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Posttransplant outcome assessments at listing: Long-term outcomes are more important than short-term outcomes

Andrew Wey[1] | Allyson Hart[1,2] | Nicholas Salkowski[1] | Melissa Skeans[1] | Bertram L. Kasiske[1,2] | Ajay K. Israni[1,2,3] | Jon J. Snyder[1,3]

[1]Scientific Registry of Transplant Recipients, Hennepin Healthcare Research Institute, Minneapolis, Minnesota

[2]Department of Medicine, Hennepin Healthcare, University of Minnesota, Minneapolis, Minnesota

[3]Department of Epidemiology and Community Health, University of Minnesota, Minneapolis, Minnesota

Correspondence
Andrew Wey
Email: awey@cdrg.org

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Posttransplant outcome assessments are publicly reported for patient and regulatory use. However, the currently reported 1-year posttransplant graft survival assessments are commonly criticized for not identifying clinically meaningful differences between programs, and not providing information about longer-term posttransplant outcomes. We investigated the association of different posttransplant outcome assessments available to patients at the time of listing with subsequent posttransplant graft survival. The posttransplant assessments were from period prevalent, rather than incident, cohorts with more timely 1-, 3-, and 5-year follow-up and 6-, 12-, 18-, 24-, and 30-month cohort windows. The association of these assessments at listing with subsequent posttransplant graft survival included candidates listed between July 12, 2011, and December 15, 2015, who subsequently underwent transplant before December 31, 2018. The assessments with 1-year follow-up had uniformly weaker associations than the assessments with 3- and 5-year follow-up. The assessments with 5-year follow-up had the strongest association in kidney and liver transplantation. For kidney, liver, and lung transplantation, assessment windows of at least 18 months typically had the strongest associations with subsequent graft survival. Posttransplant assessments with 5-year follow-up and 18-30-month cohort windows are better than the current posttransplant assessment with 1-year follow-up, particularly at the time of listing.

KEYWORDS
clinical research/practice, epidemiology, organ transplantation in general, Scientific Registry for Transplant Recipients (SRTR)

1 | INTRODUCTION

The Scientific Registry of Transplant Recipients (SRTR) publicly releases program-specific reports (PSRs), which include assessments of posttransplant outcomes. Patients and transplant programs are the two major audiences for the PSRs. These audiences use posttransplant outcome information for different purposes and therefore have different reporting requirements. For example, SRTR provides quality improvement tools to transplant programs, such as posttransplant cumulative sum charts,[1] but publishes an easily

Abbreviations: MI, multiple imputation; OPTN, Organ Procurement and Transplantation Network; PEM, piecewise exponential models; PSR, program-specific report; SRTR, Scientific Registry of Transplant Recipients.

interpretable 5-tier system of 1-year posttransplant graft survival for patients.[2-4]

The 5-tier system of posttransplant outcomes available at the time of listing was associated with subsequent posttransplant outcomes in liver and lung transplantation but not in kidney or heart transplantation.[5] The 5-tier system for liver and lung posttransplant assessments may provide useful information to patients because the assessments were associated with eventual, relevant outcomes at a time when patients make decisions. Alternative posttransplant assessments may be better than the current assessment of 1-year posttransplant graft survival, for example, 3-year graft survival. However, programs are most involved in patient care immediately following transplant, when the hazard of graft failure is highest. Thus, short-term outcomes may describe the individual program effect better than long-term outcomes. However, the relative performance of short- or long-term posttransplant outcome assessments available to candidates at the time of listing has never been empirically investigated despite the increasing transparency and public availability of outcomes data.

Serious practical problems traditionally prevented empirical investigations and public reporting of long-term posttransplant outcome assessments. Specifically, posttransplant assessments currently use an incident transplant cohort, that is, a comparison of relative outcomes from transplants performed during the cohort window. Incident transplant cohorts typically have a significant lag between follow-up and PSR release. For example, 1-year posttransplant assessments include transplants performed 1-3.5 years prior to the PSR release, whereas the 3-year posttransplant assessments include transplants performed 3.5-6 years prior to the release. Due to the significant lag between follow-up and PSR release for the current incident cohorts, long-term assessments (eg, 3 or more years posttransplant) may not reflect current transplant program practice or quality and may not be useful at the time of listing for transplant. Thus, we investigated more timely short- and long-term posttransplant outcome assessments from period prevalent cohorts.

In addition to differing lengths of follow-up, different widths of cohort windows could be used. Outcome assessments with narrow (eg, 6-12 months) cohort windows would include more recent follow-up and, therefore, more quickly respond to programs with changing posttransplant outcomes. However, wide cohort windows allow more precise estimation of transplant program effects, especially if program outcomes remain relatively constant over time. Better precision is particularly important for posttransplant outcome assessments, because even large transplant programs are subject to random variation.

We conducted a two-factor factorial study on the association of different posttransplant outcome assessments at the time of listing with subsequent graft survival for candidates who eventurally underwent kidney, liver, heart, and lung transplant. The study's primary goal was determining the posttransplant follow-up length and cohort window width with the strongest association with subsequent posttransplant graft survival across kidney, liver, heart, and lung transplantation.

2 | METHODS

This study used the SRTR data system, which includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (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.

2.1 | Analytical approach

This study used a two-factor factorial design. We simultaneously varied the length of posttransplant follow-up and the width of cohort windows. These two factors were the different experimental conditions for measuring the primary outcome of interest: the hazard ratio for the association between a posttransplant assessment provided at the time of listing (defined by the length of follow-up and width of cohort window) and subsequent posttransplant graft survival among candidates who eventually underwent transplant. This hazard ratio is defined throughout as HR-A, because it depends on the different posttransplant outcome assessments.

The rest of the Methods section is organized as follows. First, we introduce period prevalent cohorts and contrast them with incident cohorts. Second, we introduce the dimensions of interest for posttransplant follow-up and widths of cohort windows. Third, we describe the modeling framework for retroactively estimating the posttransplant hazard ratios at the time of listing from period prevalent cohorts (HR-Ls). These posttransplant assessments were never previously used and required retroactive estimation. Finally, we describe estimating the outcome of interest (HR-A), or the association between the HR-L and eventual posttransplant graft survival among candidates who eventually underwent transplant. Table 1 outlines the steps of the analysis and identifies the relevant subsection of the Methods.

2.2 | Period prevalent cohorts

To address the data lag challenge presented by incident cohorts, period prevalent cohorts, were used. Period prevalent cohorts include follow-up from any transplant at risk during the cohort window. Figure 1 compares the follow-up included by incident and period prevalent cohorts for five transplants performed from the beginning of 2013 through 2017. The incident cohort included only the two most recent transplants, whereas the period prevalent cohort included each transplant but only the most recent follow-up. For this reason, period prevalent cohorts ensure that posttransplant follow-up is proximate to the PSR release regardless of whether the assessment focuses on short- or long-term posttransplant survival. This integration of recent follow-up for short- and long-term survival likely improves the accuracy of long-term survival estimates.[7,8]

TABLE 1 Study outline

Step	Methods subsection	Description
1	Retroactive estimation of HR-Ls from period prevalent cohorts	Estimate risk-adjustment models for posttransplant graft survival in historical PSRs with a period prevalent cohort. Table S1 describes the cohorts used for these risk-adjustment models
2	Retroactive estimation of HR-Ls from period prevalent cohorts	With the risk-adjustment models from Step 1, estimate the program-specific hazard ratios in the historical PSRs. These are the hazard ratios at listing (HR-L)
3	Estimating the outcome of interest (HR-A)	After estimating the risk-adjustment models and program-specific effects for the historical PSRs, identify the appropriate HR-L for each candidate listed between July 12, 2011, and December 15, 2015, who subsequently underwent transplant before December 31, 2018. Table S1 identifies the appropriate historical PSR for each candidate
4	Estimating the outcome of interest (HR-A)	Using the candidates identified in Step 3, estimate the effect of the HR-L on subsequent posttransplant graft survival (HR-A); that is, the adjusted hazard ratio for the HR-L

HR-A, hazard ratios from assessment; HR-L, hazard ratio at listing; PSR, program-specific report.

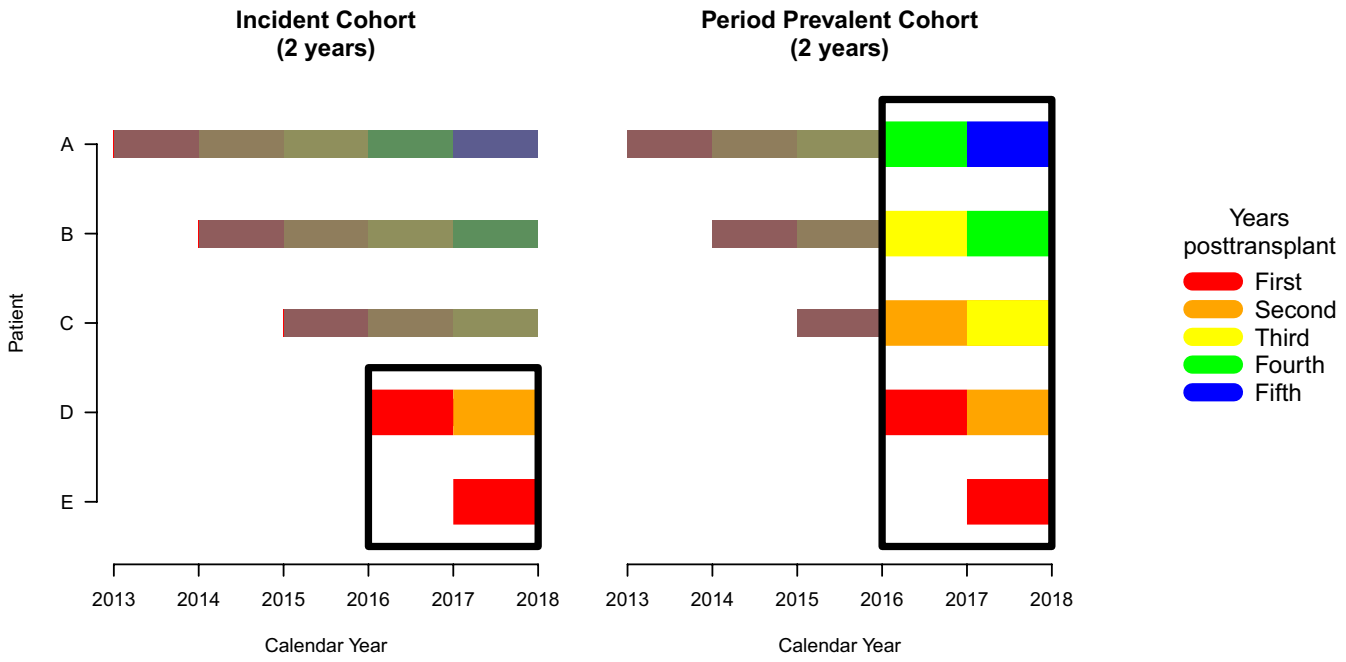

FIGURE 1 The follow-up included in incident and period prevalent cohorts for recipients who underwent transplant from the beginning of 2013 through 2017. An incident cohort with a 2-y window would include only recipients from 2016 and 2017, whereas a period prevalent cohort would include all recipients but only the 2 most recent years of follow-up

2.3 | Dimensions of interest for length of posttransplant follow-up and width of cohort windows

We investigated the effect of the length of posttransplant follow-up and the width of cohort windows on the HR-A. Three lengths of posttransplant follow-up were investigated: 1-, 3-, and 5-year posttransplant outcome assessments. The current PSRs include a 3-year assessment with an incident cohort, but a period prevalent cohort ensures more recent follow-up. A 5-year assessment would include relatively long-term outcomes, especially compared with current publicly reported posttransplant outcomes. Lastly, five widths of the cohort window were investigated: 6, 12, 18, 24, and 30 months. The current posttransplant assessments use a 30-month

incident cohort. Such a wide cohort includes old follow-up and may be less responsive to programs with changing outcomes than narrower cohorts.[3] Importantly, the program-specific hazard ratios from the 1-year assessment with a 30-month period prevalent cohort were strongly associated with, and can therefore approximate, the current 1-year assessment with a 30-month incident cohort (eg, see Figures S1-S4).

2.4 | Retroactive estimation of HR-Ls from period prevalent cohorts

We retroactively estimated posttransplant outcome assessments for deceased donor graft survival with period prevalent cohorts for nine sequential PSR cycles from July 12, 2011, to December 15, 2015. Data S1 and Table S1 provide further information on the cohort definitions for each of the historical PSR cycles. Posttransplant assessments were estimated separately for single-organ adult recipients of kidneys, livers, lungs, and hearts, and adjusted for risk factors from the appropriate organ-specific SRTR 1-year deceased donor posttransplant graft survival models (see Data S1 for a complete list). Multiple imputation (MI) handled missing data and, in contrast to the PSRs, the least beneficial value was not used for the historical program assessments.[9]

Piecewise exponential models (PEMs) with time-varying effects estimated the risk-adjustment models for the period prevalent cohorts.[10] The PEMs partitioned the baseline hazard into small intervals immediately after transplant and large intervals longer after transplant. The specific intervals for the baseline hazard were 0 to <7, 7 to <14, 14 to <30 days; 1-2, 2-3, 3-4, 4-5, 5-6, 6-12 months; and 1-2, 2-3, 3-4, and 4-5 years. PEMs with time-varying effects weaken the proportional hazards assumption from requiring a constant effect over the entire follow-up after transplant to requiring constant effects only within fixed windows after transplant. PEMs had an overall effect but allowed different effects for 0-3, 3-12 months and 1-3, and 3-5 years. Time-varying effects may improve predictive performance because some risk factors result in worse perioperative graft survival but better long-term graft survival, for example, single vs bilateral lung transplants.[11] Linear splines estimated the effects for continuous risk factors and identified potential nonlinear associations with posttransplant outcomes. Finally, the least absolute shrinkage and selection operator (LASSO) simultaneously selected risk factors with an effect and eliminated unnecessary time-varying effects.[12]

For each PSR cycle, separate PEMs with time-varying effects were estimated for cohort windows of 6, 12, 18, 24, and 30 months. Each model estimated posttransplant graft survival with administrative censoring 5 years after transplant. Posttransplant assessments for 1-, 3-, and 5-year deceased donor graft survival were estimated with the same model by, for example, considering the follow-up only within 1 year of transplant for the 1-year assessment. The period prevalent cohorts estimated the program-specific effects within the Bayesian framework used by the current posttransplant assessments;[13] that is, the program-specific hazard ratio was the observed number of graft failures plus 2 divided by the expected number of graft failures plus 2. These program-specific hazard ratios were the HR-Ls.

2.5 | Estimating the outcome of interest (HR-A)

For a given posttransplant assessment, the outcome variable of interest was the hazard ratio for the association between the HR-L and subsequent posttransplant graft survival of eventual recipients. This hazard ratio is referred to throughout as the HR-A. The appropriate HR-L at time of listing was determined from historical PSR release dates (see Data S1 for specific dates). The effect of the HR-L was estimated on the log base 2 scale. Thus, the HR-A was interpreted as the relative difference in the hazard of subsequent graft failure for a doubling of the HR-L. In other words, the HR-A measured and compared the relative ability of different posttransplant assessments to differentiate possible posttransplant outcomes at the time of listing. For example, a large HR-A indicated that programs with poor assessments at the time of listing had worse subsequent graft survival than programs with good assessments. A Cox proportional hazards model estimated the HR-A and adjusted for risk factors from the appropriate organ-specific 1-year deceased donor posttransplant graft survival model (see Data S1). Penalized splines estimated the effects of continuous risk factors. The analysis included candidates listed between July 12, 2011, and December 15, 2015, who subsequently underwent transplant before December 31, 2018. All recipients were administratively censored on December 31, 2018. MI handled missing data.

Secondary analyses investigated (1) potential nonlinearity in the association of the HR-L with subsequent outcomes, and (2) whether the HR-A was modified by program size at listing, which was defined as the tertiles for the expected number of events in the assessment at listing. Previous research suggested the possibility of nonlinear associations,[5] and program size may affect the association because posttransplant assessments for larger programs are more precise and therefore less susceptible to random variation. These secondary analyses were performed only for the posttransplant assessment with 5-year follow-up and a 24-month cohort window. Assessments with 5-year follow-up typically had the strongest associations, and 24-month windows align with the transplant and waitlist mortality rate models from the PSRs.

MI was implemented similarly across all models. Predictive mean matching imputed continuous variables, logistic regression imputed binary variables, and multinomial regression imputed categorical variables. Ten iterations of MI were performed for each model, and Rubin's rules combined estimates across the MI iterations.[14] Each analysis used R v3.5.2.[15] The "glmnet" package estimated the PEMs with time-varying effects,[16] the "survival" package estimated the Cox proportional hazards models,[17] and the "mice" package implemented the multiple imputation.[18]

3 | Results

3.1 | Kidney transplant

Kidney assessments with longer posttransplant follow-up and wider cohort windows had larger HR-As (Figure 2; top-left panel, and Table S2). For example, a doubling of the HR-L for the 1-year assessment with a 6-month window had a 6% higher hazard of graft failure (HR-A, $_{1.01}1.06_{1.12}$). The 5-year assessment with a 30-month cohort window had the strongest association (HR-A, $_{1.08}1.18_{1.29}$), although the association was similar for the 5-year assessment with a 24-month cohort window (HR-A, $_{1.07}1.16_{1.27}$).

The HR-L for the 5-year assessment with a 24-month cohort window also had a nonlinear association with subsequent posttransplant graft failure (Figure 3; top-left panel). Specifically, programs with good posttransplant assessments at listing (ie, HR-Ls below 1) had better subsequent outcomes. However, the association clearly attenuated and almost disappeared for programs with HR-Ls above 1; that is, subsequent outcomes were more similar between programs with HR-Ls greater than 1. Additionally, the number of expected events at listing did not modify the HR-A (Figure 4; top-left panel).

3.2 | Liver transplant

Liver assessments with longer posttransplant follow-up and wider cohort windows had larger HR-As (Figure 2; top-right panel, and Table S3). For example, a doubling of the HR-L for the 1-year assessment with a 6-month cohort window had an 8% higher hazard of graft failure (HR-A, $_{1.02}1.08_{1.15}$), which was the weakest association. In contrast, the 5-year assessment with a 24-month cohort window had the strongest association (HR-A, $_{1.11}1.22_{1.34}$).

The HR-L for the 5-year assessment with a 24-month cohort window had a mostly linear association with subsequent posttransplant graft failure (Figure 3; top-right panel). The association decreased at HR-Ls above 1.5, but the confidence intervals became significantly wider, likely due to fewer recipients listed at such programs. Additionally, the number of expected events at listing modified the HR-A for the 5-year assessment with a 24-month cohort window (Figure 4; top-right panel). Specifically, HR-As for programs in the first tertile of expected events at listing (ie, the smallest programs) had no association with subsequent posttransplant outcomes. However, HR-As became progressively stronger for programs in the second and third tertiles. Thus, the largest liver programs had the strongest associations.

3.3 | Lung transplant

In lung transplantation, the HR-As were larger for the 3- and 5-year assessments than for the 1-year assessments (Figure 2; bottom-left panel, and Table S4). Additionally, among assessments with the same length of follow-up, the HR-As were weakest for assessments with 6- and 12-month cohort windows and strongest for assessments with 18-, 24-, and 30-month cohort windows. For example, the

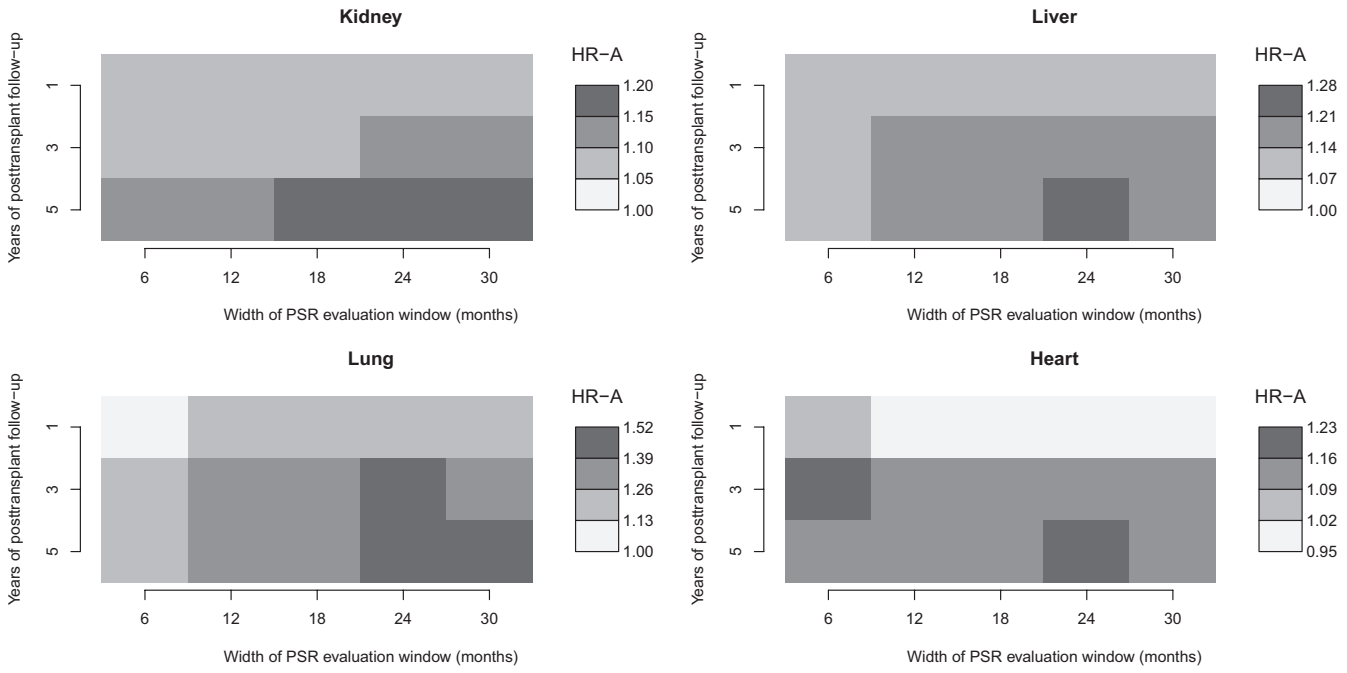

FIGURE 2 The estimated HR-A for posttransplant assessments with differing lengths of posttransplant follow-up and widths of cohort windows. The HR-A was the hazard ratio for a doubling in the HR-L (ie, the HR at listing for an assessment). The outcome of interest was the subsequent graft survival of candidates who subsequently underwent deceased donor transplant. HR-A, hazard ratio for a given posttransplant assessment; HR-L, hazard ratio at listing; PSR, program-specific report

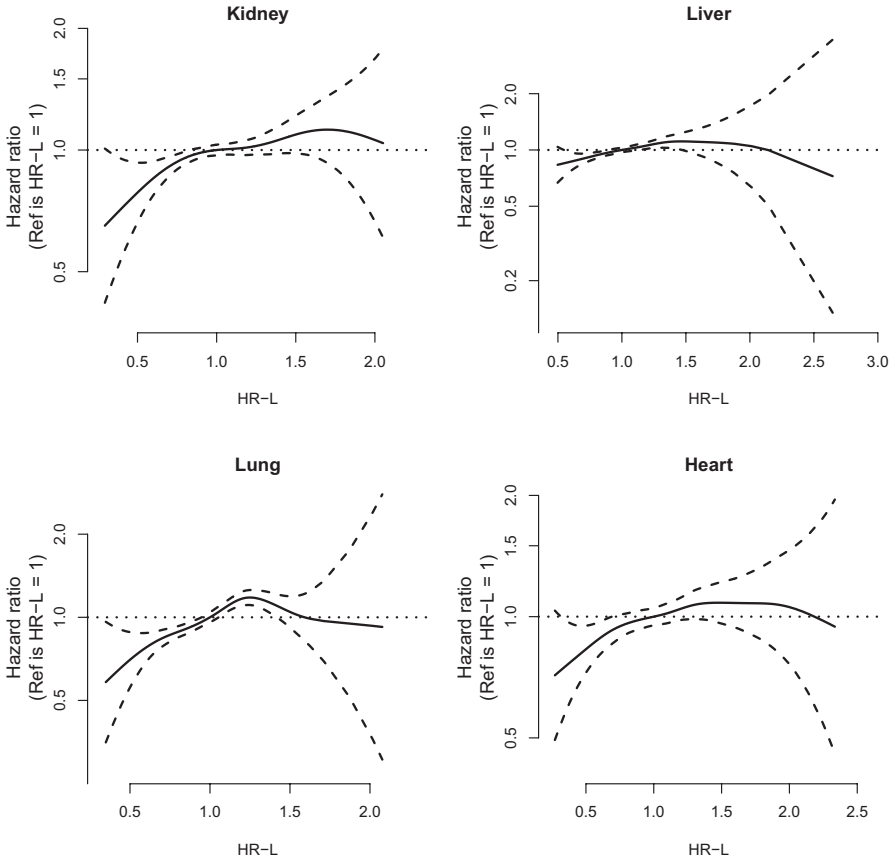

FIGURE 3 The estimated nonlinear trends of the hazard ratio at listing (HR-L) with subsequent posttransplant graft survival. The HR-L was determined from the posttransplant assessment with 5-y follow-up and a 24-mo cohort window

1-year assessment with a 6-month cohort window had the weakest association (HR-A, $_{1.03}1.11_{1.19}$), whereas the 5-year assessment with a 30-month cohort window had the strongest association (HR-A, $_{1.25}1.40_{1.56}$). The association was similar for the 5-year assessment with a 24-month cohort window (HR-A, $_{1.25}1.39_{1.55}$).

The HR-L from the 5-year assessment with a 24-month cohort window had an approximately linear effect until an HR-L of 1.2, after which programs with larger HR-Ls had progressively better rather than worse subsequent outcomes (Figure 3; bottom-left panel). Additionally, the HR-A was largest for programs in the third tertile of expected events (ie, the largest programs), although HR-As varied significantly and did not become progressively larger from the first to the third tertile (Figure 4; bottom-left panel).

3.4 | Heart transplant

The HR-As were largest for the 3- and 5-year assessments in heart transplantation (Figure 2; bottom-right panel, and Table S5). Importantly, none of the 1-year assessments had an association with subsequent graft survival, and the 1-year assessment with a 12-month cohort window had the weakest association (HR-A, $_{0.88}0.97_{1.08}$). The width of the cohort window did not consistently affect the association. For example, the 3-year posttransplant assessment with a 6-month cohort window had the strongest association (HR-A, $_{1.06}1.17_{1.29}$), but the association was similar for the 5-year posttransplant assessment with a 24-month cohort window (HR-A, $_{1.05}1.16_{1.29}$).

The HR-L from the 5-year assessments with a 24-month cohort window had a stronger association for programs with good outcomes at listing; that is, larger differences among programs with HR-Ls below 1, and a weaker association for programs with poor outcomes at listing, that is, smaller differences among programs with HR-Ls above 1 (Figure 3; bottom-right panel). Additionally, the HR-A from the 5-year assessment with a 24-month cohort window did not notably change across programs with different numbers of expected events at listing (Figure 4; bottom-right panel).

4 | DISCUSSION

This study makes two substantial contributions to the understanding of public reporting of posttransplant outcomes. First, posttransplant outcome assessments with 5 years of follow-up were associated with subsequent posttransplant graft survival in kidney, liver, lung, and heart transplantation. Importantly, the associations were stronger than for the 1-year posttransplant assessment with a 30-month cohort window, which is most similar to the current posttransplant outcome assessment on the SRTR website. In fact, posttransplant 1-year assessments in heart transplantation had no association with subsequent outcomes, which aligned with previous research.[5] Thus, extending follow-up to

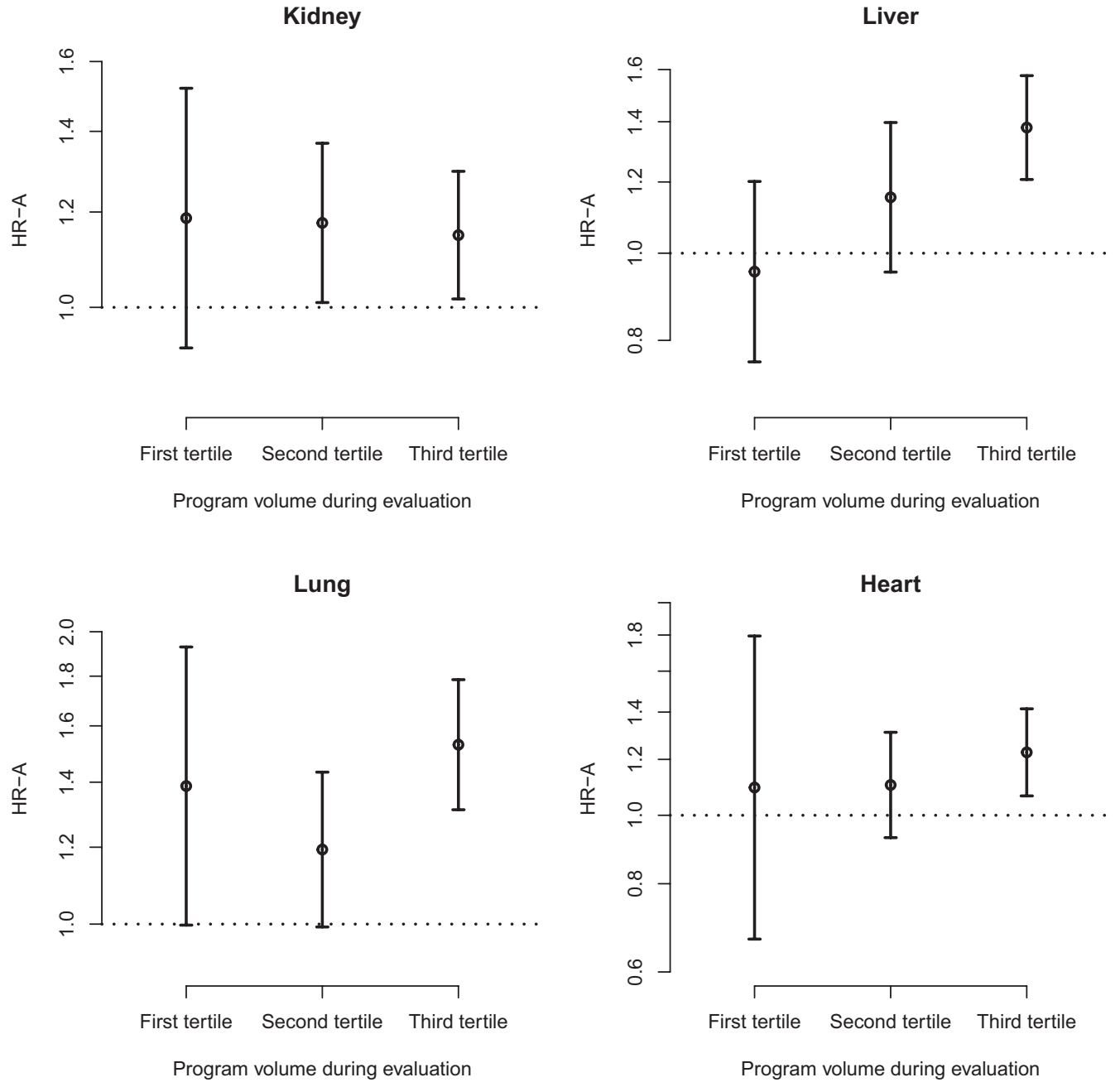

FIGURE 4 The HR-As for the assessment with 5-y follow-up and a 24-mo cohort width stratified by the tertiles of expected events at listing. For example, the first tertile contains the 33% of programs with the lowest number of expected events at the time a recipient joined the waiting list. Similarly, the third tertile contains the 33% of programs with the highest number of expected events at the time a recipient joined the waiting list. The tertiles were determined separately for each organ. HR-A, hazard ratio for a given posttransplant assessment

5 years using a period prevalent approach would improve the usefulness of posttransplant outcome assessments at the time of listing. Second, wider cohort windows usually had stronger associations with subsequent posttransplant outcomes than narrow cohort windows. Thus, despite being more responsive to changes in program outcomes, narrow cohort windows had worse differentiation of posttransplant graft survival at the time of listing.

This study has implications for SRTR's patient-friendly public reporting of posttransplant outcomes. Specifically, the current 5-tier system for posttransplant outcomes should be derived from an assessment with 5-year follow-up rather than 1-year follow-up. This modification would ensure the best differentiation of possible posttransplant outcomes across transplant programs at the time of listing. Better differentiation is critical because candidates and their families place a high priority on understanding posttransplant outcomes[19-21] despite data presentations emphasizing the trade-offs between pre- and posttransplant metrics.[22,23] Because the time of listing is approximately when patients select a transplant program, better differentiation of posttransplant outcomes may help patient decision-making.

Posttransplant outcome assessments in the PSRs are used for quality improvement. Because patients can remain on the waiting list for several years, the posttransplant outcome assessments appropriate for regulatory review and/or transplant program quality improvement could differ from those relevant at the time of listing. For example, transplant programs are likely more interested in posttransplant assessments that identify immediate and active problems.

However, posttransplant outcome assessments relevant at the time of listing may identify older issues and/or issues with causes difficult to identify. Thus, the posttransplant outcome assessments relevant to regulatory review and quality improvement deserve further investigation.

Constant quality improvement efforts complicate the historical associations of posttransplant outcome assessments at the time of listing with subsequent posttransplant outcomes.[5] Programs under regulatory scrutiny have strong financial incentives to improve posttransplant outcomes. These incentives were the primary hypothesis for the previously observed association that programs with good posttransplant assessments with 1 year of follow-up had good subsequent posttransplant outcomes, and programs with average or poor posttransplant assessments with 1 year of follow-up had similar subsequent posttransplant outcomes. These financial incentives could have a weaker effect for longer-term follow-up because regulatory agencies use only 1-year posttransplant outcomes to identify programs for review.[24] Although liver transplantation was a notable exception, similar nonlinear associations existed for kidney, lung, and heart transplantation for the assessments with 5 years of follow-up and a 24-month cohort window, suggesting that similar determinants may cause nonlinear relationships for longer-term posttransplant follow-up.

Programs reduce transplant volume after periods of poor outcomes due to regulatory intervention[25,26] or loss of staff.[27] Lower volume at programs with poor assessments could also complicate the historical associations of posttransplant assessments at the time of listing with subsequent outcomes. Fewer transplants reduce the proportion of transplants performed at programs with poor outcomes, which could attenuate the association of assessments at listing with subsequent outcomes. Thus, the nonlinear associations could be caused by lower volume or constant quality improvement efforts. However, differentiating between these two explanations is not possible with currently available observational data.

Programs with many expected events have more precise and accurate estimates of the posttransplant hazard ratio, whereas programs with few expected events have imprecise and potentially inaccurate estimates. In other words, large programs have more accurate assessments than small programs. For this reason, programs with many expected events could have stronger associations with subsequent posttransplant survival than programs with few expected events. This pattern of association was apparent in liver transplantation but not in kidney, lung, or heart transplantation. The reasons for the different patterns across organs are not clear and deserve further investigation.

This study is subject to potential limitations. The usual risks of unmeasured risk factors exist. For example, programs that consistently perform transplants in recipients with unmeasured protective factors could have (1) good posttransplant assessments at listing and (2) good subsequent posttransplant outcomes. However, the impact of unmeasured risk factors on the role of posttransplant follow-up and the width of cohort windows is unclear, because they would likely affect all historical assessments. Unmeasured risk factors would likely need to differentially affect the posttransplant assessments across length of follow-up and/or width of cohort windows, and these situations are difficult to characterize.

Several important details require resolution before integrating posttransplant outcome assessments with longer follow-up into the PSRs. First, recipients are currently censored at the expected filing date of the transplant recipient follow-up form, because the form determines the presence or lack of graft failure. Second, a 12-month lag currently exists between the end of the cohort window and the PSR release. The cohort window could end only 6 months before the PSR release with a period prevalent cohort, which would increase the temporal proximity of follow-up. However, posttransplant events (ie, graft failure or patient death) may not be accurately identified in such a situation. Lastly, the posttransplant patient survival assessments currently exclude recipients with a previous transplant. The period prevalent cohorts could instead include only the first transplant during a cohort for a given patient. Regardless, these issues for integrating period prevalent cohorts, and therefore longer posttransplant follow-up, require further investigation and clarification.

In conclusion, posttransplant outcome assessments with longer follow-up had stronger associations at the time of listing than 1-year posttransplant outcome assessments. Thus, the period prevalent cohorts for posttransplant assessments present a promising avenue for improving the public reporting of posttransplant outcomes. Additional information regarding how patients perceive this information is needed.

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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*.

DATA AVAILABILITY STATEMENT

Data are available from the Scientific Registry of Transplant Recipients.

ORCID

Andrew Wey https://orcid.org/0000-0002-2584-3018
Ajay K. Israni https://orcid.org/0000-0002-7607-0430
Jon J. Snyder https://orcid.org/0000-0001-7974-8940

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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