INTRODUCTION

Pretransplant metrics are crucial for informing patients regarding transplant program care. For example, due to severe organ shortages, less than 40% of kidney transplant candidates undergo transplantation within 3 years of listing. Even poor donor quality kidneys can improve patient outcomes compared with remaining on the waiting list. Similarly, the effect of program volume on pediatric waitlist mortality was substantially higher than the effect on posttransplant outcomes for both liver and heart transplant, emphasizing the importance of accessible public reporting of waitlist mortality. Yet regulatory review of transplant programs has historically focused on adequate posttransplant survival with no formal evaluation of pretransplant outcomes. In addition, public reporting by the Scientific Registry of Transplant Recipients (SRTR) has emphasized posttransplant outcomes through a discrete “outcome assessment.” Although the OPTN Final Rule mandates public reporting of pretransplant metrics, the metrics currently included in the program-specific reports rely on statistical terminology and can

The Scientific Registry of Transplant Recipients (SRTR) is considering more prominent reporting of program-specific adjusted transplant rate ratios (TRRs). To enable more useful reporting of TRRs, SRTR updated the transplant rate models to adjust explicitly for components of allocation priority. We evaluated potential associations between TRRs and components of allocation priority that could indicate programs’ ability to manipulate TRRs by denying or delaying access to low-priority candidates. Despite a strong association with unadjusted TRRs, we found no candidate-level association between the components of allocation priority and adjusted TRRs. We found a strong program-level association between median laboratory Model for End-stage Liver Disease (MELD) score at listing and program-specific adjusted TRRs ($r = .37; P < .001$). The program-level association was likely confounded by regional differences in donor supply/demand and listing practices. In kidney transplantation, higher program-specific adjusted TRRs were weakly associated with better adjusted posttransplant outcomes ($r = -.14; P = .035$) and lower adjusted waitlist mortality rate ratios ($r = -.15; P = .022$), but these associations were absent in liver, lung, and heart transplantation. Program-specific adjusted TRRs were unlikely to be improved by listing candidates with high allocation priority and can provide useful information for transplant candidates and programs.

KEYWORDS
health services and outcomes research, organ procurement and allocation, Organ Procurement and Transplantation Network (OPTN), Scientific Registry for Transplant Recipients (SRTR)
be difficult to interpret. Thus better public reporting of pretransplant metrics, especially transplant rates, would give patients a more complete picture of transplant program care.

SRTR may place additional emphasis on pretransplant metrics for public reporting through an outcome assessment of adjusted transplant rate ratios (TRRs) and adjusted waitlist mortality rate ratios (WMRRs). Rate ratios correspond, for example, to the observed transplant rate divided by the expected transplant rate: transplants per person-year divided by expected transplants per person-year. The TRR is interpreted as the multiplicative change in transplants performed compared with transplants expected. Due to the important role of risk adjustment in determining the expected number of transplants or deaths on the waiting list, SRTR released more thorough risk-adjustment models for transplant rate and waitlist mortality in the January 2018 program-specific reports (PSRs). The modifications to the pretransplant models and the corresponding concepts are especially important as pretransplant metrics become more prominent in public reporting.

Numerous studies have investigated the unintended consequences of public reporting and regulatory review of posttransplant outcomes. Greater emphasis on pretransplant metrics, and especially on adjusted TRRs, may generate concern about unintended consequences due to perceptions that adjusted TRRs are associated with listing practices, posttransplant outcomes, and waitlist mortality. The primary perceptions are:

1. Programs can achieve good adjusted TRRs by listing candidates with high allocation priority. This perception is sometimes cited as a reason to avoid evaluating adjusted TRRs, and it may have been valid with previous models that did not explicitly adjust for the components of allocation priority. However, the updated models adjust for these components and the relationship is therefore unlikely.

2. Programs with good adjusted TRRs have relatively poor posttransplant outcomes due to a willingness to transplant organs from marginal donors and/or accept marginal recipients. This perception may be related to the lower absolute survival associated with marginal donors and/or recipients. However, risk-adjustment removes the association of measured donor and recipient risk with adjusted posttransplant outcomes. Thus a better risk-adjusted TRR should not be associated with worse risk-adjusted posttransplant outcomes despite potentially worse unadjusted outcomes.

