

ORIGINAL ARTICLE

Comparing Scientific Registry of Transplant Recipients posttransplant program-specific outcome ratings at listing with subsequent recipient outcomes after transplant

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To improve accessibility of program-specific reports to patients, the Scientific Registry of Transplant Recipients released a 5-tier system for categorizing 1-year posttransplant program evaluations. Whether this system predicts subsequent posttransplant outcomes at the time patients are waitlisted has been questioned. We investigated the association of tier at listing and the corresponding continuous score used for tier assignment, which ranges from 0 (poor outcomes) to 1 (good outcomes), with eventual 1-year posttransplant graft survival for candidates listed between July 12, 2011, and June 16, 2014, who underwent transplant before December 31, 2016. One additional tier at listing was associated with better 1-year posttransplant outcomes in liver (hazard ratio [HR], 0.93; 95% confidence interval [CI], 0.89–0.97) and lung transplant (HR, 0.90; 95% CI, 0.84–0.97) but not kidney (HR, 0.96; 95% CI, 0.92–1.01) or heart transplant (HR, 1.02; 95% CI, 0.93–1.10). In liver and lung transplant, longer time between listing and transplant was associated with stronger protective effects for high-tier programs. In kidney, liver, and lung transplant, posttransplant evaluations at listing had nonlinear associations with eventual posttransplant outcomes: relatively flat for 5-tier scores <0.5 and decreasing for scores >0.5. After adjustment for measured recipient and donor risk factors, posttransplant evaluations at listing predicted differences in eventual outcomes in liver and lung transplant, providing useful information to patients.

KEYWORDS

health services and outcomes research, organ transplantation in general, Scientific Registry for Transplant Recipients (SRTR), statistics

1 | INTRODUCTION

The Organ Procurement and Transplantation Network (OPTN) Final Rule requires the Scientific Registry of Transplant Recipients (SRTR) to publish program-specific reports (PSRs) that can be “accurately and efficiently” used and understood. In December

2016, SRTR released a 5-tier system to improve the accessibility of 1-year posttransplant program evaluations already included in the PSRs. The statistical summary measures included in the PSRs (hazard ratios [HRs] and 95% confidence intervals [CIs]) were considered too challenging for nontechnical stakeholders, such as patients and families, to understand.^{1,2} Instead, a more accessible

Abbreviations: CI, confidence interval; CMS, Centers for Medicare & Medicaid Services; HR, hazard ratio; OPTN, Organ Procurement and Transplantation Network; PSR, program-specific report; SRTR, Scientific Registry of Transplant Recipients.

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approach would transform the statistical summary measures into a limited number of categories. SRTR previously used a 3-tier system based on statistical hypothesis testing. The 3-tier system poorly differentiated program evaluations and may have obscured potentially relevant differences, especially for small-to-moderately sized programs.³ The 5-tier system was designed to better differentiate posttransplant evaluations, and, in kidney transplant, it reduced the variability of program-specific HRs within a tier by nearly 80%.³

Because the 5-tier system narrowed the outcome differences across tiers, programs were more likely to change tiers over time than they were under the previous 3-tier system.⁴ The higher variability in tier assignment over time and long duration from listing to transplant, especially for kidney candidates,⁵ could attenuate the association between tier assignment when a candidate joins the waitlist and the posttransplant outcomes when the candidate eventually undergoes transplant. If tier assignment at listing is not associated with eventual posttransplant outcomes, then the 5-tier system would not necessarily convey the relative survival experience after transplant across programs. However, there are other considerations for public reporting of posttransplant outcomes, including, for example, creating incentives for quality improvement at all programs. Further, current regulatory review could attenuate an association between tier assignment at listing and eventual posttransplant outcomes, because programs that approach or cross regulatory thresholds have incentives to improve.⁶ Regardless, the association of tier assignment at listing and, more generally, posttransplant program evaluations at listing with eventual posttransplant outcomes has not been evaluated.

