

Effects of High-Risk Kidneys on Scientific Registry of Transplant Recipients Program Quality Reports

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There is a perception that transplanting high-risk kidneys causes programs to be identified as underperforming, thereby increasing the frequency of discards and diminishing access to transplant. Thus, the Organ Procurement and Transplantation Network (OPTN) has considered excluding transplants using kidneys from donors with high Kidney Donor Profile Index (KDPI) scores (≥ 0.85) when assessing program performance. We examined whether accepting high-risk kidneys (KDPI ≥ 0.85) for transplant yields worse outcome evaluations. Despite a clear relationship between KDPI and graft failure and mortality, there was no relationship between a program's use of high-KDPI kidneys and poor performance evaluations after risk adjustment. Excluding high-KDPI donor transplants from the June 2015 evaluations did not alter the programs identified as underperforming, because in every case underperforming programs also had worse-than-expected outcomes among lower-risk donor transplants. Finally, we found that hypothetically accepting and transplanting additional kidneys with KDPI similar to that of kidneys currently discarded would not adversely affect program evaluations. Based on the study findings, there is no evidence that programs that accept higher-KDPI kidneys are at greater risk for low performance evaluations, and risk aversion may limit access to transplant for candidates while providing no measurable benefit to program evaluations.

Abbreviations: CMS, Centers for Medicare & Medicaid Services; KDPI, Kidney Donor Profile Index; KDRI, Kidney Donor Risk Index; MPSC, Membership and Professional Standards Committee; OPTN, Organ

Procurement and Transplantation Network; PSR, program-specific report; SRTR, Scientific Registry of Transplant Recipients

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Introduction

Every 6 months, the Scientific Registry of Transplant Recipients (SRTR) produces program-specific reports (PSRs) on kidney transplantation in the United States (1). Adjusted 1-year patient and graft survival measures are used by the Organ Procurement and Transplantation Network (OPTN) Membership and Professional Standards Committee (MPSC) and by the Centers for Medicare & Medicaid Services (CMS) to identify programs that may be underperforming and require further review. In addition, private insurance providers may use PSRs to identify programs for contracting, and patients may use PSRs to help them select programs.

Although PSR results are adjusted for many donor and recipient factors known to adversely affect transplant outcomes, widespread belief persists that a program's PSR outcomes are adversely affected by transplanting kidneys expected to produce worse graft and patient survival (2,3). "Fear of flagging" has been cited as a major reason for the increasing numbers of deceased donor kidneys discarded every year. In 2012, a consensus conference considered whether PSRs should include only low-risk transplants (4). An OPTN *ad hoc* committee also considered whether some transplants should be excluded from the PSRs to prevent discouraging programs from accepting high-risk kidneys (5). More recently, the MPSC has been considering alternative methods to identify underperforming transplant programs that do not discourage programs from using high-risk kidneys. On December 1, 2015, the OPTN Board of Directors passed a resolution to form a work group to improve the methods used by the MPSC to ensure program quality and reduce disincentives to transplanting high-risk organs.

At the request of the MPSC, SRTR examined possible ways the PSRs could be used to identify programs that may be underperforming, while also combatting the

perception that transplanting kidneys from high-risk donors increases a program's likelihood of being identified as underperforming. The kidney donor profile index (KDPI) is used in the kidney allocation system to summarize deceased kidney donor risk based on measured risk factors. It has been the focus of current efforts to exempt transplants using high-KDPI kidneys from program evaluations. Using the June 2015 evaluation cohort, we examined three questions:

- (1) Does transplanting kidneys from high-KDPI donors increase the chances that a program will be identified as underperforming?
- (2) Would additionally requiring underperformance on standard-risk transplants substantially alter which programs are identified as underperforming?
- (3) Would accepting kidneys that are currently discarded put programs at risk?