3. Programs with good TRRs will have good WMRRs. This perception may be due to the better survival associated with transplant compared with remaining on the waiting list, or to the fact that patients who undergo transplant cannot die on the waiting list. However, for a single candidate, the TRR is unlikely to affect the risk of waitlist mortality during a single day conditional on the candidate being alive at the beginning of the day. Because this is a conceptual definition of the WMRR, there may be no association between TRRs and WMRRs. In fact, within the framework of competing risks, TRRs and WMRRs are independent, and no association would be expected. In contrast, the eventual probability of waitlist mortality depends on both WMRRs and TRRs, and an association with the eventual probability of transplant would be expected. The Supplementary Materials present the competing risks framework and provide illustrative examples.

Despite theoretical justifications that these perceptions are false, an empirical evaluation is necessary to alleviate concerns regarding a more prominent role of pretransplant metrics in public reporting. In addition, investigation of the perceptions may further justify reporting pretransplant outcomes, especially transplant rate, which has been suggested as a potential avenue to attenuate the unintended consequences of posttransplant evaluations. For example, if a good adjusted TRR is not associated with worse posttransplant outcomes, then more prominent reporting of TRRs would not force programs to choose between a good TRR or good posttransplant outcomes, as they could independently achieve both. In addition, if adjusted TRRs and WMRRs are not associated, then each metric likely assesses a different dimension of pretransplant care and programs can independently achieve good outcomes for both.

2 | MATERIALS AND METHODS

2.1 | Risk-adjustment models for pretransplant metrics

The updated pretransplant models use a methodology similar to that previously described for SRTR posttransplant models. Specifically, the pretransplant models were built with a 2-stage process that considers a wide range of covariates and implements linear splines to identify the effect of continuous covariates. The first step identifies covariates with potentially important effects from an exhaustive list. The second step estimates the final model with the more limited set of covariates. The updated model-building process could create instability and lead to worse predictive performance due to the larger number of covariates and the use of linear splines, which can be highly correlated. Thus similar to the SRTR posttransplant models, the updated pretransplant models are estimated with the Least Absolute Shrinkage and Selection Operator (LASSO), which can stabilize model estimation and improve predictive performance. See Supplemental Materials for more detail regarding the pretransplant model development and fitting process, including the definition of censoring and handling of missing data.

2.2 | Estimation of TRRs and WMRRs

Program-specific TRRs and WMRRs were estimated with a Bayesian methodology similar to that used to estimate hazard ratios for posttransplant outcomes. For example, TRRs were estimated by the observed number of transplants plus 2 divided by the expected number of transplants plus 2. Adding 2 to the observed and expected numbers shrinks the TRR and WMRR toward 1, which can improve estimation.
2.3 | Analysis of pretransplant perceptions

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 the Organ Procurement and Transplantation Network (OPTN), and has been described elsewhere. The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

The primary components of allocation priority at listing were the following: dialysis duration, laboratory model for end-stage liver disease (MELD) score, and lung allocation score (LAS) for kidney, liver, and lung transplantation, respectively. Heart allocation has only 3 tiers of allocation priority and was not included in the analysis. Although there are other important candidate-specific components of allocation, for example, MELD exceptions and calculated panel-reactive antibodies, it is difficult to condense every component into a single score due to allocation tables that prioritize different clinical characteristics at different points in the match run. The selected primary components of allocation priority are the main “tie-breakers” for most candidates in each box of the allocation tables. Other components of allocation priority, including MELD exceptions, were included in the pretransplant models and may have similar qualitative associations as the primary components.

The analyses of the relationship of deceased donor TRRs with the primary components of allocation priority at listing and WMRRs used the period prevalent cohort between July 1, 2014, and June 30, 2016, which would have been the 2-year evaluation cohort for the January 2017 PSR release. The analysis of the relationship between deceased donor adjusted TRRs and posttransplant outcomes used the period prevalent cohort between July 1, 2013, and December 31, 2015. This was the same as the 1-year posttransplant graft survival cohort in the January 2016 PSR release and ensured an appropriate comparison of the potential consequences of a high adjusted TRR on eventual unadjusted and adjusted posttransplant outcomes. Each cohort included only adult candidates and/or recipients.

