and acceptance criteria may help improve ancestry/ethnicity-based patient-level disparities in donor candidacy evaluation.

1. Introduction

Living donor (vs. deceased donor) transplantation is associated with shorter waiting times and better recipient and graft survival for patients who reach end-stage kidney disease (ESKD).[1,2] Yet, obtaining a living donor can be challenging. Very few individuals who initiate the donor process actually become living donors, with most potential donors dropping out early in the process.[3] Even among donor candidates who complete their evaluation, donation rates are low.[3] In 2021, the National Kidney Foundation published a Roadmap for Innovation to Advance Transplant Access and Outcomes.[4] This position statement set the expansion of opportunities for safe living donation as a first priority and endorsed "optimiz[ing] donor risk assessment" as a key strategy. Major challenges to this strategy include defining "optimal" donor risk assessment and determining how optimizing risk is equitably applied across health systems and with consideration of individual genetic and medical profiles.

Currently, each transplant center (or provider) sets their own threshold of acceptable risk for living donation.[5] Lack of consensus on the criteria for donor suitability, such as body mass index (BMI) or blood pressure threshold, may contribute to bias in donor evaluation.[6-9] In particular, Black and Hispanic individuals are less likely to serve as living donors than White individuals.[10-17] At the same time, some, but not all, studies have shown that there is a slightly higher risk of ESKD after donation, particularly if the donor is a first-degree relative of the recipient or if the donor is Black.[18-22] Most studies have not shown a higher risk of mortality among prior living donors compared with healthy non-donors.[18,23]

Although several risk calculators have been developed to inform the post-donation risk of ESKD, they have not yet been widely adopted in practice, partly due to lack of consensus on the acceptable thresholds of risk for donation.[24] Given the lack of data on the degree of provider- or center-based variability in the assessment of donor acceptability, we applied objective metrics of donors' ESKD risk using two available risk calculators among donor candidates at nine different transplant centers and examined variations in acceptance of living donors overall and by ancestry/ethnicity.[25,26]

2. Materials and Methods

2.1 Study population

This was a multicenter retrospective cohort study of living donor candidates evaluated between January 1, 2014 and December 31, 2022 at nine transplant centers in the US (Table S1). Black and White (Hispanic or non-Hispanic) potential donors over 18 years of age prospectively evaluated at transplant centers for donation (regardless of whether the transplant center accepted the donor and whether they ultimately donated) were included for analysis. University of California San Francisco served as the single Institutional Review Board of Record and deemed this study exempt from human subject's research.

Demographic data including age at donor evaluation, sex, center where evaluation occurred, and relationship to the recipient were collected. In addition, all transplant centers were asked to include data on the clinician (using scrambled identifiers) who performed the donor evaluation to assess variability in provider decisions. Data entry was centralized in Research Electronic Data Capture (REDCap) and entered in de-identified form. Donor candidates who did not have the minimal data elements to determine their post-donation risk or at least 6 months of follow-up observation time were excluded from the study.

2.2 Exposure and outcome

The primary exposure was ancestry and ethnicity as documented in the electronic health record system. To assess the objective medical risk of donation, we used the Kidney Failure Risk Projection (KFRP) model which provides an estimate of the long-term 15-year risk of ESKD in healthy donor candidates.[25] The model consists of ten characteristics, including age, sex, ancestry, smoking history, use of anti-hypertensive medications, presence/absence of non-insulin-dependent diabetes, systolic blood pressure (BP), body mass index (BMI), estimated glomerular filtration rate (eGFR), and urine albumin/creatinine ratio and projects the 15-year as well as lifetime risk of ESKD.[25] GFR was estimated using the CKD-EPI 2009 equation because this was the equation used for decision-making in most clinical practices during the study period. However, it has been reported more recently that the KFRP equation may underestimate the risk of ESKD after donor nephrectomy (since it was developed among healthy non-donors who did not actually undergo nephrectomy). Thus, a newer equation, the Kidney Donor Risk of ESKD (KDRE) was also used to provide an objective metric of the risk of ESKD in secondary analysis. The KDRE provides a refined post-donation estimate of ESKD risk (based on data from prior living donors) and includes: age, sex, ancestry, BMI, and relationship to recipient.[26]

The ultimate decision of whether the transplant center accepted the donor for nephrectomy or not were recorded as: accepted, not accepted, and donor withdrew. Last date of follow-up for confirmation of donor outcomes occurred in May 2025.