We found that (1) the proportion of high-KDPI transplants is not associated with a higher likelihood of worse outcomes evaluations; (2) removing high-KDPI donor transplants from the evaluation does not alter which programs are identified for review; and (3) accepting organs that are currently discarded would not systematically negatively affect program evaluations. Although these analyses are limited to kidney transplants, similar issues apply to other organs.

Materials and Methods

Data analyzed

The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of OPTN, and has been described elsewhere (6). The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

Institutional review

This study was conducted by SRTR under contract using SRTR data with review and approval by the US Department of Health and Human Services, and it is not subject to institutional review.

Patient population

Transplants in patients aged 18 years or older, January 1, 2012, through June 30, 2014, were included (the June 2015 PSR cohort). Patients aged younger than 18 years were excluded because they are not included in the adult program evaluations performed by the MPSC or CMS. Multi-organ transplants, defined as receiving more than one organ from the same deceased donor, were also excluded per standard PSR methodologies.

Study variables and program-specific report models

The methodology for determining the risk adjustment models that SRTR uses to evaluate program outcomes has recently been described in detail (7). Briefly, OPTN data were used to construct Cox proportional hazards models for patient and graft survival in the United States. The OPTN data were supplemented with data from CMS. Separate models

were constructed for deceased and living donor transplants and for adult (age 18 years or older) and pediatric (age younger than 18 years) transplants. New kidney models were recently built; these models were used in the June 2015 PSRs and in the current analysis. The variables used in these models are shown here: <http://www.srtr.org/csr/current/modtabs.aspx>.

Expected counts of graft failures and patient deaths are calculated for each transplant program at 1 year and compared with observed graft failures and patient deaths. These counts are used to construct the program's Bayesian hazard ratio (i.e. how much higher or lower the program's graft failure or death counts are than expected) (8,9). The PSRs are published online (<http://www.srtr.org/csr/current/Centers/Default.aspx>) every June and December.

OPTN and CMS use combined deceased and living donor transplants to identify underperforming programs. Formerly, OPTN and CMS both used the following criteria to identify programs for review: (1) observed/expected events >1.5; (2) observed minus expected events >3; (3) one-sided p-value < 0.05. However, starting in December 2014, OPTN began using a Bayesian methodology to identify underperforming programs as described below.

Statistical analysis

We examined 1-year graft and patient survival. A graft is counted as failed when follow-up information indicates that one of the following events occurred before the reporting time point: (1) graft failure, (2) retransplant, or (3) death. The OPTN follow-up forms are used to identify graft failure and retransplant dates. Transplants performed in the last 6 months of the accrual period for the 1-year reporting time point are followed for only 6 months posttransplant because the 1-year follow-up information is not yet available in the current OPTN data. Standard survival analysis methods are used to incorporate the first 6 months of experience for this subset of patients.

Donor risk was estimated using the kidney donor risk index (KDRI) (10). "High-risk" donors were classified as the top 15% of donors as measured by the KDRI, analogous to a KDPI of 85% or higher used in the OPTN kidney allocation policy effective December 2014.

Observed event counts were compared with expected event counts as derived from the risk adjustment models. Observed and expected event counts were converted to estimated hazard ratios using the Bayesian methodology adopted by SRTR in 2014 (8). Programs meeting the MPSC review criteria (9) were identified as those with:

- (1) The probability that the hazard ratio is >1.2 is >75%, or
- (2) The probability that the hazard ratio is >2.5 is >10%.

An alternative flagging algorithm considered by the MPSC requires a program to additionally meet the identification algorithm on standard-risk recipients alone to receive an inquiry:

- (1) The program meets the standard MPSC review criteria based on all transplant recipients, and
- (2) The program meets the MPSC review criteria based on transplants from donors with KDPI lower than 0.85 and age younger than 65 years.

A "safety net" would also be implemented to consider the high-risk donors alone (KDPI \geq 0.85 or age \geq 65 years). If the program met the criteria for the high-risk cases alone, it would also receive an inquiry from MPSC. We evaluated which programs would be identified for review

using this algorithm compared with the standard MPSC criteria. Analyses presented considered high-risk donors as KDPI of 85% or greater, but main results were unchanged when the donor age criterion was included.