Calibration plots examined the ability of the transplant rate model to adjust for allocation priority at listing. Specifically, we categorized patients by intervals of the primary component in allocation priority, and then calculated the unadjusted and adjusted deceased donor TTR within each interval, where the adjusted TTR accounted for every factor included in the pretransplant models (see https://www.srtr.org/reports-tools/risk-adjustment-models-waiting-list/). The closer the calibration plots for the adjusted TRRs were to 1, the better the models accounted for differential transplant rates across allocation priority at listing. The Supplementary Materials provide the interval definitions for each organ.

We also investigated the program-level relationship between the median of the primary component of allocation priority at listing and unadjusted and adjusted deceased donor TRRs for kidney, liver, and lung programs. The median of the primary component of allocation priority at listing for programs was determined with the 2-year period prevalent cohort (July 1, 2014-June 30, 2016). Pearson correlation coefficients estimated the associations with unadjusted and adjusted program-specific deceased donor TRRs. If the calibration plots did not demonstrate an association between the component of allocation priority and adjusted deceased donor TRRs, a program-level association would not indicate that programs achieved a better adjusted TRR by listing high-priority candidates. Instead, a program-level association would likely indicate the presence of confounders, for example, geographic disparities in donor supply and demand.

A Pearson coefficient evaluated the program-level association of the adjusted deceased donor TRR with 1-year posttransplant graft survival (unadjusted and adjusted) and the adjusted WMRR for kidney, liver, lung, and heart programs.

3 | RESULTS

3.1 | Candidate-level association between components of allocation priority and TRRs (Figure 1)

Dialysis duration and laboratory MELD at listing had strong nonlinear relationships with, respectively, unadjusted kidney and liver TRRs (Figure 1: top- and middle-left panels). LAS at listing had a strong increasing relationship with the unadjusted lung TRR (Figure 1: bottom-left panel). As expected, the transplant rate models removed each relationship from the adjusted TRRs (Figure 1: right panels). For example, kidney candidates listed with 5 years of dialysis underwent approximately twice the number of deceased donor transplants as expected based on the national average, but less than 10% fewer transplants than expected after adjusting for candidate characteristics including duration of dialysis at listing. Candidates with high allocation priority at listing did not have better adjusted TRRs. Thus programs were unlikely to achieve better adjusted TRRs only by listing candidates with high allocation priority. Instead, programs would have to perform transplants in such candidates at a rate higher than the national average for candidates with similar allocation priority.

3.2 | Program-level association between components of allocation priority and TTR (Figure 2)

For kidney programs, median years on dialysis at listing was weakly correlated with the program-specific unadjusted TRR (Figure 2: top-left panel), and risk-adjustment further attenuated the correlation.
transplant survival (Figures S4-S6). Thus there was no evidence that association between program-specific adjusted TRRs and 1-year post-outcomes. In liver, lung, and heart transplantation, there was no exception that a high adjusted TRR would cause poor posttransplant associations were in the opposite direction expected based on the per-

Adjusted TRRs explained, at most, a small proportion of variability in donor supply and demand. Although the PSRs present adjusted TRRs, the SRTR website currently presents unadjusted transplant rates that are difficult to interpret, and, due to lack of risk adjustment, differences can be caused by variability in patient populations rather than transplant program care. Unadjusted transplant rates are therefore not appropriate for summarizing a program’s propensity to perform transplants in waitlisted candidates. A common criticism of the 5-tier reporting system for posttransplant outcomes was lack of a comparable system for pretransplant metrics, especially transplant rates.7 A TRR adjusted for allocation priority at listing and candidate comorbid conditions would appropriately summarize the likelihood of transplant and give patients a more complete picture of transplant program care.