We investigated 3 specific dimensions of the relationship between posttransplant program evaluations at listing and eventual posttransplant outcomes. First, we investigated the overall association between tier at listing and eventual posttransplant outcomes, because tier assignment is a discrete number and could influence patient decision-making. However, the association may be small due to the potentially long delay between transplants included in the evaluation and the actual time of listing. Second, we investigated the dependence of the association on the time from listing to transplant. If the association attenuates with longer time between listing and transplant, then long waiting times could reduce the usefulness of the 5-tier system, especially in kidney transplant. Last, we investigated the association of posttransplant program evaluations at listing without categorization into tiers (ie, the continuous score used to categorize programs into tiers) with eventual posttransplant outcomes. The role of posttransplant evaluations in regulatory review could create a nonlinear relationship with eventual posttransplant outcomes due to the incentives to improve for programs close to or violating regulatory thresholds. Understanding these associations will help inform further discussion of the role of posttransplant program evaluations in public reporting, and we evaluated each dimension in kidney, liver, lung, and heart transplant to ensure relevance to the broader transplant community.

2 | MATERIALS AND METHODS

This study used SRTR data. 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.⁷ The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

Adult recipients (age ≥ 18 years at transplant) were included in the study if they were listed between July 12, 2011 (release date for the 2011 summer PSR cycle), and June 16, 2014 (day before the release of the 2014 summer PSR cycle), and underwent transplant before December 31, 2016. The appropriate PSR release for tier assignment at listing was determined by the release date of archived PSRs. In 2013 and 2014, the PSR release schedule was temporarily postponed due to problems related to determining dates of death. In these situations, the PSR release date was approximated by the prior release of the corresponding biannual PSR cycle.

The primary outcome was 1-year posttransplant graft survival; the supplementary materials provide the specific definitions of graft survival for each organ. Follow-up was censored at 1 year posttransplant or December 31, 2016, whichever occurred first. The posttransplant evaluations at listing were the 1-year posttransplant graft survival outcomes included in the PSR at the time the recipient was listed. The tier assignment was determined by the algorithm for the 5-tier system. The algorithm depends only on the number of observed and expected graft failures and therefore can be calculated with archived PSRs.^{3,8}

A linear trend estimated the association of tier at listing with eventual posttransplant graft survival. The corresponding interpretation is the average change in the hazard for 1 additional tier at listing. To determine if time from listing to transplant modified the association, recipients were separated into 3 groups: those who underwent transplant before 1 year, at 1-2 years, and at >2 years after listing. The linear trend for tier at listing was then estimated for recipients in each group.

To identify potential nonlinear associations, penalized splines were used to estimate the association of eventual posttransplant graft survival with the underlying continuous score used to categorize programs into the 5-tier system (referred to throughout as the 5-tier score). The 5-tier score ranges from 0 to 1; a 5-tier score close to 1 corresponds to above average outcomes, while a 5-tier score close to 0 corresponds to below average outcomes. Penalized splines have wider CIs than linear trends due to the additional flexibility.

The linear and nonlinear associations with 1-year posttransplant graft survival were estimated with separate Cox proportional hazards models that adjusted for recipient and donor factors. A recipient or donor factor was included if the corresponding SRTR 1-year adult graft survival model for the January 2018 PSR release had a nonzero effect for the given factor; documentation for SRTR posttransplant risk-adjustment models is accessible at <https://>

www.srtr.org/reports-tools/risk-adjustment-models-posttransplant-outcomes/. The supplementary materials list the specific donor and recipient factors included in each model. For kidney and liver transplant, living and deceased donor organs were integrated into the same model with an indicator for living donor transplant. Factors with nonzero effects in either the living or deceased donor PSR models were included. The value of deceased donor-specific factors for living donor transplants was set to the median for continuous factors and the reference level for categorical factors. Multiple imputation with 10 iterations accounted for missing data.⁹

The effects of the continuous factors were estimated with the use of penalized splines. Robust standard errors accounted for correlation among transplants at the same program. The supplementary materials include a sensitivity analysis for the effect of an additional tier in the traditional 3-tier system based on statistical hypothesis testing.

All analyses were completed in R v3.3.3.¹⁰ Cox proportional hazard models were estimated with the “survival” package,¹¹ and multiple imputation was completed with the “mice” package.¹²

3 | RESULTS

A significant proportion of kidney transplant recipients (46%) underwent transplant within 1 year of listing, although the time between listing and transplant was strongly associated with donor type and metrics of allocation priority (eg, dialysis duration at transplant; Table S1). Most liver (80%; Table S2), lung (88%; Table S3), and heart (79%; Table S4) recipients also underwent transplant within 1 year of listing.

