REVIEW

CURRENT OPINION

Scientific Registry of Transplant Recipients program-specific reports: where we have been and where we are going

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Purpose of review

Reporting provider data on quality to patients and the general public is increasingly common in healthcare. Reporting outcomes in solid organ transplantation has always been controversial and deserves careful consideration to ensure optimal results.

Recent findings

As mandated by Federal law, the Scientific Registry of Transplant Recipients publishes program-specific reports on transplant candidates, recipients, donors, and transplant outcomes every 6 months. Recent changes designed to make the results more easily understood by patients and the general public have been well received by patients and controversial among providers. In particular, outcomes are now reported using a five-tier system that distinguishes program results better than the old three-tier system, in which almost all programs were reported ''as expected.'' Metrics that reflect access to transplant are also reported, including transplant rate and survival on the waiting list. Possible measures of longer term outcomes and program rates of accepting organs for transplant are being explored.

Summary

Providing detailed information regarding transplant program practices and outcomes in ways that patients and the general public can understand remains a major focus of the Scientific Registry of Transplant Recipients. Efforts to improve data collection and metrics reported are ongoing.

Keywords

Bayesian methodology, *C*-statistic, five-tier assessment, organ procurement, transplantation network

INTRODUCTION

Very soon after solid organ transplants had become accepted clinical practice, scrutiny of transplant program outcomes was suggested to ensure quality. In 1975, Opelz, Mickey, and Terasaki reported results for kidney transplants performed between January 1969 and December 1973 [1]. Ninety-five programs submitted data on deceased donor kidney transplants in the United States and Canada to the University of California, Los Angeles, registry, and 84 programs submitted data on living donor transplants. One-year graft survival among 3192 deceased donor transplants was 49% and among 1355 living donor transplants 70%. The authors noted heterogeneity in outcomes and proposed a rudimentary statistical method to determine when program performance was worse than expected. In the process, they recognized a number of challenges that remain today. These included taking into account: ''numerous factors,'' ''lower limit of acceptability . . . depending on the number of transplants,'' ''methods by which deviant centers or procedures can be identified,'' ''patient's point of view,'' ''objective criteria,'' and ''high-risk patients.''

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KEY POINTS

- Publishing assessments of transplant program performance is mandated by law in the United States.
- Better data on differences in risk are needed to improve the statistical assessment of program outcomes.
- Additional metrics are needed to better characterize transplant programs.
- Efforts should continue to make information easier for patients and families to interpret.

The National Organ Transplantation Act of 1984 directed the United States Department of Health and Human Services (HHS) to regulate solid organ transplantation in the United States (Table 1) [2]. HHS awarded two contracts to the United Network for Organ Sharing (UNOS), one in 1986 to manage the Organ Procurement and Transplantation Network (OPTN), and one in 1987 to establish the Scientific Registry of Transplant Recipients (SRTR). UNOS began collecting data from transplant programs in 1987 and issued its first center-specific report of outcomes in 1992 [3]. In 1993, the OPTN Board of Directors approved the use of center-specific reports to identify programs that needed further scrutiny by the OPTN Membership and Professional Standards Committee (MPSC). In 1997, the MPSC published a method for identifying underperforming programs by collecting additional information and conducting site visits [4].

In 2000, the HHS Final Rule was implemented (Table 1), stipulating that OPTN and SRTR

> Make available to the public timely and accurate program-specific information on the performance of transplant programs. This shall include free dissemination over the Internet, and shall be presented, explained, and organized as necessary to understand, interpret, and use the information accurately and efficiently. These data shall ... include risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant, risk-adjusted graft and patient survival following the transplant, and risk-adjusted overall survival following listing.... [5]

The Centers for Medicare and Medicaid Services (CMS) published regulations governing organ procurement organizations in 2006 and transplant programs in 2007 [6]. CMS uses SRTR data, but has developed its own methods for determining which programs to inspect for compliance. CMS methods differ from those currently used by the MPSC [7].