The updated pretransplant models are critical for further public reporting of adjusted TRRs because, first, the previous models may not have adequately adjusted for candidate comorbidity or allocation priority at listing; for example, previous kidney models did not include dialysis duration. The updated models also consider many factors, including linear splines for continuous covariates. Second, the updated models focus on candidate status at listing, while the previous models used candidate status at the beginning of the cohort or, for candidates listed during the cohort, status at listing. Transplant rate and waitlist mortality are affected by the clinical trajectory after listing (eg, a higher MELD score increases the likelihood of both outcomes) and, since changes in clinical status could be caused by program care or decision-making (eg, status 1 and ventilator assist devices in heart allocation), adjusting for the changes in clinical status could remove the program effect from adjusted TRRs and WMRRs. Furthermore, candidate status at listing better aligns the TRR with an intent-to-treat analysis, which describes the program effect for candidates with a similar status at listing. Thus the updated pretransplant models should provide better risk adjustment and better identify the effect of program care on waitlist outcomes.

This study showed that components of candidate-level allocation priority at the time of listing were not associated with adjusted TRRs, suggesting that program-specific adjusted TRRs cannot be improved or manipulated by listing candidates with characteristics included in the transplant rate model, for example, high laboratory MELD. Specifically, good adjusted TRRs can be achieved only if candidates undergo transplant at rates faster than the national average for candidates listed with similar allocation priority. In addition, calibration of the liver transplant rate model across quartiles of donor supply and demand was relatively good, shifted up for high-supply DSAs and down for low-supply DSAs (Figures S7-S8). Listing candidates with high laboratory MELD was unlikely to improve the program-specific adjusted TRR beyond the effect of local liver supply.

Further emphasis on adjusted TRRs in public reporting could lead to unintended consequences. Although listing candidates with higher allocation priority is unlikely to improve a program’s adjusted TRR, individual programs could achieve better adjusted TRRs by interpretable system for pretransplant metrics, especially transplant rates.7

3.3 Program-level association between adjusted TRRs and 1-year posttransplant graft survival (Figure 3)

In kidney transplantation, there was a significant association between high program-specific adjusted TRRs and better 1-year unadjusted graft survival rates and a similar association for adjusted hazard ratios for 1-year posttransplant graft survival. These associations were in the opposite direction expected based on the perception that a high adjusted TRR would cause poor posttransplant outcomes. In liver, lung, and heart transplantation, there was no association between program-specific adjusted TRRs and 1-year posttransplant survival (Figures S4-S6). Thus there was no evidence that good adjusted TRRs caused poor posttransplant outcomes.

3.4 Program-level association between adjusted TRRs and WMRRs (Figure 4)

In kidney transplantation, there was a weak but significant association between good adjusted TRRs and good adjusted WMRRs. There were no associations in liver, lung, and heart transplantation. Adjusted TRRs explained, at most, a small proportion of variability in adjusted WMRRs. Thus program-specific adjusted TRRs and WMRRs identified different dimensions of transplant program care.

4 DISCUSSION

Although the PSRs present adjusted TRRs, the SRTR website currently presents unadjusted transplant rates that are difficult to interpret, and, due to lack of risk adjustment, differences can be caused by variability in patient populations rather than transplant program care. Unadjusted transplant rates are therefore not appropriate for summarizing a program's propensity to perform transplants in waitlisted candidates. A common criticism of the 5-tier reporting system for posttransplant outcomes was lack of a comparable system for pretransplant metrics, especially transplant rates.7 A TRR adjusted for allocation priority at listing and candidate comorbid conditions would appropriately summarize the likelihood of transplant and give patients a more complete picture of transplant program care.

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Kidney

Median Years on Dialysis at Listing

Unadjusted Transplant Rate Ratio

Adjusted Transplant Rate Ratio

Liver

Median MELD at Listing

Unadjusted Transplant Rate Ratio

Adjusted Transplant Rate Ratio

Lung

Median LAS at Listing

Unadjusted Transplant Rate Ratio

Adjusted Transplant Rate Ratio

- Kidney
  - Median Years on Dialysis at Listing
  - Unadjusted Transplant Rate Ratio: $r = 0.11$, $p = 0.103$
  - Adjusted Transplant Rate Ratio: $r = 0.04$, $p = 0.504$

- Liver
  - Median MELD at Listing
  - Unadjusted Transplant Rate Ratio: $r = 0.56$, $p < 0.001$
  - Adjusted Transplant Rate Ratio: $r = 0.37$, $p < 0.001$