2.3 Statistical analysis

We used linear mixed models to examine whether ancestry/ethnicity were associated with the KFRP or KDRE scores, which were log-transformed due to non-normality. These models were unadjusted, as the most important factors for whether a donor is accepted for donation are already incorporated in the KFRP. These models were clustered by transplant center and provider in a hierarchical model to determine center- and provider-level variations. We initially also included random "slopes" at the provider and transplant center level to capture differences in the variability for different patient ancestry/ethnicity. However, because there were no variations by ancestry/ethnicity at the level of the provider or transplant center, these random slopes for ancestry/ethnicity were omitted in the final model. We derived standard deviations in the KFRP score based on these mixed models to assess variability in decisions surrounding living donor candidacy, both at the center and provider level.

In secondary analysis, we used *ancestry/ethnicity* as the primary predictor for the outcome of transplant center acceptance or non-acceptance using mixed logistic regression to determine whether there were differences in the threshold of acceptance (or non-acceptance) for donation by ancestry/ethnicity, clustered by provider and transplant center.

3. Results

3.1 Characteristics of the Study Population, Overall and by Ancestry/Ethnicity

Among the nine transplant centers in the U.S., 1894 living donor candidates met our inclusion criteria and were included for analysis (Table 1). The median age at evaluation was 42 years, 62.5% of donor candidates were women, and most donors had private insurance (70%). The median eGFR was 99 mL/min/1.73 m^2, median BP 122/74 mm Hg and median BMI 27 kg/m^2 . Hypertension was present in 5.2% of donor candidates, and 65% of donor candidates had no comorbidities. Among potential donors, 758 (40%) were first-degree relatives to their intended recipient, 26% were acquaintances, and 5% were altruistic (i.e., not previously known to the potential recipient).

White donor candidates tended to be older (median 47 years) compared with Hispanic (median 36 years) and Black (median 38 years) candidates (Table 1). A higher proportion of Hispanic and Black potential donors were uninsured at the time of evaluation (16.6% and 31%, respectively). The median eGFR obtained at the donor evaluation was higher in Black (108 mL/min/1.73 m^2) and Hispanic donor candidates (109 mL/min/1.73 m^2), compared with White

candidates (94 mL/min/1.73 m^2). The median BMI was also higher in Black and Hispanic donor candidates (28 kg/m^2), compared with White donor candidates (26 kg/m^2). Hispanic donor candidates were more likely to have no comorbidities (76%) than White or Black donor candidates. White donor candidates were more likely to be non-related individuals who knew the recipient candidate (32.5%), whereas potential Hispanic and Black donors were more likely to be seeking donation to first degree relatives.

3.2 Characteristics of donors by transplant center decision

The characteristics of donor candidates by their evaluation outcomes are shown in Table S2. Of the 1894 living donor candidates evaluated, 66.9% (N=1268) were accepted by the transplant center for donation, and 912 (71.9%) of those had donated at last follow-up. Another 8.8% of donor candidates withdrew from consideration, and 24.2% were determined to have a contraindication to donation and were not accepted. Donor candidates who were accepted were more commonly older, White, privately insured, with lower BMI, less likely to be current smokers, and with slightly lower KFRP predicted risk of ESKD than donor candidates who were not accepted (Table S2).