PROGRAM-SPECIFIC REPORTING METHODS

In 2000, the HHS SRTR contract moved from UNOS to the University Renal Research and Education Association, which became Arbor Research Collaborative for Health in July 2006. Arbor Research Collaborative for Health used frequentist statistical methods to generate confidence intervals and *P* values to determine programs with outcomes better or worse than expected [8]. Detailed tables of outcomes and other statistics were published every 6 months for each transplant program in the United States. In 2010, the SRTR contract moved from Arbor Research Collaborative for Health to the Minneapolis Medical Research Foundation, recently renamed Hennepin Healthcare Research Institute, where it remains. The current contractor held a consensus conference in early 2012 to solicit feedback from the transplant community on how program outcomes should be measured and reported [9]. The consensus

Table 1. Notable events in the development and use of SRTR program-specific reports

1984	NOTA as amended [2]
1986	OPTN contract awarded to UNOS
1987	SRTR contract awarded to UNOS
1987	UNOS data collection began
1992	First OPTN/UNOS center-specific report ($n = 28\,858$; October 1, 1987–December 31, 1989) [3]
1993	OPTN/UNOS Board of Directors approves using center-specific report for ''flagging'' for programs
1997	OPTN MPSC publishes method for ''flagging'' underperforming programs [4]
1999	OPTN/UNOS center-specific reports appear on the internet for the first time
2000	Final rule operationalizing NOTA takes effect [5]
2006	CMS regulations of organ procurement organizations are published
2007	CMS regulations for transplant programs are published

CMS, Centers for Medicare and Medicaid Services; MPSC, Membership and Professional Standards Committee; NOTA, National Organ Transplant Act; OPTN, Organ Procurement and Transplantation Network; SRTR, Scientific Registry of Transplant Recipients; UNOS, United Network for Organ Sharing.

conference made a number of specific recommendations that have guided recent changes made to the SRTR program-specific reports (PSRs).

SRTR changed the methods for calculating program-specific outcomes from a frequentist statistical analysis to a Bayesian methodology [10–12]. In addition, SRTR now offers more tools for programs and patients, including making cumulative sum control chart reports available to every transplant program [13]. Finally, SRTR strives to make the PSRs better suited to the needs of all users, particularly patients [14▪]. In doing so, SRTR has adopted a five-tier system for reporting outcomes and other metrics in a manner that is more understandable for patients.

RELIABILITY OF DATA USED TO ADJUST PROGRAM OUTCOMES

Not surprisingly, with change has come controversy. A persistent question is whether the OPTN data are adequate for risk adjustments used in SRTR program-specific reporting. Unmeasured risk may differ between programs and could explain differences in outcomes [15,16]. In particular, cardiovascular disease risk may not be adequately accounted for, and the data needed to adjust for this risk could be collected. On the other hand, not all risk factors for outcomes should be used to adjust program outcomes. Variables that indicate clinical care judgment, such as the type of immunosuppression used and whether desensitization regimens are used, represent clinical practices for which programs should arguably be held accountable. Whether socioeconomic characteristics should be used to adjust outcomes is controversial, with some arguing that adjusting for socioeconomic factors may impede the needed additional efforts to care for high-risk patients [17].

RELIABILITY OF STATISTICAL MODELS

Another common concern is that SRTR models do not predict outcomes reliably and therefore are not sufficiently accurate for measuring expected differences between programs. The *C*-statistic has often been used to question the accuracy of SRTR models. For graft survival models, the *C*-statistic measures how well the ordering of the predicted events matches the order of the observed events. A *C*-statistic of 1.00 implies that a model perfectly orders the observed failure times, whereas a *C*-statistic of 0.50 implies that the predictions had no association with observed failure times. *C*-statistics are useful for comparing the performance of competing models but provide no information about the performance of a particular model for program evaluation [18].

THE MOVE TO FIVE-TIER ASSESSMENTS

SRTR recently changed from a three to a five-tier system for presenting program quality metrics [19▪]. Under the three-tier system, graft survival at almost all programs was labeled ''as expected.'' In the January 2017 PRSs, proportions labeled ''as expected'' were 94% for kidney, 98% for liver, 97% for lung, and 98% for heart transplants. The three-tier system thus provided almost no discrimination for patients or the general public even though failure rates varied threefold or more across programs. Although there are more four and five-tier programs than one and two-tier programs, the five-tier system nevertheless provides a greater degree of discrimination between programs. While this better fulfills the directive of the Final Rule, and most patients have reacted favorably, not all transplant programs and transplant professionals, understandably, have been pleased to be rated in this manner.