- Lung
  - Median LAS at Listing
  - Unadjusted Transplant Rate Ratio: $r = 0.44$, $p < 0.001$
  - Adjusted Transplant Rate Ratio: $r = 0.24$, $p = 0.048$
delisting candidates unlikely to undergo transplant at the program. This could be especially true for programs with large waiting lists, where large proportions of candidates may be unlikely to ever undergo transplant; for example, the program may lack the hospital resources and/or organ availability to perform the number of expected transplants. However, delisting is not necessarily a bad

![Graph showing the association between program-specific kidney deceased donor transplant rate ratios and 1-year unadjusted graft survival rates](image1)

**FIGURE 3** The association between program-specific kidney deceased donor transplant rate ratios (TRRs) and 1-year unadjusted graft survival rates (right panel) and adjusted hazard ratios for 1-year posttransplant kidney graft survival (left panel). Only adult candidates and programs were included in the analysis. A complete list of factors included in the adjusted TRRs is available at [https://www.srtr.org/reports-tools/risk-adjustment-models-waiting-list/wileyonlinelibrary.com](https://www.srtr.org/reports-tools/risk-adjustment-models-waiting-list/wileyonlinelibrary.com) [Colour figure can be viewed at wileyonlinelibrary.com]

![Graphs showing the association between transplant rate ratios and waitlist mortality rate ratios](image2)

**FIGURE 4** The association between program-specific adjusted deceased donor transplant rate ratios (TRRs) and adjusted waitlist mortality rate ratios for kidney (top-left), liver (top-right), heart (bottom-left), and lung (bottom-right) programs. Only adult candidates and programs were included in the analysis. A complete list of factors included in the adjusted TRRs is available at [https://www.srtr.org/reports-tools/risk-adjustment-models-waiting-list/wileyonlinelibrary.com](https://www.srtr.org/reports-tools/risk-adjustment-models-waiting-list/wileyonlinelibrary.com) [Colour figure can be viewed at wileyonlinelibrary.com]
outcome, especially for candidates unlikely to undergo transplant at the program. Alternatively, programs could restrict overall access by reducing the probability of listing any candidate. The feasibility of this approach is less clear. For example, if every program in the nation similarly restricted access, no program would achieve a better adjusted TRR. Furthermore, programs must list candidates to guarantee offers for potential donor organs and, ultimately, to perform transplants. Programs that restrict access may have difficulty performing the same number of transplants and may not achieve a better adjusted TRR. Although listing practices are difficult to monitor, trends among listed candidates can be evaluated for potential changes, which may be especially important for programs with large waiting lists. Regardless, better data on listing practices and, in particular, likelihood of a program listing a referred candidate, would elucidate a largely unknown component in the continuum of transplant care.16

Geographic variability in likelihood of undergoing deceased donor transplant is substantial across DSAs.1,17-19 A program’s TRR could be higher than other local programs’ rates but lower than the national average. This dependency on geographic differences in local donor supply likely prevents use of adjusted TRRs in regulatory review because differences in adjusted TRRs may not be under the control of the transplant program. However, public reporting should not obscure geographic disparities in access that are potentially relevant to patient decision-making regardless of the underlying cause. Although the adjusted TRR could potentially account for local deceased donor supply, the primary TRR should not adjust for such geographic disparities. However, a relative TRR among local programs remains relevant because patients may have access only to local programs. SRTR is considering a separate online tool to allow patients and programs to compare geographically adjusted TRRs for programs within a certain number of miles of a ZIP code. This approach may balance the reality of geographic disparities in access to deceased donor organs, while simultaneously providing patients and programs with relevant information on the likelihood of transplant at local programs.

Socioeconomic factors are associated with disparities in access to kidney transplantation.20,21 Despite potentially allowing continued disparities in access, public reporting should identify differences in the care provided, not differences in the patient population. Therefore, the pretransplant models should adjust for socioeconomic factors.22 A limited number of socioeconomic factors, for example education level, are included in the pretransplant models; however, additional measures associated with the ZIP code of the listed candidate, for example, median income, may better identify the socioeconomic status. These ideas deserve further investigation.