3.3 Absolute and variability in ESKD risk by Ancestry/Ethnicity among all donor candidates and by donor outcome

The median 15-year predicted risk of ESKD in the cohort was 0.17% across all donor candidates, ranging from 0.13% among those who withdrew their candidacy to 0.20% among those not accepted (Table 2A). Differences in ESKD risk were also observed by ancestry/ethnicity. Overall, for Black donor candidates, the median predicted risk of reaching ESKD within 15 years was 0.30%, compared with White (0.17%) or Hispanic (0.08%) donor candidates (Table 2B).

Differences between donors by ancestry/ethnicity, stratified by donor decision

The mean geometric risk of kidney failure in Hispanic candidates was 0.1% in analyses clustered by transplant center and provider for those accepted for donation, when holding variability by transplant center and provider constant at zero. The 15-year predicted risk of ESKD for donor candidates who were accepted by transplant centers was 1.43 times higher for White donor candidates and 3.25 times higher for Black donor candidates compared with Hispanic candidates (Table 3). The 15-year predicted risk of ESKD for donor candidates who were not accepted was 1.36 times higher for White and 3.12 times higher for Black donor

candidates compared with Hispanic candidates (whose mean geometric risk was 0.13%) (Table 3).

For donor candidates who withdrew, the 15-year predicted risk of ESKD was 1.47 times higher for White than Hispanic donor candidates and 3.22 times higher for Black donor candidates compared with Hispanic donor candidates (whose mean geometric ESKD risk was 0.1%).

After accounting for fixed effects for ancestry/race and provider, among accepted donors, the residual between-center variability had a corresponding geometric SD of 1.49 (i.e., centers who were one SD above the mean had a 49% higher 15-year risk of ESKD among their accepted donors [95% CI 1.21-1.84]). Similarly, the residual between-provider variability had a corresponding geometric SD of 1.20 [(i.e., providers who were one SD above the mean had a 20% higher 15-year risk of ESKD among their accepted donors 95% CI 1.09-1.32]). However, this variability at the level of the transplant center or provider did not differ by donors' ancestry/ethnicity.

After accounting for fixed effects for ancestry/race and provider, among non-accepted donors, the residual between-center variability had a corresponding geometric SD of 1.53 (i.e. centers who were one SD above the mean had a 53% higher 15-year risk of ESKD among their accepted donors [95% CI 1.17-1.99]). Similarly, the residual between-provider variability had a corresponding geometric SD of 1.18 [(i.e., providers who were one SD above the mean had a 18% higher 15-year risk of ESKD among their accepted donors 95% CI 0.91-1.54]). However, this variability at the level of the transplant center or provider did not differ by donors' ancestry/ethnicity.

The distribution of the odds of donor acceptance across provider and transplant center are shown in Figure 1. For every 1% increase in the 15-year risk of kidney failure estimation, the odds of acceptance for donation were substantially higher for White donor candidates (OR 1.47; 95% CI 1.14-1.89) compared with Hispanic (referent) and Black candidates (0.81; 95% CI 0.57-1.16) whose odds did not differ from that of the referent group (Table 4). Results were consistent when we used the KDRE (Table 4).

4. Discussion

The National Kidney Foundation has emphasized that efforts to improve transparent communication of risks and long-term donor safety are critical to sustaining the trust of living

donor candidates and to informing evidence-based education and donor selection practices.[4] Better understanding of potential risks of living donation is essential to improving living donor access across all ancestral/ethnic groups. The present study applied validated donor risk tools to a retrospective cohort of living donor candidates who were evaluated for donation across nine transplant centers with varying transplant volumes and size of living donor programs in a real-world setting. Across centers, we examined differences in donor decision-making on the whole and by ancestry/ethnicity. The overall predicted 15-year risk of ESKD for accepted donors was extremely low (less than 1%) across ancestries/ethnicities for nearly all candidates who completed their evaluations, regardless of which metric was used to estimate risk of donation. These results suggest that the selection criteria are stringent across all centers and meet the goal of minimizing risk of ESKD to donors. However, there was substantial variation in acceptance of donors across nine transplant centers with over 80 providers.