3.1 | Kidney transplant

An additional tier at listing had a 4% lower hazard (Figure 1, left) of kidney graft failure 1 year after transplant, although the

association was not significant (HR, 0.96; 95% CI, 0.92–1.01). The association was not modified by time from listing to transplant, although, likely due to the smaller sample sizes, the CIs were wider for each category of time from listing to transplant (eg, 1 additional tier at listing for recipients who underwent transplant within 1 year was associated with a 4% reduction in the hazard of graft failure; HR, 0.90; 95% CI, 0.96–1.04).

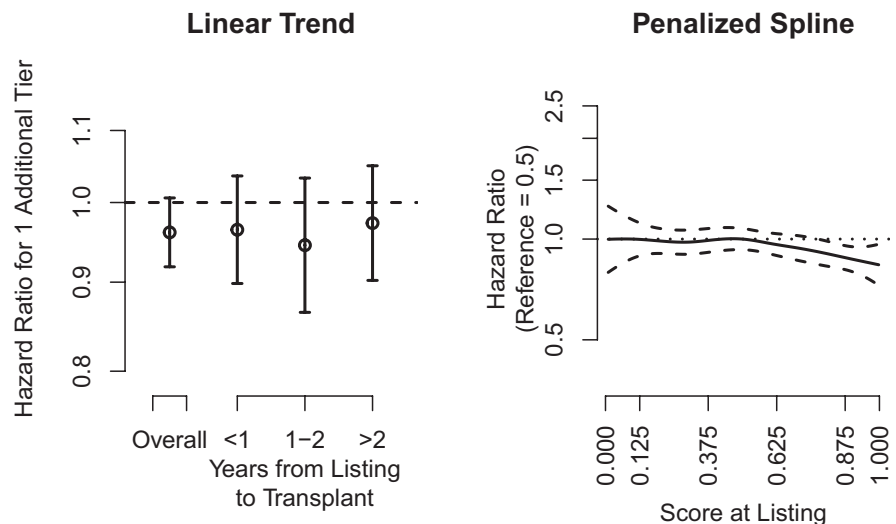
The 5-tier score at listing had a nonlinear association with eventual posttransplant graft survival (Figure 1, right). The 5-tier score had an association that was relatively flat until a score of 0.5 was reached, after which the risk of graft failure slowly decreased. In summary, outcomes did not differ for recipients who listed at programs with average or below average evaluations, but recipients who listed at programs with above average evaluations had improved posttransplant graft survival.

3.2 | Liver transplant

An additional 1 tier at listing was associated with a 7% lower hazard (Figure 2, left) of 1-year posttransplant liver graft failure (HR, 0.93; 95% CI, 0.89–0.97), and the effect was larger for recipients who waited >2 years. For example, 1 additional tier at listing for recipients who underwent transplant within 1 year of listing was associated with a 6% lower hazard of graft failure (HR, 0.94; 95% CI, 0.90–0.98), while 1 additional tier for recipients who underwent transplant >2 years after listing was associated with a 32% lower hazard of graft failure (HR, 0.68; 95% CI, 0.56–0.81). Posttransplant evaluations in liver transplant were associated with eventual posttransplant graft survival, and a longer time between listing and transplant strengthened the association.

Posttransplant liver graft survival had a nonlinear relationship with the 5-tier score at listing (Figure 2; right). The hazard of graft failure for the 5-tier score at listing gradually decreased for programs with scores >0.2. Thus, recipients who listed at programs with better posttransplant evaluations tended to have better eventual 1-year

FIGURE 1 Kidney transplant. The association of the hazard ratio at listing and the 5-tier score at listing with eventual posttransplant 1-year kidney graft survival. The dashed lines are the pointwise 95% confidence intervals, and the dotted line is a hazard ratio of 1. The 5-tier score is the underlying continuous score used to categorize programs into the 5-tier system. The x-axis tick marks for the 5-tier score correspond to the cut-points used to categorize programs into tiers; for example, programs with a 5-tier score >0.875 were categorized as tier 5



posttransplant graft survival, although the differences attenuated for programs with 5-tier scores <0.2.

3.3 | Lung transplant

An additional tier at listing was associated with a 10% lower hazard (Figure 3, left) of 1-year posttransplant graft failure (HR, 0.90; 95% CI, 0.84–0.97), and the effect was stronger for recipients who waited longer after listing. For example, 1 additional tier at listing for recipients who underwent transplant within 1 year was associated with an 8% lower hazard of graft failure (HR, 0.92; 95% CI, 0.85–1.00), while 1 additional tier for recipients who underwent transplant between 1 and 2 years after listing was associated with a 24% lower hazard (HR, 0.76; 95% CI, 0.59–0.97). Posttransplant evaluations in lung transplant were associated with eventual posttransplant graft survival, and a longer time between listing and transplant strengthened the association.

The effect for the 5-tier score at listing was relatively constant until a score of ≈0.6 and then sharply decreased for 5-tier scores at listing >0.6, corresponding to programs with better posttransplant evaluations

at listing (Figure 3, right). Thus, recipients who listed at programs with above average posttransplant evaluations experienced gradually better outcomes, while recipients who listed at programs with average or below average posttransplant evaluations experienced similar outcomes.

3.4 | Heart transplant

Tier assignment at listing (Figure 4, left) and the 5-tier score at listing (Figure 4, right) were not associated with eventual posttransplant outcomes in heart transplant. Thus, heart recipients who listed at programs with better posttransplant evaluations did not experience better or worse outcomes than heart recipients who listed at programs with worse posttransplant evaluations.

4 | DISCUSSION

For liver and lung recipients, posttransplant evaluations at listing were moderately associated with eventual posttransplant outcomes,

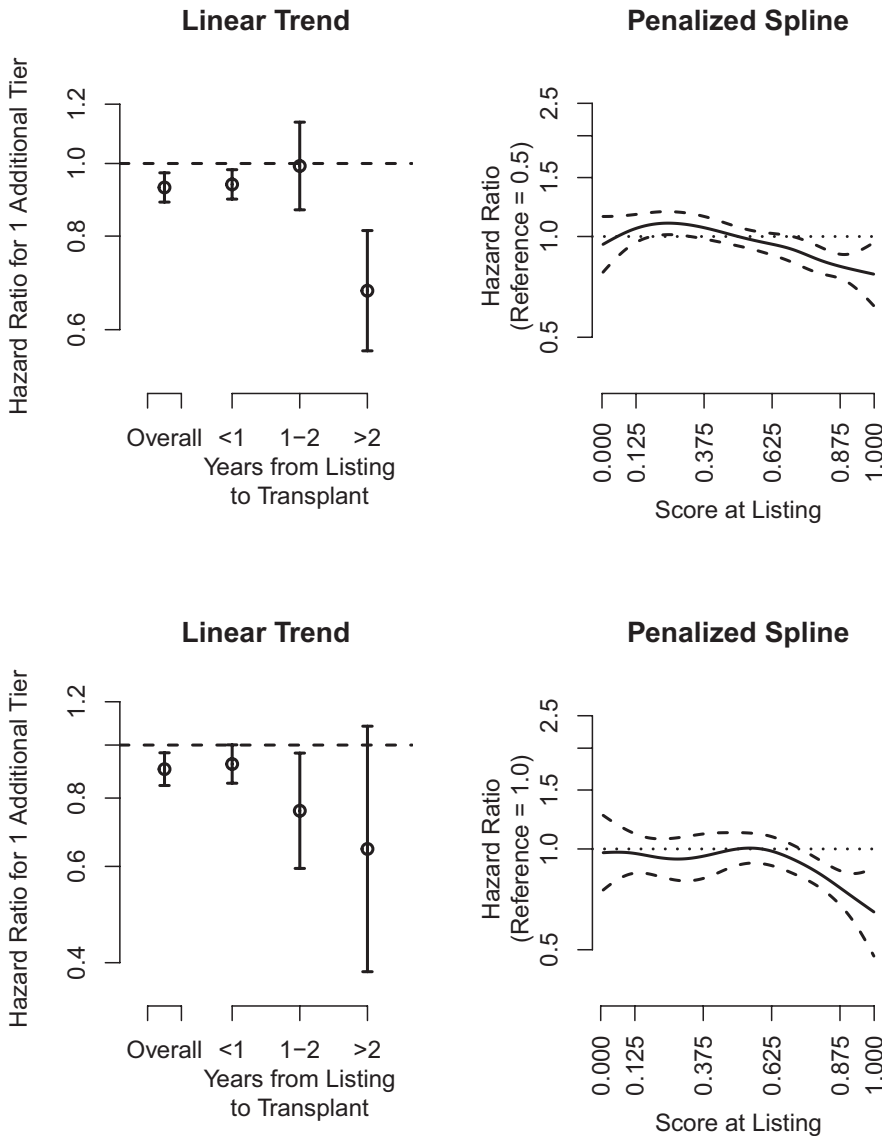
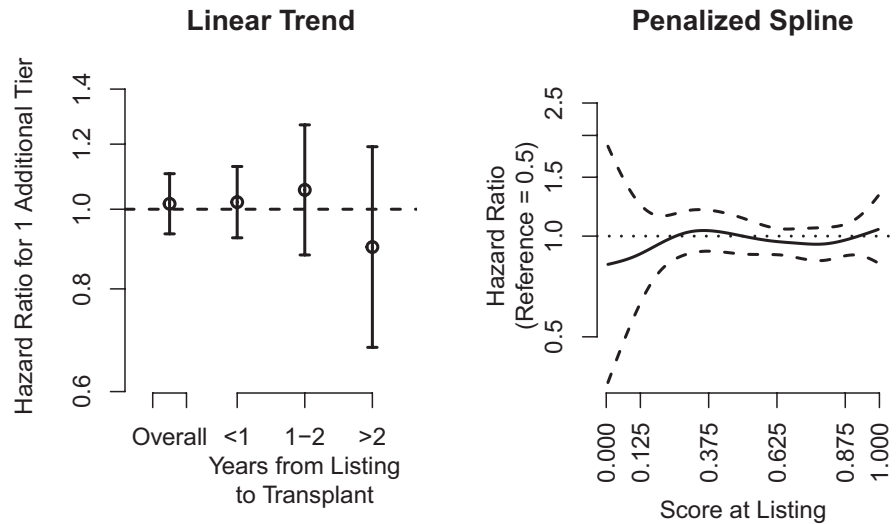


FIGURE 2 Liver transplant. The association of the hazard ratio at listing and the 5-tier score at listing with eventual posttransplant 1-year liver graft survival. The dashed lines are the pointwise 95% confidence intervals, and the dotted line is a hazard ratio of 1. The 5-tier score is the underlying continuous score used to categorize programs into the 5-tier system. The x-axis tick marks for the 5-tier score correspond to the cut-points used to categorize programs into tiers; for example, programs with a 5-tier score >0.875 were categorized as tier 5

FIGURE 3 Lung transplant. The association of the hazard ratio at listing and the 5-tier score at listing with eventual posttransplant 1-year lung graft survival. The dashed lines are the pointwise 95% confidence intervals, and the dotted line is a hazard ratio of 1. The 5-tier score is the underlying continuous score used to categorize programs into the 5-tier system. The x-axis tick marks for the 5-tier score correspond to the cut-points used to categorize programs into tiers; for example, programs with a 5-tier score >0.875 were categorized as tier 5

FIGURE 4 Heart transplant. The association of the hazard ratio at listing and the 5-tier score at listing with eventual posttransplant 1-year heart graft survival. The dashed lines are the pointwise 95% confidence intervals, and the dotted line is a hazard ratio of 1. The 5-tier score is the underlying continuous score used to categorize programs into the 5-tier system. The x-axis tick marks for the 5-tier score correspond to the cut-points used to categorize programs into tiers; eg, programs with a 5-tier score >0.875 were categorized as tier 5



and the associations did not attenuate with longer durations between listing and transplant but instead became stronger. Interestingly, posttransplant evaluations had a nonlinear association with eventual posttransplant outcomes in kidney, liver, and lung transplant: notable differences in eventual outcomes between programs with above average to average evaluations but attenuated or no differences between programs with average to below average evaluations. In heart transplant, a better tier assignment at listing was not associated with better or worse outcomes, and it is not clear that any categorization system would be associated with posttransplant outcomes in heart transplant because the 5-tier score at listing had no association with eventual outcomes.

We performed a sensitivity analysis that repeated the primary analysis for the traditional 3-tier system based on statistical hypothesis testing. The analysis for the 3-tier system showed larger effects but also higher variability for 1 additional tier at listing than the associations for the 5-tier system (Table S5). The larger effect size is not surprising because 1 additional tier in the 3-tier system corresponds to ≈ 2 additional tiers in the 5-tier system, while the higher variability is likely explained by the smaller number of recipients in tiers 1 and 3.

There are at least 2 frameworks for understanding the usefulness of posttransplant evaluations: first, the ability of posttransplant evaluations to predict eventual outcomes, and second, creating incentives for quality improvement. The former framework has a direct role in patient decision-making because an association with eventual posttransplant outcomes would create an incentive for patients to list at programs with good posttransplant evaluations. In contrast, the latter framework is only indirectly related to patient outcomes through the potentially better outcomes at all programs due to the incentive for quality improvement.

Unfortunately, these frameworks may work in opposition to each other; that is, an incentive for quality improvement could attenuate or remove the ability of posttransplant evaluations to predict eventual outcomes. For example, regulatory agencies (ie, the Centers for Medicare & Medicaid Services [CMS] and OPTN) use 1-year

posttransplant evaluations to identify programs for regulatory intervention. Regulatory agencies may then force transplant programs that consistently violate the thresholds to institute quality improvement measures.⁶ Additionally, transplant programs in violation of, or close to, the regulatory thresholds have strong financial incentives to improve posttransplant outcomes due to the financial burden associated with regulatory interventions. This incentive structure could reduce the differences in eventual survival outcomes among programs with below average posttransplant evaluations, although the incentive structure may not be strong enough for programs with average or better evaluations to pursue similar, but potentially costly, quality improvement measures. The trends that could occur within this incentive structure are consistent with the nonlinear associations observed in kidney, liver, and lung transplant; that is, the association would be relatively flat for HRs >1 and decrease for HRs <1. The 5-tier system for categorizing posttransplant outcomes could create an incentive for all programs, not only programs with below average evaluations, to pursue quality improvement measures,¹³ and the incentive could hypothetically eliminate any association with eventual posttransplant outcomes.¹⁴ Yet, in this hypothetical situation, public reporting would still have an important role despite less direct use in patient decision-making.

Both frameworks can justify further public reporting of posttransplant evaluations. For example, an association with eventual posttransplant outcomes would motivate prominent and accessible reporting of posttransplant evaluations. In contrast, in the absence of an association with eventual posttransplant outcomes (eg, heart transplant), the approach to public reporting would be more nuanced. Specifically, the reporting must sufficiently motivate quality improvement efforts,¹³ while minimizing the risk that patients overemphasize posttransplant evaluations at the cost of other important components of transplant program care, such as access to transplant as measured by transplant rate. In this situation, the presentation of posttransplant evaluations must balance accessible and adequately differentiated observed outcomes, while ensuring that stakeholders, such as patients, understand that the transplant rate evaluation may

predict their long-term survival better than the posttransplant evaluation. A potential approach to balancing these issues is integrating into the public reporting a plain-language description of the association of posttransplant evaluations with eventual posttransplant outcomes.

The focus on transplant recipients is an inherent limitation of our analysis because many patients, especially in liver and kidney transplant, die or are removed from the waiting list before transplant.^{5,15} While the association of posttransplant evaluations with eventual recipient outcomes is information sought by patients,² posttransplant evaluations may not be particularly informative of the experience of most candidates after listing and, instead, the transplant rate ratio evaluation may have a stronger association with survival. In fact, posttransplant evaluations were associated with overall mortality after listing for liver and lung transplant but not for kidney or heart transplant. Further, in kidney transplant, the transplant rate evaluation at listing was associated with overall mortality after listing.¹⁶ These associations suggest that the process of undergoing a kidney transplant is more important than posttransplant outcomes for survival after listing. Thus, SRTR plans to better integrate transplant rate and waitlist mortality evaluations into the public reporting and will emphasize only posttransplant evaluations for organs with a strong association with candidate mortality after listing.

Our analysis helps inform the role of posttransplant evaluations in public reporting, not in regulatory review. SRTR is mandated to provide program-specific information that can be used "accurately and efficiently," and understanding the importance of program-specific posttransplant evaluations in eventual patient outcomes is important for accurate use by patients and their families. In contrast, CMS developed conditions of participation to "improve quality and protect the health and safety of beneficiaries,"¹⁷ which suggests greater priority on incentivizing quality improvement in transplant, not informing patients of potential outcomes. The different role of posttransplant evaluations in regulatory review was also evident in the justification of recent revisions to the criteria for review of CMS: a more difficult standard to violate because patient survival improved during the past decade.¹⁸ Thus, the association of posttransplant evaluations with prospective graft survival is less important for informing the role of posttransplant evaluations in regulatory review.

For each organ, the differences in eventual posttransplant outcomes were relatively small, especially compared with the differences suggested by the posttransplant evaluations. However, smaller differences were expected because the predictive performance of statistical models is almost always worse for future outcomes than for outcomes used to estimate the model.¹⁹ For example, a tier-5 program had an 81% probability of a truly better HR than a tier-3 program within a PSR cycle.³ A prospective, rather than within-PSR cycle, probability would naturally be lower because program care can change due to quality improvement efforts and/or staff turnover. However, the association in liver and lung transplant suggests that the 5-tier system remained predictive despite these challenges.

Public reporting of posttransplant evaluations may create unintended consequences. The introduction by CMS of regulatory review of posttransplant evaluations was associated with lower transplant volume and higher rates of waitlist removals for programs under regulatory review.^{6,20,21} Better public reporting with, for example, the 5-tier system, may result in similar risk-averse behavior because programs may fear, for example, loss of referrals and/or pressure from private insurers. The unintended consequences of public reporting may have an association different from that of regulatory review due to indirect rather than direct interaction with programs. That is, CMS directly interacted with programs under review and sometimes required quality improvement efforts. In contrast, public reporting indirectly interacts with programs through, for example, the potential loss of referrals and/or pressure from private insurers. The unintended consequences of public reporting deserve further investigation, especially with respect to long-term survival of candidates awaiting transplant, and risk-averse behavior may be reduced through further education about the role of risk adjustment in posttransplant evaluations.²²

While these results may partially reflect changes in programs over time, the variability in tier assignment over time is not an inherently informative metric for evaluating the categorization of posttransplant outcomes.⁴ The 5-tier system was explicitly designed to improve the differentiation of program performance at the cost of a higher misclassification rate.³ As a direct consequence, the 5-tier system would be expected to be more variable in tier assignment over time because better differentiation was achieved by narrowing the differences in outcomes between tiers. More importantly, variability in tier assignment over time does not answer the clinical concern: that variability in posttransplant evaluations over time may mislead patients about their eventual posttransplant survival experience due to long waiting times.⁴ Yet, longer waiting times did not modify the association of posttransplant evaluations at listing with eventual outcomes for kidney recipients, and the association was stronger for liver and lung recipients with longer waiting times, despite the relatively shorter organ-specific waiting times. Finally, in heart transplant, posttransplant evaluations had no association with eventual recipient outcomes, and waiting times did not modify the association. Thus, tier assignment at listing was associated with eventual recipient outcomes in kidney, liver, and lung transplant, and either the time from listing to transplant did not modify the associations or the associations were modified in the direction opposite what was expected.

Our analysis is subject to potential limitations. First, it is difficult to understand the causal mechanisms that modify the association of tier at listing with posttransplant outcomes across the different durations of time on the waiting list. For example, if liver recipients who waited for >2 years were more likely to have unmeasured risk factors at programs in tiers 1-3 than at programs in tiers 4 and 5, then listing at a tier-4 or tier-5 program could have an apparent protective effect. This could occur, for example, if programs with good posttransplant evaluations more carefully monitored candidates on their waiting lists and therefore were more likely than programs with

poor posttransplant evaluations to identify candidates who develop risk factors after listing that are not collected by OPTN. If these risk factors are not contraindications to transplant, then the best approach for alleviating their impact is collection of additional data. Second, the posttransplant evaluations in this cohort used previous risk-adjustment models that incorporated fewer risk factors and did not consider flexible linear splines for continuous covariates.²³ In both the current PSR models and the risk-adjustment models described here, we adjusted for a much wider range of risk factors and included flexible splines that can identify nonlinear effects of continuous covariates. The differences in risk adjustment could bias the association between posttransplant evaluations and eventual outcomes if, for example, the previous models inappropriately identified programs as performing poorly due to a high-risk tolerance, while the new risk-adjustment models more accurately identify the program's risk tolerance. This hypothetical situation could cause programs with poor posttransplant evaluations to have average posttransplant outcomes, which would bias the relationship between the baseline evaluation and subsequent outcome. Last, patients likely choose transplant programs at the time of referral and evaluation rather than at listing, but listing date may be a reasonable approximation given lack of data on referral and evaluation.

Posttransplant evaluations at listing and, specifically, the 5-tier system were associated with eventual posttransplant outcomes in liver and lung transplant but not in kidney or heart transplant. Thus, the 5-tier system differentiated eventual recipient-outcomes in liver and lung transplant that were unexplained by measured recipient and donor risk factors.

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DISCLOSURE

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