The association between good adjusted TRRs and good posttransplant outcomes for kidney transplant programs dramatically demonstrates the fallacy of the perception that restricting pretransplant access leads to better posttransplant outcomes. The associations, especially with unadjusted posttransplant survival, are surprising because programs with good adjusted TRRs may perform transplants using a higher proportion of marginal donors and/or recipients, which would have suggested an association with worse unadjusted posttransplant survival. The association may have identified programs with poor outcomes that then restricted access to transplant due to the regulatory environment.23,24 Although the cohorts for the pretransplant and posttransplant evaluations were identical to ensure an appropriate comparison, programs were likely aware of the potential for a poor posttransplant evaluation and may have restricted access before the PSR release and even during the cohort. Even if the associations identified risk aversion due to poor outcomes, there is still no evidence that high adjusted TRRs, or transplants with high measured risk, are associated with worse adjusted posttransplant outcomes.9

Lack of an association between adjusted TRRs and posttransplant evaluations may further justify more prominent public reporting of pretransplant metrics. Specifically, poor posttransplant evaluations are associated with lower transplant volume and higher waitlist removal rates in kidney transplantation.23,24 More prominent reporting of adjusted TRRs may incentivize programs to maintain transplant volume or otherwise risk low adjusted TRRs. However, long-term outcomes should be carefully monitored to ensure that good adjusted TRRs are not achieved at the cost of poor long-term outcomes. Alternatively, since poor donor quality organs can provide a survival benefit compared with remaining on the waiting list, a metric that integrates pretransplant and posttransplant outcomes could provide a more holistic measure of the patient experience at a program.25

The significant association between adjusted deceased donor TRRs and WMRRs in kidney transplantation could be caused by longer waitlist times compared with times for other organs,4 or by unmeasured risk factors associated with low transplant rates but high waitlist mortality. The association in kidney transplantation was weak and, in general, a good adjusted TRR did not guarantee a good adjusted WMRR. Furthermore, variability in adjusted WMRRs was relatively low for kidney transplant programs compared with nonkidney programs, and more prominent reporting of kidney adjusted WMRRs may identify relatively small differences. Best practices in public reporting caution against reporting too many metrics,24 and identifying small differences in adjusted WMRRs could create unnecessary difficulties in interpreting the public reports. SRTR plans to further evaluate waitlist mortality for each solid organ, and may consider more prominent reporting for certain organs (eg, liver, lung, and heart) but not others (eg, kidney).

The analysis has potential limitations. First, the new kidney allocation system (KAS) was implemented 5 months after the beginning of the pretransplant data cohort (December 4, 2014). Before KAS, candidates were primarily prioritized by waiting time, not dialysis duration. Although number of days on the waiting list at the beginning of the cohort was included in the pretransplant models, implementation of KAS could influence the effects of dialysis duration and days on the waiting list at the beginning of this cohort. This could bias the association of program-specific deceased donor TRRs with 1-year posttransplant outcomes and waitlist mortality, although the direction of the potential bias is unclear. The analysis
did not adjust for KAS because the adjusted TRRs would not correspond to the metrics included in SRTR PSRs, and there were a priori reasons (ie, the numbered list in the Introduction) that the adjusted kidney TRRs may not be associated with dialysis duration at listing, posttransplant outcomes, or waitlist mortality. Second, proper risk adjustment is critical to public reporting of pretransplant and posttransplant outcomes. The model building process for posttransplant outcomes and the updated model building process for pretransplant outcomes considers a wide range of covariates and potential nonlinearity in continuous covariates. However, statistical models cannot adjust for unmeasured risk factors, and there are concerns that programs may restrict access for candidates with unmeasured risk factors, for example, avoid listing candidates with cardiovascular disease. The best solution for mitigating concerns regarding unmeasured risk factors is collection of additional data. Further data standardization and quality control could also improve risk-adjustment of currently collected data. The OPTN Data Advisory Committee, which is responsible for recommending collection of additional data, could consider the potential improvement of including, for example, cardiovascular risk factors. Program-specific adjusted TRRs cannot be manipulated only by listing candidates with high allocation priority. In addition, adjusted TRRs are not strongly associated with adjusted WMRRs or with posttransplant outcomes. Thus further public reporting of pretransplant metrics, especially adjusted TRRs, may provide patients with a more complete picture of transplant program care.

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DISCLOSURE

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REFERENCES


SUPPORTING INFORMATION

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