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Brief Communication

Updating the kidney donor risk index: Removing donor race and hepatitis C virus status

Jonathan M. Miller [1,*], Kelley Poff [2], Jesse N. Howell [2], Oscar K. Serrano [3,4], Jim Kim [5], Alejandro Diez [6], Grace R. Lyden [1], Bryn W. Thompson [1], David Zaun [1], Jon J. Snyder [1]

[1] Scientific Registry of Transplant Recipients, Hennepin Healthcare Research Institute, Minneapolis, Minnesota, USA
[2] Organ Procurement and Transplantation Network, United Network for Organ Sharing, Richmond, Virginia, USA
[3] Department of Surgery, Hartford Hospital, Hartford, Connecticut, USA
[4] Department of Surgery, University of Connecticut, Farmington, Connecticut, USA
[5] Department of Surgery, University of Southern California, Los Angeles, California, USA
[6] Department of Medicine, The Ohio State University College of Medicine, Columbus, Ohio, USA

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ABSTRACT

This study reports the results of a recalculation of the kidney donor risk index (KDRI) formula requested by the Organ Procurement and Transplantation Network's Minority Affairs Committee to remove the donor race and hepatitis C virus (HCV) status variables. The updated KDRI model was fit on adult, deceased donor, solitary kidney, first-time transplants from 2018-2021. Deceased donors from 2018 through 2021 were included in a counterfactual analysis to evaluate how the kidney donor profile index (KDPI) would change if race and HCV seropositivity were excluded. When recalculating the original KDRI models on 2018-2021 transplants, the donor Black race coefficient was only slightly lower ($\beta = 0.18$ in the original model; $\beta = 0.15$ in the 2018-2021 cohort), while the donor HCV seropositivity coefficient was substantially lower ($\beta = 0.24$ in the original model; $\beta = -0.04$ in the 2018-2021 cohort). Among Black donors, the probability of being classified as KDPI $\leq$20% increased and the probability of being classified as KDPI >85% decreased notably when the Black race and HCV variables were removed from the model. Removing the donor race and donor HCV status variables in an updated KDRI model resulted in more racially equitable KDPI distributions.

Abbreviations: DAA, direct-acting antiviral; DCD, donation after circulatory death; HCV, hepatitis C virus; KDPI, kidney donor profile index; KDRI, kidney donor risk index; MAC, Minority Affairs Committee; OPTN, Organ Procurement and Transplantation Network; SRTR, Scientific Registry of Transplant Recipients.

* Corresponding author. Scientific Registry of Transplant Recipients, Hennepin Healthcare Research Institute, Minneapolis, MN, USA.
E-mail address: Jonathan.Miller@cdrg.org (J.M. Miller).

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1. Introduction

The kidney donor risk index (KDRI) and its transformation to a percentile scale, the kidney donor profile index (KDPI), are measures of the predicted risk of kidney graft failure that have been used to stratify donor kidneys for allocation since 2014. The KDPI is used in kidney allocation to better match the expected longevity of the donated kidney with the expected longevity of the recipient (ie, a young recipient should be matched with a kidney that is expected to have low risk of short-term failure). The model that provided the equation for the KDRI was published in 2009 and used a cohort of kidney transplants from 1995-2005.[1]

There have been changes in practice in the nearly 20 years since the most recent of the original KDRI cohort transplants. In particular, the original KDRI model included indicators for donor Black race and for donor hepatitis C virus (HCV) status. Since the original analysis, scientific consensus has grown that for metrics of individual patient risk, the average experience in a racial group cannot be assumed to represent the experience of an individual in that group, and therefore, race should not be used as a proxy for more precise biological measures. A number of studies have shown that removing the donor race indicator would not substantially change the predictive ability of the KDRI model but would reduce the overrepresentation of Black donors among the "highest risk" kidneys.[2-5]

Practice has also changed regarding the use of kidneys from HCV-positive donors. Following a 2017 study that demonstrated that direct-acting antiviral (DAA) treatments could be used to allow transplant of kidneys from HCV-positive donors into HCV-negative recipients,[6] the use of HCV-positive organs has increased dramatically and the risk associated with these organs has decreased substantially.[7,8] Given the reduced risk from kidneys from HCV-positive donors, there have been calls to reconsider the inclusion of donor HCV status in the KDRI.[8,9]

In August 2023, the Minority Affairs Committee (MAC) of the Organ Procurement and Transplantation Network (OPTN) requested from the Scientific Registry of Transplant Recipients (SRTR) a recalculation of the KDRI excluding the Black race and HCV status variables for the purpose of updating the equation used to calculate KDRI for kidney allocation. To allow expeditious implementation of the possible removal of donor race and HCV status, the recalculation was constrained to using all other variables as they were in the original analysis. This study reports the methods used and model fit results for the updated OPTN KDRI that excludes the donor race and HCV status variables.

2. Methods

2.1. Study cohort

This study used data from SRTR. The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the OPTN, and has been described elsewhere.[10] The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors. SRTR data are not considered human subjects research, as they are data collected for the federal government for the purpose of public health surveillance. Work performed by the SRTR is, therefore, exempt from institutional review board review as a Public Benefit and Service Program under the Code of Federal Regulations (CFR) at 45 CFR 46.101(b)(5) of the pre-2018 Common Rule, which is now detailed at 46.104(d)(5) as "Research and demonstration projects that are conducted or supported by a Federal department or agency" under the Common Rule 2018 version.

Using exclusion criteria reported in the original analysis,[1] this updated KDRI model was fit on adult, deceased donor, kidney-alone, first transplants from January 1, 2018, through December 31, 2021, with follow-up through December 31, 2022. The model fitting cohort was chosen to include the era after HCV-positive donor to HCV-negative recipient transplants became more common. Therefore, the cohort window is only 4 years, with up to 5 years of follow-up, compared with the 11-year window, with up to 11 years and 4 months of follow-up, in the original analysis. A sensitivity analysis calculating model coefficients and global model fit statistics on an 11-year cohort with up to 12 years of follow-up was conducted to ensure that coefficient inferences were not substantially changed.

To explore how the KDPI would change if the new coefficients were applied, all deceased donors from January 1, 2018, through December 31, 2021, from whom a kidney was procured for the purpose of transplant were included in a counterfactual analysis of KDPI from KDRI calculated with versus without donor race and HCV status included.

2.2. Statistical analysis

To explore external global model fit, the model fitting cohort was split into 80% training and 20% testing datasets using stratified random sampling to account for model stratification on transplant center, age at transplant, and diagnosis of diabetes. Models were estimated in the training dataset first using all the variables originally reported in the original analysis[1] as well as recipient variables selected through backward selection, replicating the variable selection process reported in the original analysis for variables that were not reported but were likely to have been in the original model. Next, models were estimated in the training dataset with all variables except the donor Black race and donor HCV status variables.

Global model fit was assessed in the testing datasets using concordance to estimate model discrimination and the integrated Brier score to estimate model prediction accuracy. A higher concordance represents better model fit, while a lower Brier score represents better model fit. Calibration plots compared observed and predicted probabilities of graft failure by the maximum follow-up time in the test sample (ie, up to 5 years) using the nearest neighbor of the model-predicted survival method and observed survival estimated by the Kaplan-Meier method. Global model fit was compared for the model without Black race and HCV coefficients to the model with all the original covariates, both overall and within strata of donor race, donor HCV status, donor allocation KDPI, recipient sex, and recipient age.

After estimating external global model fit using the training and testing datasets, the models were refit using all transplants in the cohort to estimate the final coefficients. Internal concordance as a measure of global model fit was calculated for these models using all transplants. Coefficients from models with and without the donor Black race and donor HCV variables were compared with percent differences. A negative percent difference means that the coefficient has become a weaker predictor, while a positive percent difference means that the coefficient has become a stronger predictor. An absolute percent change of 10% or more is often considered meaningful. Removing predictors from a model is equivalent to setting their coefficients to 0, so removing the Black race and donor HCV variables means that their percent change would be equivalent to −100%.

Donor-specific coefficients from the models fit on the 2018-2021 cohort were applied to all deceased donors in the counterfactual cohort to estimate KDRI from models both with and without the donor Black race and donor HCV variables. KDPI for each donor was calculated from their KDRI using the OPTN method[11] for mapping KDRI to KDPI; ie, all mapping tables and inputs were recalculated based on the KDRI calculated from our models, as opposed to using published mapping tables that are based on the KDRI calculated from the original models. Numbers and percentages of donors who move between the KDPI sequences used in kidney allocation (0%-20%, 21%-35%, 36%-85%, and 86%-100%) when the Black race and HCV variables are removed were compared overall and for donor race and HCV status subgroups.

Models of kidney nonuse were used to predict changes in numbers and percentages of kidneys not used, overall and for donor race and HCV status subgroups, when the Black race and HCV variables are removed.

3. Results

3.1. Cohort statistics

3.1.1. Model fitting cohort

The model fitting cohort included 50 769 kidney transplants between January 1, 2018, and December 31, 2021. The mean donor age among these transplants was 40.06 years, 13.44% of donors were Black, and 10.72% of donors were HCV positive (either antibody, nucleic acid test, or both) (Table 1).

3.1.2. Counterfactual donor analysis cohort

The counterfactual donor analysis cohort included 46 159 deceased donors between January 1, 2018, and December 31, 2021, with at least one kidney recovered for the purpose of transplant. The mean age among these donors was 40.89 years, 14.76% of donors were Black, and 10.04% of donors were HCV positive (either antibody, nucleic acid test, or both) (Table 2).

3.2. Global model fit

The overall and subgroup-specific external concordances and Brier scores did not change substantially when removing Black donor race and donor HCV status from the model. Among Black

Table 1
Model fitting cohort characteristics.

Variable	
N	50 769
Donor age, y, mean (SD)	40.06 (14.89)
Female donors, n (%)	19 236 (37.89%)
Donor race, n (%)	
Asian	1281 (2.52%)
Black	6824 (13.44%)
Hawaiian/Pacific Islander	137 (0.27%)
Multiracial	227 (0.45%)
Native	396 (0.78%)
White	41 904 (82.54%)
Donor creatinine, mean (SD)	1.33 (1.15)
Hypertensive donors, n (%)	14 977 (29.5%)
Diabetic donors, n (%)	4184 (8.24%)
Donors with stroke death, n (%)	11 539 (22.73%)
Donor height, cm, mean (SD)	169.95 (14.39)
Donor weight, kg, mean (SD)	81.98 (21.57)
DCD donors, n (%)	14 564 (28.69%)
Donor HCV status, n (%)	
Positive: NAT and antibody	3206 (6.31%)
Positive: NAT only	103 (0.2%)
Positive: Antibody only	2139 (4.21%)
Not positive	45 321 (89.27%)
HLA-B mismatches	
No mismatches	3285 (6.47%)
1 mismatch	12 415 (24.45%)
2 mismatches	35 069 (69.08%)
HLA-DR mismatches	
No mismatches	7837 (15.44%)
1 mismatch	24 767 (48.78%)
2 mismatches	18 165 (35.78%)
Cold ischemic time, mean (SD)	18.51 (8.37)
Transplant type	
En bloc	373 (0.73%)
Double	421 (0.83%)
Recipient age, y, mean (SD)	54 (13.24)
Female recipients, n (%)	20 200 (39.79%)
Recipient diagnosis, n (%)	
Cystic kidney disease	5085 (10.02%)
Diabetes	17 262 (34%)

(*continued on next page*)

Table 1 (*continued*)

Variable	
Glomerulonephritis	7748 (15.26%)
Hypertension	13 134 (25.87%)
Other/unknown	7540 (14.85%)
Recipient blood type, n (%)	
A	17 405 (34.28%)
AB	2593 (5.11%)
B	7400 (14.58%)
O	23 371 (46.03%)
Recipient weight, kg, mean (SD)	83.5 (19.64)
Recipient dialysis, y, mean (SD)	4.52 (3.45)
Recipient PVD, n (%)	6194 (12.2%)
Recipient COPD, n (%)	86 (0.17%)
Recipient HCV, n (%)	1904 (3.75%)
Recipient race, n (%)	
Asian	4053 (7.98%)
Black	17 830 (35.12%)
Hawaiian/Pacific Islander	288 (0.57%)
Multiracial	456 (0.9%)
Native	484 (0.95%)
White	27 658 (54.48%)
Diabetic recipient, n (%)	20 304 (39.99%)
HIV-positive recipient, n (%)	912 (1.8%)
Recipient cPRA: mean,(SD)	0.19 (0.32)

Cohort dates are January 1, 2018-December 31, 2021. Recipient and donor race are reported by transplant centers and organ procurement organizations respectively to the Organ Procurement and Transplantation Network on the Transplant Recipient Registration and Deceased Donor Registration forms.
cPRA, calculated panel-reactive antibody; COPD, chronic obstructive pulmonary disease; DCD, donation after circulatory death; HCV, hepatitis C virus; NAT, nucleic acid test; PVD, peripheral vascular disease; HLA, human leukocyte antigen.

donors, the concordance was lower than among non-Black donors; however, the difference in concordance between Black and non-Black donors did not worsen when removing donor race and HCV status from the models (Supplementary Table 1).

While the calibration plots highlighted some of the limitations of the overall KDRI/KDPI measure—in particular, that the model tends to overestimate the risk in the "highest risk" donors—there was no evidence from the comparison of the calibration plots that removing donor race and HCV status would have any substantial impact on the goodness of the model fit, either overall (Fig. 1) or in any of the donor or recipient subgroups (Supplementary Figs. S1-5).

When fitting the model on all observations in the cohort, the internal concordance overall and among the strata by race and HCV status was approximately 0.6 and did not change substantially when race and HCV status variables were removed from the model fitting (Supplementary Table 2).

Table 2
Counterfactual donor analysis cohort characteristics.

Variable	
N	46 159
Donor age, y, mean (SD)	40.89 (16.45)
Female donors, n (%)	17 786 (38.53%)
Donor race, n (%)	
Asian	1144 (2.48%)
Black	6811 (14.76%)
Hawaiian/Pacific Islander	144 (0.31%)
Native	324 (0.7%)
White	37 517 (81.28%)
Multiracial	219 (0.47%)
Donor creatinine, mg/dl, mean (SD)	1.46 (1.36)
Hypertensive donors, n (%)	15 677 (33.96%)
Diabetic donors, n (%)	5255 (11.38%)
Donors with stroke death, n (%)	11 428 (24.76%)
Donor height, cm, mean (SD)	168.57 (18.28)
Donor weight, kg, mean (SD)	82.65 (25.99)
DCD donors, n (%)	12 124 (26.27%)
Donor HCV status, n (%)	
Positive: NAT and antibody	2695 (5.84%)
Positive: NAT only	92 (0.2%)
Positive: Antibody only	1845 (4%)
Not positive	41 527 (89.97%)

Cohort dates are January 1, 2018–December 31, 2021. Donor race is reported by organ procurement organizations to the Organ Procurement and Transplantation Network on the Deceased Donor Registration form.
DCD, donation after circulatory death; HCV, hepatitis C virus; NAT, nucleic acid test.

3.3. Comparison of coefficients

Compared with the original 2009 coefficients,[1] when recalculating the original KDRI models on the cohort of transplants from 2018-2021, the donor Black race coefficient was only slightly lower, while the donor HCV-positive status coefficient was substantially lower and was no longer statistically significant, consistent with the change in treatment of recipients of HCV-positive donor kidneys. Donor diabetes status and donor donation after circulatory death (DCD) status were notably stronger predictors of graft survival in the 2018-2021 cohort compared with the 2009 analysis. When the donor Black race and donor HCV status variables were removed, among the remaining variables, only the coefficient for 2 human leukocyte antigen mismatches at the DR locus and the indicator for transplant year 2019 coefficients changed >10%, although the absolute change for each of these coefficients was small. All coefficients for the remaining donor-specific variables, which are used in the calculation of KDRI for the purpose of organ allocation excluding recipient-specific variables, changed less than 10% (Fig. 2).

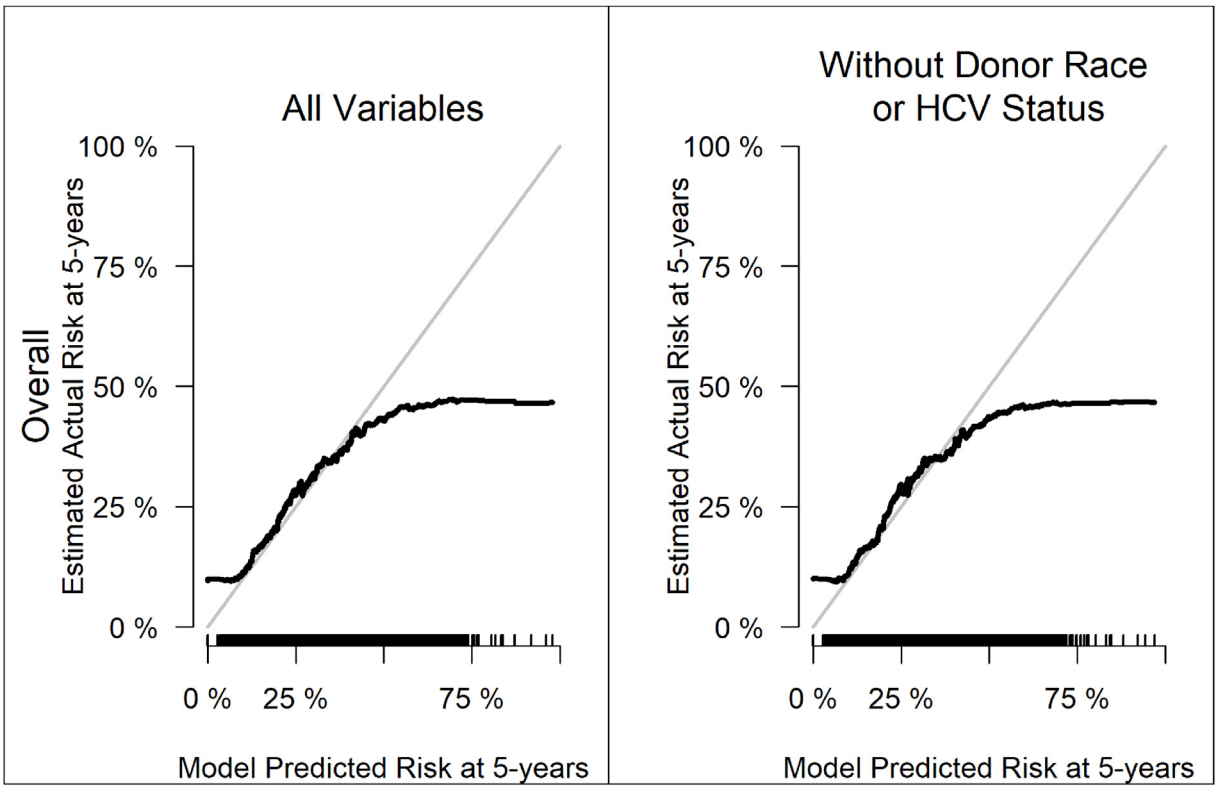

Figure 1. Overall calibration plots for the model with all variables and the model with donor race and HCV status excluded. HCV, hepatitis C virus.

Variable	Original Coefficients	Recreation of Original Coefficients	Recreation without Race and HCV Variables	Percent Change without Race and HCV
Donor Age Less than 18 spline	-0.0194	0.0125	0.0113	-9.68
Donor Age	0.0128	0.0097	0.0092	-5.41
Donor Age greater than 50 spline	0.0107	0.0063	0.0067	5.87
Donor Black Race	0.1794	0.1534		-100
Donor Creatinine	0.2198	0.1962	0.2128	8.43
Donor Creatinine greater than 1.5 spline	-0.2093	-0.2027	-0.2199	8.48
Donor Hypertension	0.1262	0.1017	0.1106	8.82
Donor Diabetes	0.1301	0.2528	0.2577	1.91
Cause of Donor Death: Stroke	0.0881	0.0685	0.0743	8.53
Donor Height	-0.0464	-0.0571	-0.0557	-2.37
Donor Weight less than 80 spline	-0.0199	-0.0332	-0.0333	0.35
Donation after Cardiac Death	0.1329	0.2022	0.1966	-2.77
Donor HCV Positive	0.2403	-0.0405		-100
Zero HLA-B mismatches	-0.0766	-0.0693	-0.0759	9.43
One HLA-B mismatch	-0.061	-0.0543	-0.0542	-0.19
Zero HLA-DR mismatches	-0.13	-0.0683	-0.0698	2.14
Two HLA-DR mismatches	0.0765	0.0103	0.0139	33.96
Cold Ischemia Time	0.0055	0.0094	0.0093	-0.53
Enbloc Transplant	-0.364	-0.1915	-0.1925	0.53
Double Kidney Transplant	-0.148	-0.2338	-0.2208	-5.56
Recipient Black Race		0.1286	0.1347	4.73
Recipient Diagnosis: Diabetes		0.2669	0.2685	0.62
Recipient Diagnosis: Glomerulonephritis		0.1702	0.1708	0.31
Recipient Diagnosis: Hypertension		0.141	0.1426	1.11
Recipient Diagnosis: Other		0.2802	0.2806	0.14
Recipient Sex: Male		0.0779	0.0773	-0.84
Recipient Weight		0.0047	0.0047	-0.43
Recipient cPRA		0.1904	0.1983	4.12
Recipient Years on Dialysis		0.0458	0.0467	1.93
Recipient PVD		0.2634	0.263	-0.17
Recipient Age		0.0092	0.0092	0.93
Transplant Year: 2019		-0.0033	-0.0063	93.37
Transplant Year: 2020		0.1717	0.1697	-1.18
Transplant Year: 2021		0.0982	0.0959	-2.31

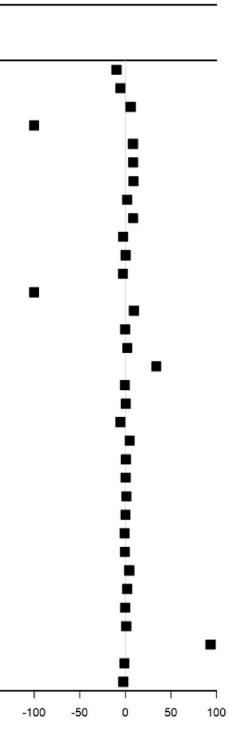

Figure 2. Original and updated KDRI coefficients. Recipient and donor race are reported by transplant centers and organ procurement organizations, respectively, to the Organ Procurement and Transplantation Network on the Transplant Recipient Registration and Deceased Donor Registration forms. cPRA, calculated panel-reactive antibody; HCV, hepatitis C virus; KDRI, kidney donor risk index; PVD, peripheral vascular disease; HLA, human leukocyte antigen.

The donor diabetes status and donor DCD status coefficients were not as strong in the updated 11-year cohort of transplants from 2011-2021 compared with the 2018-2021 cohort of transplants. To better understand the reason the diabetes and DCD coefficients were stronger in the 5-year cohort than the 11-year cohort, a post hoc analysis of the proportional hazards assumption was performed that showed that the DCD status variable violated the proportional hazards assumption for both the 2011-2021 ($P = .01$) and the 2018-2021 ($P = .000007$) cohorts. Unadjusted Kaplan-Meier graft survival curves of DCD donors compared with donation after brain death donors in the 2011-2021 cohort showed that the difference in risk seems to be somewhat greater between DCD and donation after brain death donors in the early years posttransplant and somewhat less in the later years posttransplant (Supplementary Fig. S6, Supplementary Table 3).

3.4. Comparison of KDPI

Among Black donors, the probability of being classified as KDPI ≤20% increased notably and the probability of being classified as KDPI >85% decreased notably when the Black race and HCV variables were removed from the model fit. Among HCV-positive donors, there were decreases in the probability of being classified as KDPI ≤20% when the Black race and HCV variables were removed from the model fitting, although this comparison is in the updated cohort in which HCV is not significant, and the change from the HCV coefficient currently in policy, which is significant, should be monitored (Supplementary Table 4).

3.5. Comparison of nonuse

The overall predicted change in kidney nonuse if model coefficients without the race and HCV variables had been used from 2018-2021, compared with the model coefficients with these 2 variables, was very small, at 7.55 more predicted nonused kidneys. The additional predicted nonused kidneys would have been among HCV-positive donors, while a decrease in nonuse among Black donors of 38.89 kidneys would have been offset by a small increase in nonuse among non-Black donors of 46.44 kidneys (Table 3).

Table 3
Observed kidney nonuse from 2018-2021 and predicted numbers of nonuse change when removing race and HCV.

Variable	Observed nonuse: 2018-2021	Predicted change in no. nonuse when removing race and HCV
Overall	19 136 (21.26%)	7.55
Race		
Black	3238 (24.51%)	−38.89
Non-Black	15 898 (20.7%)	46.44
HCV status		
Positive	1501 (27.15%)	6.92
Not positive	17 635 (20.87%)	0.63

Donor race is reported by organ procurement organizations to the Organ Procurement and Transplantation Network on the Deceased Donor Registration form. HCV, hepatitis C virus.