Simulating potentially adverse effects of transplanting currently discarded kidneys

We investigated the potential impact of transplanting discarded kidneys on program evaluations by matching each discarded kidney to an actually transplanted kidney with the nearest KDPI and donor age. The outcome of the hypothetical transplant of the discarded kidney was assumed to be identical to the outcome of the actual transplant of the matched kidney. In other words, the analysis assumed that programs would transplant discarded kidneys into recipients similar to recipients of similar organs in the past and would achieve similar outcomes. Programs were then evaluated on their performance including actual transplants plus the hypothetical transplants of the discarded kidneys. The effect of discarded kidneys on program evaluation will depend on their allocation across programs because increasing the number of transplanted kidneys will also increase the power to detect underperforming centers; therefore, we considered two potential scenarios for the allocation of discarded kidneys:

- (1) Programs received a matched kidney proportional to their current probability of accepting a high-risk kidney among all completed high-risk kidney transplants. This scenario acknowledges that some programs are more likely than others to perform transplants with high-risk kidneys, and that this behavior would not change if discarded kidneys were instead transplanted.
- (2) Programs received a matched high-risk kidney proportional to their total number of performed transplants. This scenario assumes that the perceived disincentive to perform transplants with high-risk kidneys no longer exists and that all programs are equally likely to perform a transplant with a high-risk kidney.

For each transplant program, the observed and expected numbers of events for low-risk and high-risk deceased donor kidneys under the two allocation scenarios was estimated by simulating the allocation of matched kidneys and averaging across the simulated observed and expected numbers of events. We simulated allocation 2000 times for both scenarios.

Results

This analysis evaluated 229 adult kidney transplant programs included in the June 2015 PSR evaluation. First-year outcomes were evaluated using adult transplants performed January 1, 2012, through June 30, 2014; the average KDPI during this evaluation cycle was 42% (interquartile range 38–49%).

High-KDPI kidneys ($\geq 85\%$) were more often transplanted into older recipients and recipients with worse expected posttransplant survival (EPTS, as used in the current kidney allocation system) scores. The average age of recipients of high-KDPI kidneys was 62 years, versus 53 years for recipients of low-KDPI kidneys ($< 85\%$; $p < 0.0001$). Additionally, EPTS was high (≥ 80 th percentile of risk) for 40% of recipients of high-KDPI kidneys and for only 20% of recipients of low-KDPI kidneys.

Effect of measured donor risk on program performance evaluations

There was a clear relationship between donor risk, as assessed by the KDPI, and risk of graft failure and recipient death; the higher the KDPI, the greater the risk of graft failure (Figure 1, left panels). However, this association was no longer evident after applying the SRTR risk-adjustment models (Figure 1, right panels), confirming that the PSR models efficiently adjust for the risk of graft failure and recipient death based on measured donor characteristics. We compared the adjusted risk for graft failure in the PSRs across programs with different proportions of high KDPI transplants ($\geq 85\%$) (Figure 2), and found no relationship between a program's hazard ratios for graft or patient survival and the proportion of high-risk donor transplants performed at the program.

Effect of limiting program performance assessment to low-risk donor transplants

We examined a hypothetical change to the flagging algorithm that would also require programs to meet the flagging requirement for their low-risk donor transplants or their high-risk donor transplants when evaluated separately. We examined the numbers of programs that would be identified based on the current MPSC criteria applied to all transplants, and the number identified by low-risk transplants alone, high-risk transplants alone, or criteria that would require the program to flag on all transplants *plus* either the low-risk or high-risk subsets alone (Table 1).