As expected, accepted donors tended to have lower risk for ESKD, such as lower blood pressure and lower BMI, and were more likely to have private health insurance. Of note, 21% of donors who were not accepted and 29% of donors who withdrew were uninsured. Given the recognized economic burden to living donors, these findings support the need for public policy efforts, such as the Living Donor Protection Act, to improve insurance access for living donors.[27-29]

The results of this study demonstrated differences in decisions about acceptance of living donors by ancestry/ethnicity. In terms of absolute risk among the candidates evaluated, Hispanic living donor candidates had the lowest estimated 15-year ESKD risk (median 0.08%), and Blacks had the highest estimated 15-year ESKD risk (median 0.30%). However, for each 1% increase in 15-year risk of kidney failure, the odds of acceptance for donation were substantially lower for Hispanic and Black candidates compared with White donor candidates. This suggests that when the objective metric or risk is equivalent, there are differences in the willingness to tolerate risk that varies by ancestry/ethnicity.

We did not observe varying rates of donor acceptance by ancestry/ethnicity at the level of providers or transplant centers. These results suggest that there is no clear support for the presence of bias across centers or providers. A recent study suggested that genetic testing for the apolipoprotein L1 gene (*APOL1*) has been adopted by some transplant centers or providers, though not widely used and often applied inappropriately to exclude donors or provide false reassurance.[30] However, our results do not support that this is occurring at the level of sites or providers.

This study has limitations. Unmeasured confounders may have been present due to the retrospective cohort design. The cohort also included only donor candidates who underwent evaluation and had the necessary variables to calculate an ESKD risk score. Thus, donor candidates who may have been at higher risk for ESKD were likely already excluded from study after initial contact with the transplant center. We cannot exclude the possibility of bias during the initial screening process that led to exclusion of donors from this cohort. However, these results are highly relevant to real-world practice, since donor candidates with clear contraindications to donation and who are at very high risk for ESKD (e.g. presence of CKD) would not proceed to evaluation by a transplant center.

In conclusion, this study showed that overall living donor candidates accepted for kidney donation had extremely low risk of developing ESKD within 15 years of donation based on current prediction models. Yet, despite most candidates demonstrating such low risk per the KFRP or KDRE, there was variability in determination of living donor acceptability across transplant centers by ancestry/ethnicity. These observed differences in decision-making by ancestry/ethnicity highlight the need to better capture true biologically relevant constructs associated with heightened donor risk, such as by leveraging the rapidly evolving field of genetic testing, to reduce subjective risk perception based on a living donor candidate's ancestral or ethnic background.

Acknowledgements / Funding

This study was supported by NIH R01 DK120886.

We'd like to acknowledge Isabelle Lopez at University of California, San Francisco for her help with study coordination.

Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the American Journal of Transplantation.

Data availability statement

The data were collected under data use agreements that do not allow for direct sharing.

Figure Legends

Figure 1: Average adjusted probability of acceptance by provider and transplant center.

Supporting Information

Additional Supporting Information may be found online in the "Supporting Information section"

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Table 1. Patient characteristics by ancestry/ ethnicity