4. Discussion

This study found that coefficients from an updated KDRI model refit on transplants from 2018-2021 and removing the donor Black race and donor HCV status variables resulted in more racially equitable KDPI distributions and relatively little predicted difference in kidney nonuse. In particular, in this cohort of transplants, from an era when DAA treatment was common to allow HCV-negative candidates to accept kidneys from HCV-positive donors, HCV is no longer a significant predictor of graft failure. Removing race and HCV status from the calculation of KDRI does not substantially affect model discrimination and calibration, and Black donors would no longer be substantially overrepresented as the "most risky" kidneys.

The OPTN MAC requested these analyses in August 2023 to support decision making about changing the KDRI and KDPI calculation for kidney and kidney–pancreas allocation policy to remove the donor race and donor HCV status variables. These analyses were submitted by SRTR to the OPTN MAC in September 2023. This policy-making process was initiated in response to growing support in the scientific literature for removing the donor race[2-5] and HCV status[9] variables from the calculation of KDRI. The policy proposal that was informed by this analysis was part of the OPTN public comment period from January 23, 2024, to March 19, 2024. Feedback from the public comment period was supportive of this policy change, and a few additional analyses were requested, particularly additional subgroups in which to examine discrimination and calibration; these were reported to the OPTN MAC as an addendum report in March 2024. This policy change was approved by the OPTN Board of Directors on June 17, 2024, and is currently pending implementation.

This policy-making process was specifically limited to recalculating KDRI coefficients without the donor race and donor HCV status while keeping all other variables in the model in the form they had been used in the original[1] analysis—again, in an era when DAAs were commonly used to allow transplant of kidneys from HCV-positive donors to HCV-negative candidates. While this policy-making process could not address the broader concerns around KDRI, particularly the relatively low discrimination of the model, by fully recalculating a donor risk model, some of the findings from this study may be useful for undertaking such a recalculation in the future.

The report of the original analysis only included an examination of model discrimination overall and in a small set of subgroups and did not examine calibration whatsoever. The present analysis confirms that the calibration of the KDRI model is relatively weak among the lowest risk and the highest risk donors and that discrimination is weaker in the low-KDPI and high-KDPI categories. This may reflect overfitting in the original model building, particularly with a very large number of stratifying variables used. Given

the demonstrated "labelling effect," whereby higher KDPI kidneys have higher rates of nonuse,[12,13] future analyses to improve donor risk models should focus on improving calibration in the higher risk donors or, at a minimum, better communicating poor calibration in this group. The calibration in the high- and low-risk groups reflects how well the model predicts graft failure among patients in those groups, so for the purposes of this study, it is encouraging that the calibration in the high- and low-risk groups does not seem to demonstrably change with the notable movement of Black donors out of the higher risk groups and into the lower risk groups.

This study also found that the KDRI coefficient for DCD donors violates the proportional hazards assumption—meaning that the coefficient for a 11-year cohort model may not accurately reflect the risk for a 5-year cohort model. Future analyses to improve donor risk models should carefully consider such nonproportionality in hazards. As the DCD donor and donor diabetes coefficients are stronger in the present study than in the original or with a long follow-up period, postimplementation monitoring of a policy to remove donor race and HCV status should also monitor the use of kidneys from donors with diabetes and from DCD donors for any unintended consequences.

Improving prediction of donor risk should be an ongoing process and should continually be adjusted to changing clinical practice. Although the present study was not meant to address all the limitations of the current KDRI and KDPI, it does support policy changes that can be made quickly to improve equity in the prediction of risk from deceased kidney donors as longer-term efforts to improve risk prediction continue.

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Declaration of competing interest

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

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajt.2025.01.015.

ORCiD

Jonathan M. Miller https://orcid.org/0000-0002-9562-7337
Jesse N. Howell https://orcid.org/0009-0004-6700-437X
Oscar K. Serrano https://orcid.org/0000-0001-5076-0938
Jim Kim https://orcid.org/0000-0003-4466-5517
Alejandro Diez https://orcid.org/0000-0002-9576-5422
Grace R. Lyden https://orcid.org/0000-0003-1408-851X
David Zaun https://orcid.org/0000-0003-3787-2470
Jon J. Snyder https://orcid.org/0000-0001-7974-8940

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