The current algorithm (criteria applied to all transplants) identifies 19 programs for poor graft survival outcomes, and the algorithm that would require the program to also flag based on either its low-risk donors or high-risk donors would flag the same 19 programs (Table 1). The current patient survival evaluation identifies 21 programs for review, and the proposed algorithm would identify 20; however, as the program that avoided the patient survival flag was also flagged for graft survival, the overall number of flagged programs remained at 30. The same 30 programs were identified for MPSC review under the proposed change. In addition, all programs flagged for review based on all of their transplants (current system) had worse than expected outcomes for low-risk donor transplants alone (Figure 3, all flagged programs are to the right of the vertical lines at 1.0) and most had poor performance for both low-risk donor and high-risk donor transplants (Figure 3, upper-right quadrants).

We performed a power analysis to assess the probability that the current flagging system would flag a program for poor performance based on high-risk donor transplants if its low-risk donor performance was as expected. The probability that the current system would flag a pro-

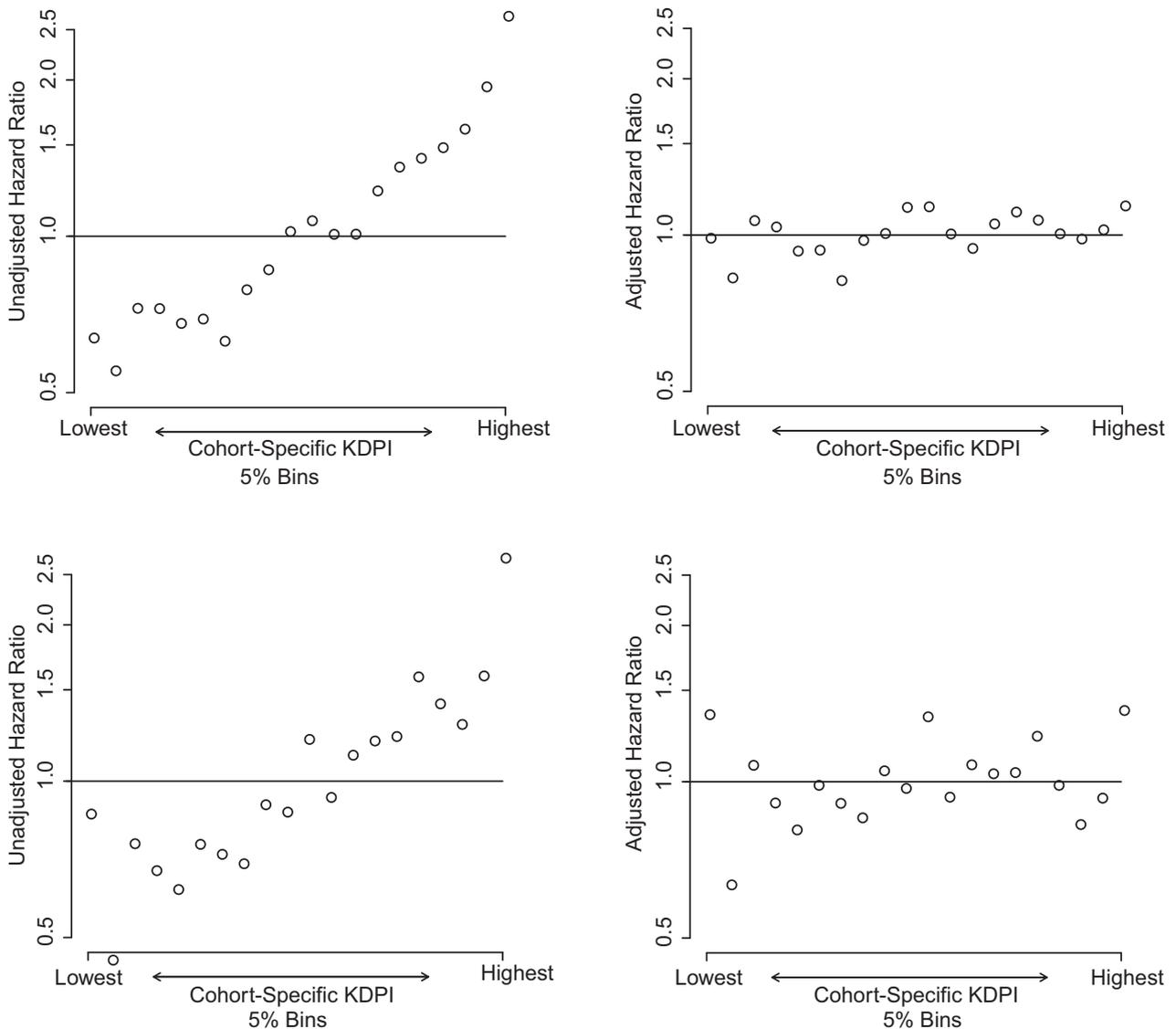


Figure 1: Unadjusted (left panels) and adjusted (right panels) hazard ratios for graft failure (top panels) and patient death (bottom panels) across the range of KDPI for deceased donor kidneys transplanted into adult recipients. KDPI, Kidney Donor Profile Index.

gram with a 60% higher failure rate than expected for its high-risk donor transplants (hazard ratio 1.60) when its low-risk donor transplants were as expected was <10% (Figure 4). The highest observed hazard ratio for high-risk donor transplants was just under 2.0 (Figure 4, tick marks along the x-axis). Even at this extreme hazard ratio of 2.0, the probability that the current system would flag the program would be just 11% if the program is performing as expected with low-risk donor transplants.

Effect on program performance of transplanting currently discarded kidneys

Despite a proportionally larger increase in high-risk donor transplants by including discarded kidneys in the

PSR analysis, the correlation between the current PSR hazard ratios and the hazard ratios including the discard analysis was >0.98 for graft and patient survival (data not shown). This suggests that program evaluations would remain largely unchanged if programs transplanted discarded kidneys into recipients similar to current recipients of high-risk kidneys, and the programs would achieve outcomes with the discarded kidneys similar to outcomes of current high-risk donor transplants. Results were similar regardless of whether we allocated these kidneys only to programs that had performed similar transplants in the past or proportionally across all transplant programs. Finally, after the discarded kidneys were included, the correlation between

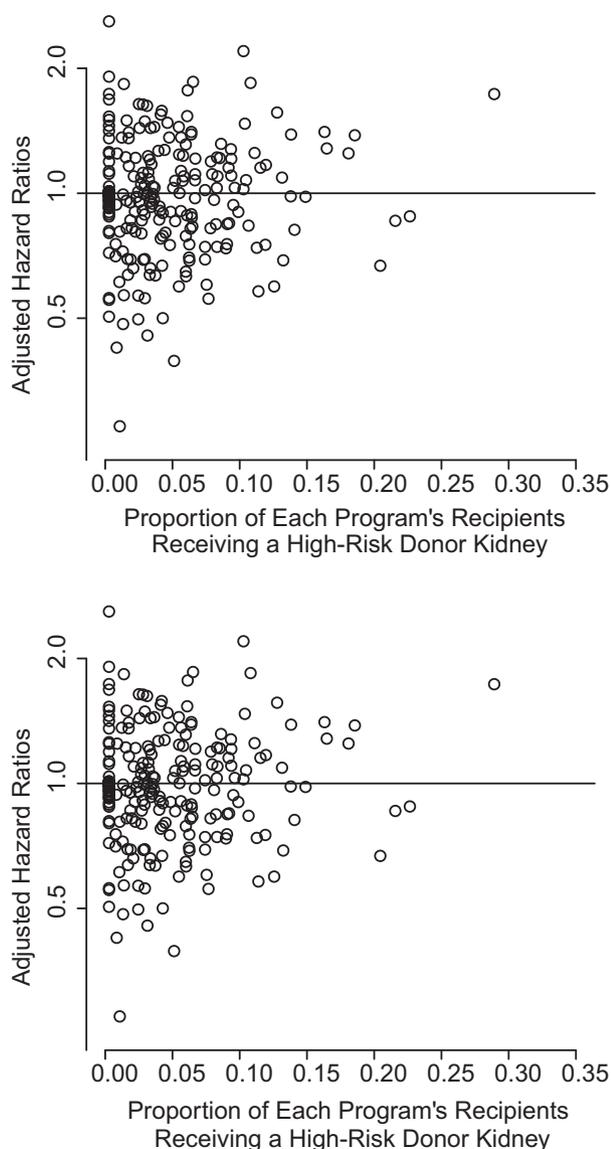


Figure 2: Adjusted hazard ratios for graft survival (top panel) and recipient survival (bottom panel) based on the proportion of each program's transplants that were from high-risk donors (KDPI ≥ 85). Hazard ratios include both deceased and living donor recipients per standard Organ Procurement and Transplantation Network methods for performance evaluation. Living donor recipients were assumed to be low-risk transplants and were not counted in the high-risk donor proportions. KDPI, Kidney Donor Profile Index.

the hazard ratio for low-risk donor transplants and the hazard ratio for all transplants was >0.94 (data not shown). This suggests that low-risk donor transplants rather than high-risk donor transplants would remain the key determinant in program evaluation even if every discarded kidney were transplanted, which is unlikely since many kidneys are discarded for reasons beyond simply a high KDPI.

Table 1: Numbers of programs flagged for graft and patient survival for the various combinations of flagging criteria

Donor population for applying review criteria	Graft survival	Patient survival	Overall
All transplants ¹	19	21	30
Low-risk donor transplants alone ²	20	19	31
High-risk donor transplants alone ³	9	13	17
All transplants + (low- or high-risk donor transplants alone) ⁴	19	20	30
All transplants + low-risk donor transplants alone ⁵	17	16	25
All transplants + high-risk donor transplants alone ⁶	2	5	7

KDPI, Kidney Donor Profile Index.

¹Criteria applied to all transplants (current).

²Criteria applied *only* to transplants from donors with KDPI <85 (low-risk donors).

³Criteria applied *only* to transplants from donors with KDPI ≥ 85 (high-risk donors).

⁴Criteria applied to all transplants *and* criteria applied to transplants from either low-risk donor transplants alone *or* high-risk donor transplants alone.

⁵Criteria applied to all transplants *and* criteria applied to low-risk donors.

⁶Criteria applied to all transplants *and* criteria applied to high-risk donors.

Discussion

It is widely believed that the threat of poor PSR outcomes causes programs to avoid accepting high-KDPI kidney donors, thereby impairing access to transplant for many suitable candidates with end-stage renal disease. An informal survey at the 17th Annual United Network for Organ Sharing Transplant Management Forum in 2009 found that respondents from low-performing centers were more likely to use more stringent selection criteria for candidates and donors due to the threat of poor performance classification (11). Whether rational or irrational, this effect of limiting access to transplant, even at poorly performing programs, may be detrimental to patients (12). Programs identified as underperforming have been shown to decrease the numbers of transplants they perform (13), but it is less clear whether the threat of underperforming in the PSRs causes programs to preferentially reduce high-KDPI versus low-KDPI transplants.

The most important finding of this study is that accepting high-risk donors as summarized by the KDPI does not adversely affect risk-adjusted PSR outcomes, and does not increase the likelihood of identifying programs for regulatory oversight, or "flagging." Rather, the PSR models are doing a reasonably good job of adjusting for donor risk, at least to the extent that the risk is reflected by the data currently collected by OPTN. These results also strongly suggest that avoiding high-risk donors based on KDPI (or other factors included in the risk adjustment) is a flawed strategy that will not improve PSR outcomes or

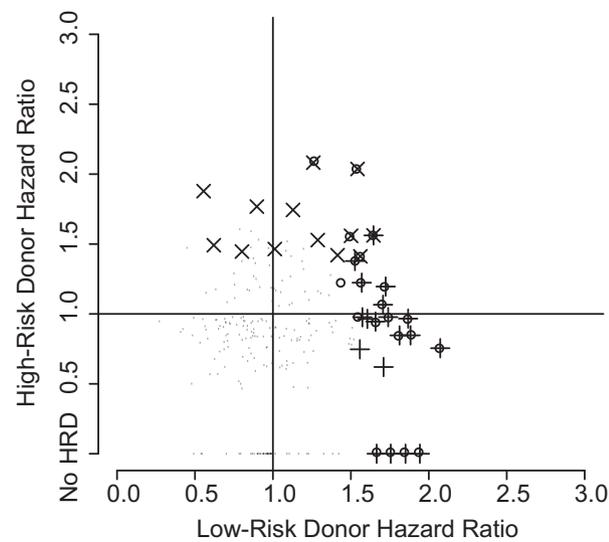
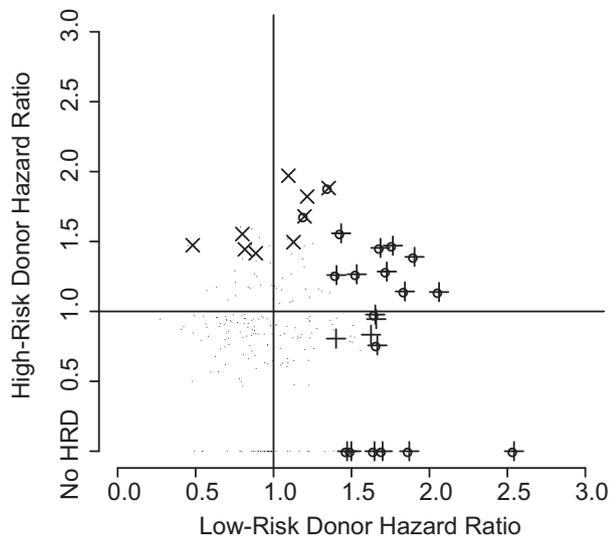


Figure 3: Programs identified for review for graft survival (top panel) and patient survival (bottom panel) based on all transplants (circles), low-risk donor transplants (KDPI <0.85) (+), high-risk donor transplants (KDPI ≥0.85) (x), and not identified for review (.), stratified by low-risk donor evaluations (x-axis) and high-risk donor evaluations (y-axis). HRD, high-risk donor; KDPI, Kidney Donor Profile Index.

the risk of identification as underperforming in the current transplant environment. In addition, these results suggest that the proposed strategy to remove from the PSRs some transplants determined by current OPTN data to be high risk is neither necessary nor feasible. Such a strategy would reduce the overall statistical power of the PSR models and would penalize programs that accept high-risk donors and patients and perform well (Figure 3, all programs below the horizontal lines at 1.0).

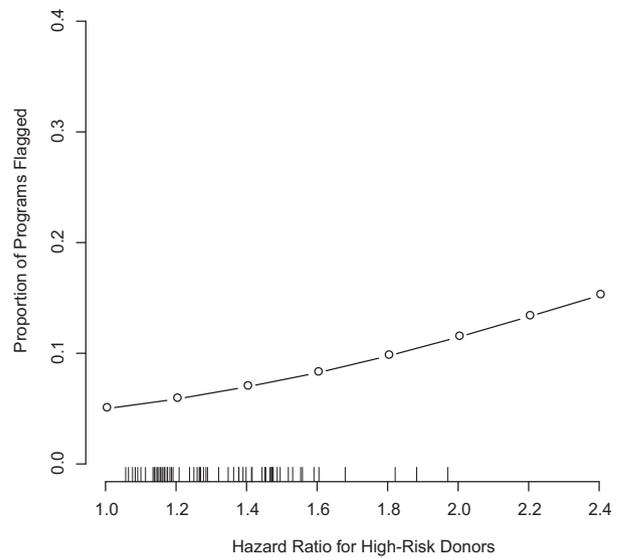


Figure 4: The probability of identifying a program for review under the current Organ Procurement and Transplantation Network criteria if the program is performing as expected with low-risk transplants but has an elevated hazard ratio for high-risk transplants (KDPI ≥85). For example, if a program performs as expected with low-risk transplants, but has double the failure rate for high-risk transplants (HR = 2.0 on the x-axis), the probability that this program would be flagged is 11%. The tick marks above the x-axis indicate actual high-risk donor hazard ratios in the June 2015 PSR evaluations, the highest being just below 2.0. KDPI, Kidney Donor Profile Index; PSR program-specific report.

Several studies have shown that risk factors not measured in the PSRs with current OPTN data could improve the risk prediction of PSR models. Global comorbidity indexes (14,15), community risk factors (15), and cardiovascular risk factors (16) have all been shown to predict risk independent of PSR models. These studies suggest that some transplants with donor or recipient risk factors not collected by OPTN could reduce a program’s performance evaluation in the current PSRs. If unaccounted risk factors have a large enough effect on patient and/or graft survival beyond the risk explained by variables included in the PSR models, and if differences among programs in the prevalence of these alternative risk factors are substantial, then some programs may be unfairly “penalized” for performing poorly defined high-risk transplants. The present study can neither confirm nor refute this possibility, and the long-term answer may depend on additional studies that better define risk factors that OPTN can collect to improve the PSR models. OPTN established an *ad hoc* Data Advisory Committee that is working in conjunction with SRTR to examine additional risk factors that should be collected. In the meantime, the present analysis suggests that the risk adjustment models effectively account for risk from currently available data, and therefore excluding patients from the PSR

analysis based on risk measured with current variables is unlikely to improve program-specific outcomes, and may be detrimental.

Our results are in general agreement with those of Schold et al (17), who examined whether programs accepting higher-risk donors might be unfairly identified as underperforming despite good quality of care. These authors compared graft survival of paired donor kidneys and unpaired donor kidneys allocated to high-performing and low-performing programs. They found that differences between programs were unaffected by use of paired or unpaired donations, suggesting that donor selection bias is not significantly affecting program evaluations. They concluded that transplanting higher-risk kidneys is not a major threat to performance (17).

There are some important limitations of this study. Although our analysis suggests that removing patients from the PSRs using current data to assess risk does not appear to be necessary or effective, it is still possible that doing so could have a psychological effect on transplant programs, discouraging them from avoiding high-risk transplants for fear of regulatory scrutiny. In other words, removing patients from the PSR calculations may encourage programs to accept higher-risk donors and recipients based on psychological, but not statistically valid, reasons. Another limitation discussed above is that this study cannot address the question of whether risk factors not collected by OPTN and not included in the PSR models may affect outcomes. This may be true for both donors and recipients, and deserves further study. If factors beyond those currently collected in the OPTN system (such as anatomical abnormalities or vascular injury in the hilum of donor kidneys or cardiovascular risk factors in recipients) could be collected, SRTR could incorporate these factors into the risk adjustment. Finally, the assumptions of the discard-matching analysis may not hold if previously discarded kidneys were transplanted into recipients at higher risk than current recipients of similar organs, or if programs lacking experience with similar transplants performed relatively poorly with these kidneys. However, if outcomes became worse nationally—if, for example, inexperienced programs began to transplant previously discarded organs—the risk adjustment models would recalibrate to the new national norm during each evaluation cycle.

In summary, this study demonstrates that adult kidney transplant programs are not systematically identified for regulatory scrutiny simply because they accept deceased donor kidneys at increased risk for graft failure as determined by current OPTN data. Programs that perform poorly with high-KDPI kidneys relative to other programs' performances with similar kidneys would benefit from review of those cases to determine opportunities for improvement. However, our results suggest that it may

not be necessary or effective to remove transplants from the PSRs because they are determined to be at increased risk based on current OPTN data. These results do not address the important question of whether risk factors not identified in current OPTN data should be collected and included in future PSR models.

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Disclosure

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

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