n (Column %) or Median (IQR)	Total 1,894 (100.0%)	White 1,033 (54.5%)	Hispanic 458 (24.2%)	Black 403 (21.3%)
Age at evaluation (years)	42.0 (32.0, 53.0)	47.0 (36.0, 57.0)	36.0 (29.0, 47.0)	38.0 (29.0, 49.0)
Sex				
Female	1,183 (62.5)	644 (62.3)	294 (64.2)	245 (60.8)
Male	711 (37.5)	389 (37.7)	164 (35.8)	158 (39.2)
Insurance Type				
None	254 (13.4)	53 (5.1)	76 (16.6)	125 (31.0)
Private	1,326 (70.0)	825 (79.9)	273 (59.6)	228 (56.6)
Medicare	204 (10.8)	117 (11.3)	64 (14.0)	23 (5.7)
Medicaid	87 (4.6)	26 (2.5)	42 (9.2)	19 (4.7)
Military/Veterans Affairs	23 (1.2)	12 (1.2)	3 (0.7)	8 (2.0)
15-Year KFRE				
<1%	1,790 (94.5)	997 (96.5)	456 (99.6)	337 (83.6)
1-1.99%	85 (4.5)	31 (3.0)	2 (0.4)	52 (12.9)
2-2.99%	10 (0.5)	3 (0.3)	0 (0.0)	7 (1.7)
3-4.99%	7 (0.4)	0 (0.0)	0 (0.0)	7 (1.7)
>=5%	2 (0.1)	2 (0.2)	0 (0.0)	0 (0.0)
15-Year KFRP	0.2 (0.1, 0.3)	0.2 (0.1, 0.2)	0.2 (0.1, 0.2)	0.5 (0.3, 0.7)
15-Year KFRP				
<1%	1,831 (96.7)	1,033 (100.0)	455 (99.3)	343 (85.1)
1-1.99%	61 (3.2)	0 (0.0)	3 (0.7)	58 (14.4)
2-2.99%	2 (0.1)	0 (0.0)	0 (0.0)	2 (0.5)
eGFR (mL/min/1.73m^2)	99.3 (87.9, 113.5)	93.6 (83.7, 104.2)	109.1 (97.9, 120.0)	108.3 (92.8, 123.3)
Albumin Creatinine Ratio (mg/g)	16.0 (5.2, 59.3)	26.2 (6.6, 67.3)	9.3 (5.0, 42.7)	11.0 (4.7, 46.9)
Systolic Blood Pressure (mmHg)	122.0 (113.0, 132.0)	122.0 (113.0, 133.0)	120.0 (112.0, 129.0)	122.0 (114.0, 133.0)
Diastolic Blood Pressure (mmHg)	74.0 (67.0, 80.0)	75.0 (68.0, 80.0)	71.0 (65.0, 78.0)	75.0 (68.0, 82.0)
BMI	27.2 (24.3, 30.1)	26.3 (23.7, 29.4)	27.9 (25.2, 30.6)	28.0 (25.4, 31.2)
Use of anti-hypertensive medications	87 (4.6)	56 (5.4)	15 (3.3)	16 (4.0)
Non-insulin-dependent diabetes	11 (0.6)	6 (0.6)	4 (0.9)	1 (0.2)

Former Smoker	404 (21.3)	265 (25.7)	81 (17.7)	58 (14.4)
Current Smoker	90 (4.8)	56 (5.4)	11 (2.4)	23 (5.7)
Diabetes	6 (0.3)	2 (0.2)	3 (0.7)	1 (0.2)
Hypertension*	99 (5.2)	62 (6.0)	13 (2.8)	24 (6.0)
Depression	167 (8.8)	109 (10.6)	34 (7.4)	24 (6.0)
Anxiety	148 (7.8)	98 (9.5)	30 (6.6)	20 (5.0)
Other Comorbidity	406 (21.4)	234 (22.7)	57 (12.4)	115 (28.5)
No Comorbidities	1,236 (65.3)	639 (61.9)	348 (76.0)	249 (61.8)
Hemoglobin A1c Available	969 (51.2)	480 (46.5)	231 (50.4)	258 (64.0)
Hemoglobin A1c	5.3 (5.1, 5.6)	5.3 (5.1, 5.5)	5.4 (5.2, 5.6)	5.4 (5.1, 5.6)
Blood type				
A	538 (28.4)	326 (31.6)	125 (27.3)	87 (21.6)
B	183 (9.7)	100 (9.7)	27 (5.9)	56 (13.9)
O	1,141 (60.2)	590 (57.1)	301 (65.7)	250 (62.0)
AB	32 (1.7)	17 (1.6)	5 (1.1)	10 (2.5)
Relation to recipient				
Sibling	292 (15.4)	117 (11.3)	106 (23.1)	69 (17.1)
Parent	158 (8.3)	61 (5.9)	51 (11.1)	46 (11.4)
Child	309 (16.3)	132 (12.8)	88 (19.2)	89 (22.1)
Spouse	288 (15.2)	162 (15.7)	77 (16.8)	49 (12.2)
Other family member	258 (13.6)	140 (13.6)	54 (11.8)	64 (15.9)
Non-Related but known to recipient (friend, neighbor, etc)	493 (26.0)	336 (32.5)	74 (16.2)	83 (20.6)
Directed, altruistic (saw an advertisement)	29 (1.5)	24 (2.3)	3 (0.7)	2 (0.5)
Non-Directed, altruistic	67 (3.5)	61 (5.9)	5 (1.1)	1 (0.2)
First Degree Biological Relative	759 (40.1)	310 (30.0)	245 (53.5)	204 (50.6)
Transplant Center				
A	89 (4.7)	43 (4.2)	31 (6.8)	15 (3.7)
B	199 (10.5)	125 (12.1)	17 (3.7)	57 (14.1)
C	45 (2.4)	18 (1.7)	7 (1.5)	20 (5.0)
D	200 (10.6)	91 (8.8)	103 (22.5)	6 (1.5)
E	150 (7.9)	17 (1.6)	4 (0.9)	129 (32.0)