The five-tier rating system has been described as too ''volatile,'' because programs may change tiers from one rating period to another [20]. However, one expects that programs divided into five tiers would be more likely to change tiers over time than the same number of programs divided into three tiers, especially when most programs are no longer in one ''as expected'' tier. Moreover, it is not possible to determine when changes in tiers reflect real changes in performance, for example, intended improvements, versus random variation.

Differences in 1-year transplant graft survival among the five tiers have been described as lacking clinical relevance, especially for kidney transplants. However, clinical relevance is in the eye of the beholder. In the PSRs for transplants from July 1, 2012, to December 31, 2014, differences in 1-year graft failure between one-tier and five-tier programs were 3.4-fold for kidney, 2.9-fold for liver, 3.4-fold for heart, and 3.3-fold for lung transplants [21]. Corresponding absolute differences in predicted 1-year graft survival for an average-risk patient between tiers 1 and 5 were 4% (93–97%) for kidney, 9% (85–94%) for liver, 11% (85–96%) for heart, and 14% (80–94%) for lung transplant programs. These are *mean* differences across tiers, and certainly differences that many patients would like to know about.

The suggestion from programs and transplant professionals that a program's quality should be measured by more than just 1-year patient and graft survival is well founded. Indeed, we are currently developing measures that may be equally as, if not more, important to patients. We intend to apply the five-tier classification system to these other measures, following Agency for Healthcare Research and Quality guidelines [22], making quality comparisons easier for patients to understand.

THE SPECTER OF RISK AVERSION

A major criticism of SRTR PSRs relates to fear of unintended consequences, especially transplant program risk aversion. It has been argued that publicly reporting program outcomes, and using these outcomes to identify programs possibly needing additional scrutiny by MPSC and/or CMS, as well as use of SRTR data by private insurance providers to award contracts and determine ''centers of excellence,'' all discourage programs from performing ''risky'' transplants that they would otherwise perform [23]. Evidence for this is largely circumstantial.

Risk-adjustment models work [24▪▪]. Avoiding risky transplants is not an effective method of improving program outcomes, except for avoiding transplants that the program is not capable of performing or avoiding futile transplants. Despite concerns that risk aversion is an unintended consequence of PSRs, numbers of transplants (Fig. 1) and their outcomes (Fig. 2) have continued to improve. Possibly, programs with better outcomes are picking up the slack from risk-averse programs with worse outcomes, but in any case, there is little evidence that recent changes in PSR reporting have led to fewer high-risk transplants.

There has been argument that risk aversion stifles innovation and that transplant programs participating in innovative projects or studies should be exempt from regulatory scrutiny. The Collaborative Innovation and Improvement Network (COIIN) is an effort by OPTN/UNOS to allow transplant programs to share best practices that encourage use of kidneys with kidney donor profile index above 50 and increase kidney transplants. Participation in COIIN ''removes current performance flagging criteria for participating kidney transplant programs'' [25]. Although COIIN's goals and methods are admirable, the lack of a control group will make results difficult to interpret. Whether participation in studies such as COIIN should allow programs to be removed from usual quality assurance measures remains to be determined. It may be possible, and preferable, to monitor program participation in studies and determine the impact of the study intervention on PSRs. In general, it may be better to monitor and adjust than to exempt and remove.

PRETRANSPLANT METRICS

In many cases, undergoing transplant, even at a program whose posttransplant outcomes are suboptimal, is better than remaining on the waiting list, in which mortality is high and quality of life is low [26]. Patients should be informed about their chances on the waiting lists at different programs and whenever possible should be given the opportunity to list at programs in which they are most likely to undergo transplant. Therefore, we have begun reporting waitlist mortality rates and transplant rates on the basis of the standardized mortality rate ratio and standardized transplant rate ratio,