F	642 (33.9)	321 (31.1)	257 (56.1)	64 (15.9)
G	83 (4.4)	53 (5.1)	10 (2.2)	20 (5.0)
H	388 (20.5)	300 (29.0)	7 (1.5)	81 (20.1)
I	98 (5.2)	65 (6.3)	22 (4.8)	11 (2.7)

*Defined as using antihypertensive medications or listed as a comorbidity in medical records

KFRP = Kidney failure risk projection; KFRE = Kidney Failure Risk Equation

Table 2A. 15 year ESRD risk by outcome of the donor evaluation

ESRD 15 Year Risk	Min	p10	p25	p50	p75	p90	Max
Accepted	0.01	0.04	0.08	0.16	0.33	0.63	5.24
Not Accepted	0.01	0.05	0.10	0.20	0.40	0.89	8.01
Donor Withdrew	0.01	0.03	0.06	0.13	0.31	0.61	4.79
Total	0.01	0.04	0.08	0.17	0.34	0.67	8.01

Table 2B. 15 year ESRD risk by ancestry/ ethnicity

ESRD 15 Year Risk	Min	p10	p25	p50	p75	p90	Max
White	0.01	0.05	0.09	0.17	0.33	0.60	8.01
Hispanic	0.01	0.03	0.04	0.08	0.18	0.33	1.45
Black	0.03	0.11	0.18	0.30	0.66	1.37	4.79
Total	0.01	0.04	0.08	0.17	0.34	0.67	8.01

Table 3. Differences in 15 year donor kidney failure risk by ancestry/ ethnicity stratified by donor evaluation outcome

	Accepted			Not accepted			Donor withdrew		
	Risk Ratio	**95% CI**	**p-value**	**Risk Ratio**	**95% CI**	**p-value**	**Risk Ratio**	**95% CI**	**p-value**
Race									
White	1.43	[1.26, 1.62]	<0.001	1.36	[1.07, 1.73]	0.012	1.47	[1.04, 2.06]	0.027
Hispanic		Reference			Reference			Reference	
Black	3.25	[2.71, 3.89]	<0.001	3.12	[2.35, 4.17]	<0.001	3.22	[2.08, 4.96]	<0.001