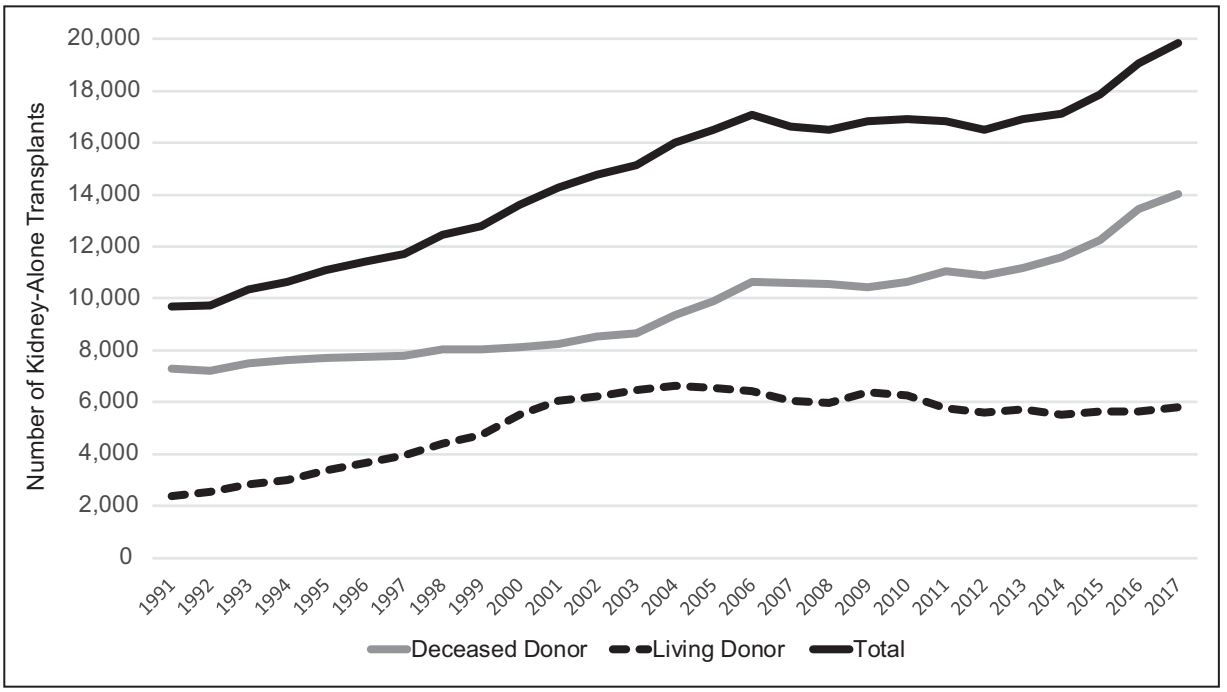

FIGURE 1. Trends in the numbers of deceased and living donor kidney-alone transplants in the United States. Data are from the Organ Procurement and Transplantation Network (https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#).

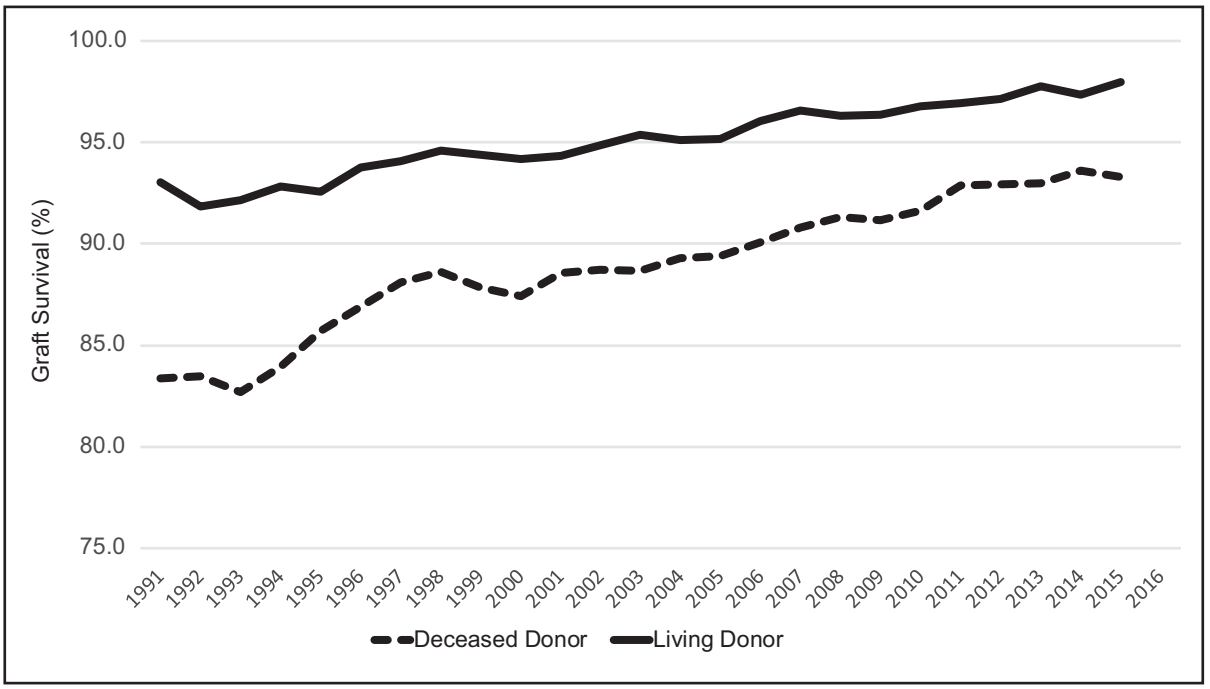

FIGURE 2. Trends in 1-year graft survival of deceased and living donor transplants in the United States. Data are from the 2013 and 2016 Organ Procurement and Transplantation Network/Scientific Registry of Transplant Recipients Annual Data Reports (https://www.srtr.org/).

respectively [27]. Although it is true that transplant rates currently reflect regional differences in organ supply and demand that are not necessarily under a program's control, the metric is nevertheless important to patients regardless of the causes of differences. Ultimately, eliminating geographic disparities in organ distribution may help alleviate this problem.

ACCEPTANCE RATES OF DECEASED DONOR ORGAN OFFERS

The availability of organs for transplant remains one of the most critical issues in transplantation. Discard rates are unacceptably high, and organ acceptance rates are plagued by unexplained variability. SRTR has developed models of organ acceptance that are included in the PSRs [28,29]. In the meantime, developing tools and patient education materials that describe when accepting an organ for transplant is likely in a patient's best interest remains an SRTR priority [30].

LONGER TERM OUTCOMES

There may still be opportunities to improve long-term outcomes. A recent study of 379 257 first kidney-only transplants, 1988–2014, compared outcomes in four countries on three continents [31▪]. Compared with the United States, 1-year risk for graft failure was greater in the United Kingdom (hazard ratio 1.22) and New Zealand (hazard ratio 1.29), but lower in Australia (hazard ratio 0.90). However, among recipients surviving at least 1 year with a functioning kidney graft, the risk of subsequent graft failure was 25% greater in the United States compared with the other three countries: Australia (hazard ratio 0.74), New Zealand (hazard ratio 0.75), and the United Kingdom (hazard ratio 0.74). These differences were not explained by adjusting for multiple patient and donor characteristics. As the authors pointed out, it is possible that country-specific differences could be accounted for by unmeasured confounders. However, their analyses suggested that this was likely not the case.

Currently, the PSRs report 3-year outcomes. But, additional measures could possibly be taken to improve long-term outcomes, and reporting outcomes past 3 years, or over different intervals of follow-up time, may be an important step to focus efforts to improve long-term outcomes in the United States.

CONCLUSION

The United States government mandates that information on outcomes at transplant programs be made available to the general public. SRTR makes PSRs available on its website every 6 months. Recently, the PSRs began providing summary

statistics using a five-tier assessment system to replace the old three-tier assessments that failed to distinguish meaningful differences between programs. In addition, pretransplant metrics are now reported to allow patients and families to better assess their chances of undergoing transplant at different programs nationwide. SRTR strives to provide program information using the most up-to-date statistical and graphical techniques. Future efforts should focus on better data collection by OPTN, additional pretransplant metrics to measure access to transplant, and educational tools to help patients make decisions.

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Conflicts of interest

There are no conflicts of interest.

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- ■■ of outstanding interest

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This provocative study shows that long-term outcomes are worse in the United States than in other countries. It suggests the need for studies to better understand the reasons for these discrepancies and possibly improve long-term outcomes in the United States.