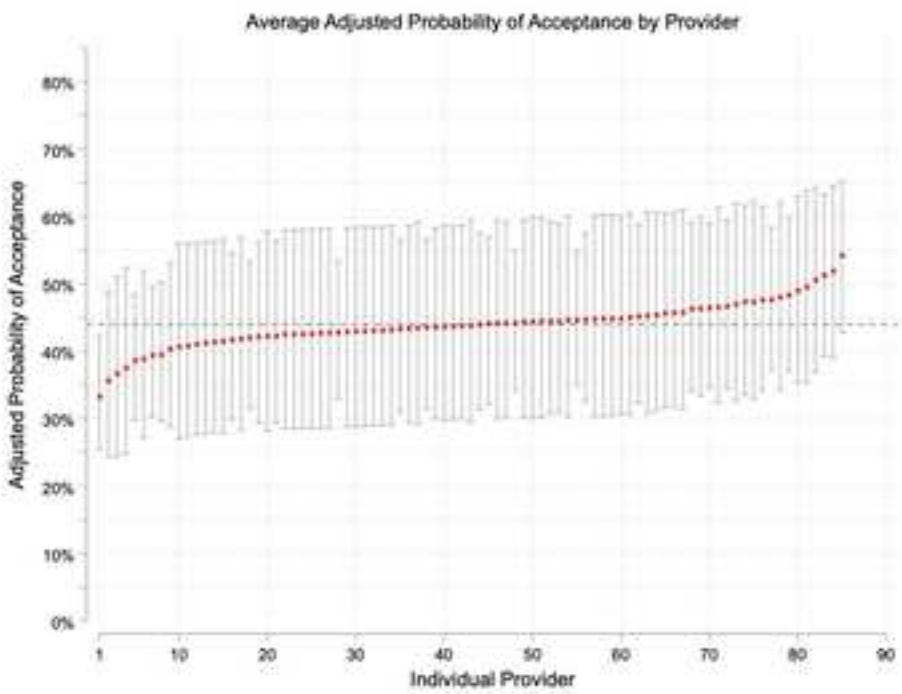
All models account for clustering of patients by provider and transplant center.

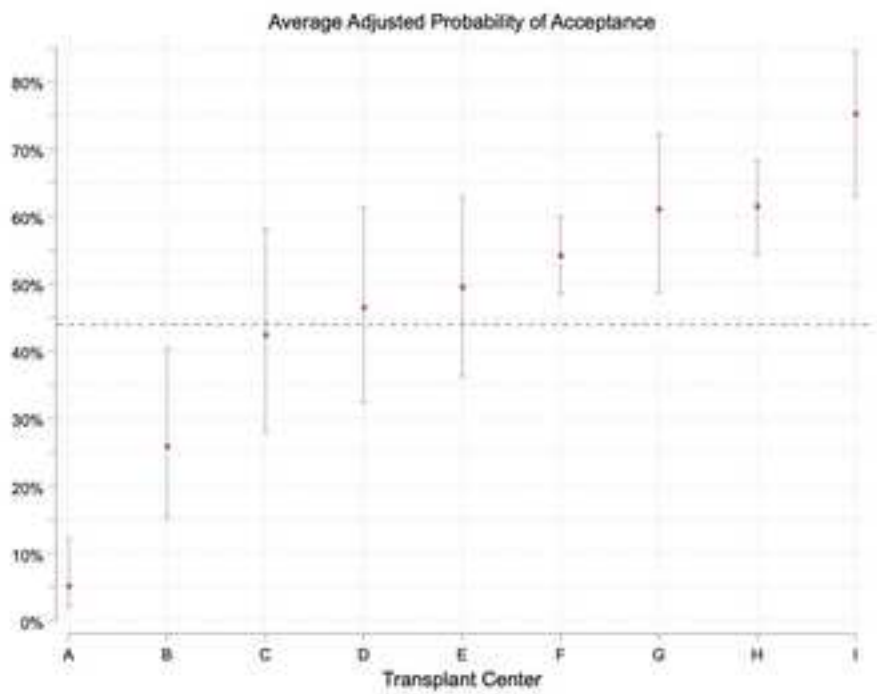
Table 4. Likelihood of donor acceptance by donor 15 year ESRD risk equation

	KFRP			KDRE		
	OR	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
Race						
White	1.47	[1.14-1.89]	0.003	1.45	[1.12-1.86]	0.004
Hispanic		Reference			Reference	
Black	0.81	[0.57-1.16]	0.25	0.96	[0.65-1.41]	0.83

Accounting for clustering of patients by provider and transplant center.

Figure





Declaration of interests

☒The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: