

## Meeting Report

# Report of a Consensus Conference on Transplant Program Quality and Surveillance

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**Public reports of organ transplant program outcomes by the US Scientific Registry of Transplant Recipients have been both groundbreaking and controversial. The reports are used by regulatory agencies, private insurance providers, transplant centers and patients. Failure to adequately adjust outcomes for risk may cause programs to avoid performing transplants involving suitable but high-risk candidates and donors. At a consensus conference of stakeholders held February 13–15, 2012, the participants recommended that program-specific reports be better designed to address the needs of all users. Additional comorbidity variables should be collected, but innovation should also be protected by excluding patients who are in approved protocols from statistical models that identify underperforming centers. The potential benefits of hierarchical and mixed-effects statistical methods should be studied. Transplant centers should be provided with tools to facilitate quality assessment and performance improvement. Additional statistical methods to as-**

**sess outcomes at small-volume transplant programs should be developed. More data on waiting list risk and outcomes should be provided. Monitoring and reporting of short-term living donor outcomes should be enhanced. Overall, there was broad consensus that substantial improvement in reporting outcomes of transplant programs in the United States could and should be made in a cost-effective manner.**

**Key words:** Program-specific reports, OPTN, SRTR

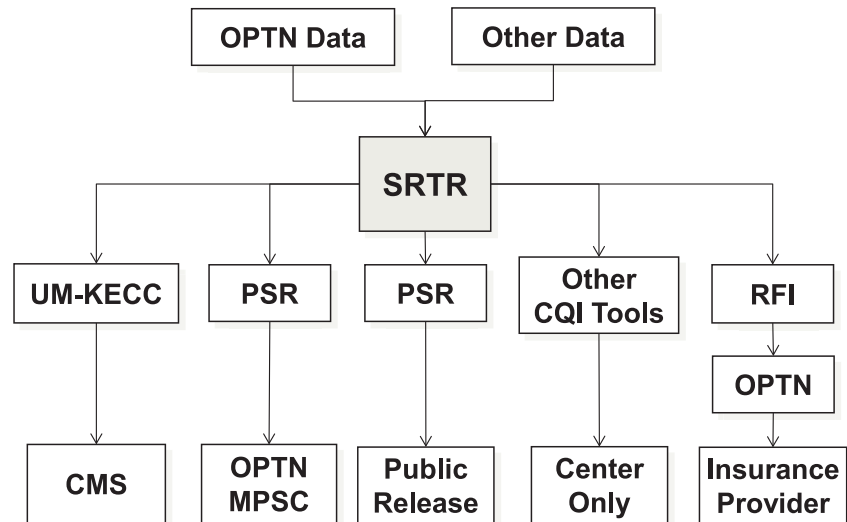
**Abbreviations:** ACD, Adult Cardiac Surgery Database; CABG, coronary artery bypass grafting; CIBMTR<sup>®</sup>, Center for International Blood and Marrow Transplant Research; CMS, Centers for Medicaid and Medicare Services; CPM, composite pretransplant metric; CUSUM, cumulative sum; MPSC, Membership and Professional Standard Committee; OPTN, Organ Procurement and Transplantation Network; PSRs, program-specific reports; SRTR, Scientific Registry of Transplant Recipients; STAC, SRTR Technical Advisory Committee; SSADMF, Social Security Administration Death Master File; STS, Society of Thoracic Surgeons; UNOS, United Network for Organ Sharing.

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## Introduction

Under the National Organ Transplantation Act of 1984, the Department of Health and Human Services awards separate contracts for the administration of the Organ Procurement and Transplantation Network (OPTN) and for the Scientific Registry of Transplant Recipients (SRTR) (1). The charge to SRTR is described in the Final Rule (2). SRTR meets its obligation to provide information on transplant center performance in several ways (Figure 1). However, publication of program-specific reports (PSRs) and oversight of transplant programs have been controversial.

OPTN and SRTR cosponsored a consensus conference in Arlington, Virginia, February 13–15, 2012. The purpose of the conference was to examine the methods SRTR uses in the surveillance of solid organ transplant programs, and to make recommendations for improvements. Presentations addressed current uses and future needs of the SRTR



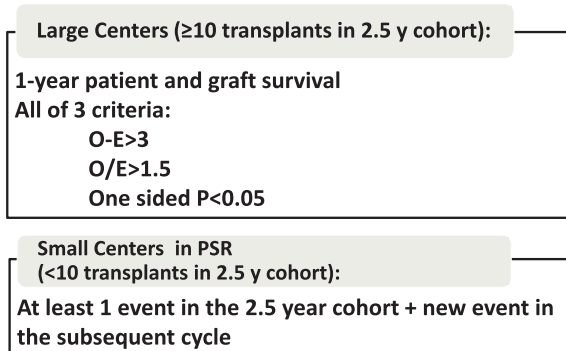
**Figure 1: Role of SRTR in providing transplant PSRs for quality improvement.** Abbreviations: CMS, Centers for Medicaid & Medicare Services; CQI, continuous quality improvement; OPTN, Organ Procurement and Transplantation Network; PSR, program-specific reports; RFI, request for information; SRTR, Scientific Registry of Transplant Recipients; UM KECC, University of Michigan Kidney Epidemiology and Cost Center.

PSRs, unintended consequences of PSRs, lessons from other areas of medicine and analytical techniques. These presentations were followed by breakout group discussions on methods, risk adjustment, outcomes and data, and a general discussion of recommendations. Details can be found at <http://www.srtr.org/>.

**Current Uses**

**Use of SRTR data by OPTN**

The OPTN Membership and Professional Standards Committee (MPSC) oversees the compliance of OPTN members with federal regulations and OPTN policies. The OPTN MPSC uses the PSRs to identify programs that need further scrutiny (Figure 2). This scrutiny is intended to improve outcomes of underperforming programs.



**Figure 2: Methods used by OPTN to identify transplant programs that warrant further scrutiny to enhance quality improvement.** Abbreviations: E, expected; O, observed; PSR, program-specific report.

**Use of SRTR data by the Centers for Medicare & Medicaid Services**

The Centers for Medicare & Medicaid Services (CMS) oversees transplant programs that receive Medicare reimbursement, as do most but not all US programs. In late 2007, CMS began periodic reviews of all Medicare-approved transplant programs. Currently, SRTR provides data to the CMS contractor, who in turn provides data and analysis to CMS (Figure 1). Like the MPSC, CMS works with centers to develop a plan for improvement.

**Use of SRTR data by private insurance providers**

Private insurance providers use data published by SRTR to help determine which centers will provide organ transplants for their insured patients. To limit the amount of time and effort required by transplant programs to fulfill multiple data requests from different insurance providers, the United Network for Organ Sharing (UNOS) has worked with insurance providers and transplant programs to establish a mechanism for fulfilling annual requests for information. SRTR provides some data not already included in published PSRs.

**Use of SRTR data by transplant programs**

Many transplant programs use the SRTR PSRs as a tool for self-assessment and continuous quality improvement. SRTR also provides transplant programs with a spreadsheet tool that allows the programs to examine outcomes of patient subgroups and understand how various factors affected the PSR outcomes (<https://securertr.transplant.hrsa.gov/>).

**Use of SRTR data by transplant candidates and potential living organ donors**

Patients can examine the PSRs published every 6 months (<http://www.srtr.org/>). SRTR has recently undertaken an effort to make the reporting of the PSRs easier to read and interpret. Transplant programs also use these reports to

provide candidates and potential organ donors with information mandated by CMS.

## The Case for Change

### **Possible unintended adverse consequences of the SRTR PSRs**

SRTR adjusts the PSRs for differences in donor and recipient risk, but these risk-adjustments may not adequately account for differences in outcomes (3). For example, patients with cardiovascular disease and patients who have undergone procedures to remove donor-specific antibodies are at increased risk for poorer outcomes posttransplant, yet these conditions are not taken into account in the PSRs. Fearing that their PSR outcomes may be adversely affected, programs may be reluctant to perform transplants in higher-risk patients. Similarly, centers may turn down suitable organs that are likely to yield acceptable but not ideal outcomes, perceiving the risks associated with transplanting these organs to be not fully accounted for in the PSRs.

An informal survey was conducted at the annual Transplant Management Forum in 2009 (4). Of 63 respondents, 55% indicated that their centers had received low or near-low performance ratings within the past 3 years. Respondents from low-performing centers were more likely to indicate that they had become more restrictive in selecting transplant candidates (81% vs. 38%,  $P = 0.001$ ) and donors (77% vs. 31%,  $P < 0.001$ ). The planners of this consensus conference conducted an informal survey of the OPTN Transplant Administrators electronic mailing list regarding issues related to PSRs; 70% to 80% of respondents said their programs tolerated less risk as a result of the PSRs (Table 1).

## Recommendations

### **Statistical methods**

I.1. PSRs should be better suited to the needs of all users, particularly patients.

Different stakeholders use PSRs for different purposes. Regulatory agencies charged with overseeing transplant programs need indicators to alert them to programs requiring further scrutiny. Because these indicators, or flags, result in more detailed investigations, they should err on the side of being too sensitive, rather than too specific. However, flagging can have unintended detrimental consequences. Payers want to identify both programs that are underperforming and programs that are performing in an exemplary manner. Patients may need to identify centers that excel at transplants for patients like themselves. Transplant programs need appropriate tools to help them maintain optimal outcomes and to alert them to potential problems that require additional attention. Currently, only large transplant centers have resources adequate for this purpose.

**Table 1:** Summary of results of an informal survey of transplant administrators regarding PSRs

Percent of respondents	Survey item
60–70	Think that PSRs accurately reflect program outcomes.
40–50	Clearly understand the PSR elements used in risk adjustment.
40–50	Think that PSRs are helpful to patients.
20–30	Think that PSR risk adjustment is fair and appropriate.
30–40	Think that additional data are needed.
50–60	Are willing to spend more time and effort to collect more data.
40–50	Are concerned that the data submitted are not accurate.
60–70	Use clinical and support staff to enter data.
70–80	Think that their program tolerates less risk as a result of the PSRs.

Survey was distributed via the transplant administrators' electronic mailing list. Of the 63 respondents, 49 were administrators, 8 Quality Assessment and Performance Improvement (QAPI) directors, 2 surgeons, 2 physicians, 1 an advanced practice provider and 1 a registered nurse.

Opportunities to improve the methods used by regulatory agencies to identify underperforming centers include ensuring that the observed outcomes are correct, using the best methods for estimating expected outcomes, reducing lag time and more effectively addressing issues specific to small-volume centers. For transplant programs, analyzing past data is one key to understanding how to improve future outcomes, and timely data that help predict the future are as important as knowing the past. Thresholds should foster reaching the top, not avoiding the bottom. Ideally, PSRs should be tailored to targeted users and provide additional information and education to ensure that limitations of the methodology are well understood.

I.2. Rather than each model being refit every 6 months, the time between revisions should be increased and used to more carefully review the models and data elements.

The process for model improvement is currently ineffective. SRTR makes minor changes in the PSR models every 6 months. Instead, models should be more extensively re-examined every 3 to 5 years, with appropriate input from the transplant community and the SRTR Technical Advisory Committee (STAC).

I.3. The potential benefits of hierarchical and mixed-effects methods should be studied.

Mixed-effects models take center effects into account (5). They improve accuracy at the center of the distribution rather than at the extremes and may be more useful for public reporting than identifying program underperformance. Hierarchical, mixed-effects and Bayesian

models require external input to define expected outcomes (6–8). Outcomes at individual centers can be compared with expected outcomes not only by p-values, but also by examining the probability that the center's results differ from the norm. This strategy has been adopted by the Society of Thoracic Surgeons (STS) in its risk-adjusted models for outcomes after thoracic surgery (9–11).

I.4. Provide transplant centers, the MPSC and CMS with tools such as the cumulative sum (CUSUM) technique and tools to allow subgroup analysis to facilitate quality assessment and performance improvement.

A common criticism of current methodologies for calculating observed-to-expected outcomes is the inherent delay in obtaining results. Process control methods could yield more timely results (12). The CUSUM method graphically depicts currently collected, risk-adjusted data, and alerts users when an outcome reaches a pre-determined threshold value. It has been applied to organ transplantation (13–18). Compared with current methods for calculating observed-to-expected outcomes, CUSUM can identify underperforming centers sooner (19) and is therefore a better quality control instrument. It has been used successfully for monitoring outcomes of transplant programs in the United Kingdom (20). CUSUM may detect worsening outcomes more rapidly than the current observed-to-expected approach, but it depends on obtaining outcome data more quickly. Therefore, CUSUM could encourage transplant centers to follow patients more closely and report outcomes sooner, but centers would need adequate education and support to use it. Other techniques may also be helpful. Funnel plots, for example, may help centers compare their outcomes with the norm (20,21).

I.5. Consider monitoring outcomes of small-volume centers more equitably by increasing the observed-to-expected thresholds and/or using p-values reduced proportionally to center volume.

Comparing outcomes for small-volume centers with low statistical power to detect differences is inherently difficult. Volume *per se* can be an indicator of quality in outcomes. This has been demonstrated in lung (22), heart (23), liver (24) and kidney transplantation (24). However, balanced against the poorer outcomes associated with small-volume centers is the need for access to transplants in isolate geographical areas where volumes are necessarily lower. Using longer cohort times would reduce false positives at the expense of increasing false negatives.

I.6. Mortality data from the Social Security Administration Death Master File (SSADMF) should continue to be available to SRTR.

In November 2011, the Social Security Administration began removing deaths reported by states from the SSADMF.

This is estimated to reduce the number of deaths listed in the SSADMF by approximately one-third. Since SRTR has relied on SSADMF data to determine many deaths used in its analyses, this decision has serious adverse consequences for the accuracy of the observed-to-expected calculations in the PSRs.

I.7. SRTR should substitute missing data with values that are least favorable to the center, thus encouraging centers to accurately record data, and should consider including the timeliness and completeness of data submission as a quality indicator.

I.8. Avoid converting continuous data elements to categorical elements, and use smoothed splines only when continuous linear values are not appropriate.

### **Risk adjustment**

II.1. Consider protecting innovation by excluding patients who are in approved protocols from PSR models that identify underperforming centers.

There is legitimate concern that failure to adequately account for risk in adjusting outcomes in the PSRs may discourage centers from using innovative treatments. Conference participants agreed that establishing a national body, e.g. an *ad hoc* subcommittee of the MPSC, would be feasible, to approve unique clinical circumstances and innovative treatment protocols that warrant special consideration. The *ad hoc* subcommittee would prospectively review and approve protocols and/or individual patients for exclusion from PSR models that identify underperformance. The process should be transparent; the numbers of patients excluded and the reasons for exclusion should be available for each transplant center. Outcomes for patients treated under this exclusion should be defined and reported separately to enable program comparison.

Participants discussed but did not reach consensus on providing two separate PSRs. One PSR used for regulatory oversight and quality assurance could be shared with the transplant center and not with the general public; another could be produced for the general public. Questions were raised regarding whether a federal report used for regulatory oversight could be sequestered from the general public or would be discoverable under the Freedom of Information Act. Also, the sequestered SRTR reports could possibly be reproduced merely by applying the SRTR methodology to the original data.

Participants also discussed whether a separate PSR could be generated that included only low-risk patients and donors. However, event rates would be much lower in a low-risk subpopulation, and difficulties in monitoring outcomes of small transplant programs would be greatly exaggerated.

II.2. Identify centers that manage high-risk patients and donors well.

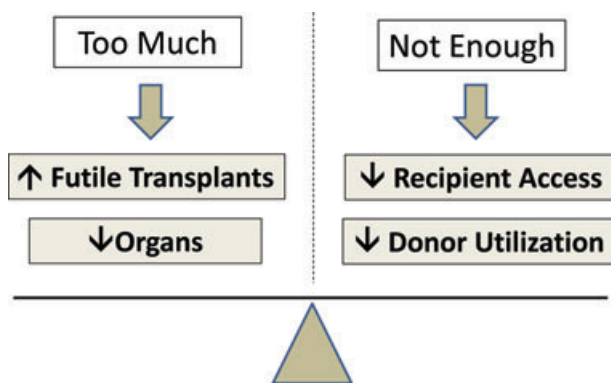
Measuring risk is important not only to avoid inappropriately discouraging centers from providing transplants to high-risk patients, but also to allow patients to identify centers with good outcomes for high-risk patients. Patients, especially high-risk patients, need to identify centers in their geographic areas that perform transplants in “patients like me”. Similarly, patients should be able to locate centers that accept living and deceased donors with increased risk.

II.3. Collect more reliable organ-specific data on coronary heart disease (e.g. revascularizations), peripheral vascular disease (e.g. revascularizations and amputations), diabetes mellitus, zip code socioeconomic status, donor risk and ventricular assist devices.

Collecting additional data to more adequately adjust for comorbidity could remove disincentives to performing transplants in high-risk but otherwise suitable candidates (25;26). Adjusting for all risk could encourage centers to perform futile transplants, thereby wasting organs that could be used in more appropriate candidates. Thus, risk adjustment must find a balance: performing transplants that do little to improve a patient’s well-being should not be protected, but performing transplants that are indicated but avoided due to being high risk should be (Figure 3).

II.4. Provide more data on waiting list risk and outcomes.

Currently, the PSRs focus on posttransplant outcomes. However, patients also need to be able to compare centers with regard to waiting list experiences. What are the chances of undergoing transplant and what is the time-frame? What are the chances of dying while on the waiting



**Figure 3: The right balance in adjusting program-specific outcomes for risk.** “Too much” adjustment could forgive centers for performing futile transplants and wasting organs. “Not enough” adjustment could discourage centers from performing transplants in suitable high-risk candidates, and/or accepting high-risk donors.

list? SRTR is currently working on risk methods to perform these calculations.

**Outcomes**

III.1. Enhance reporting of access to transplant and pre-transplant outcomes.

Programs and patients are as interested in patient experiences before transplant as after. The composite pretransplant metric (CPM), combining waiting list mortality, transplant rate and organ acceptance rate, is a potentially useful metric. The CPM will be influenced by listing practices, geographical differences and factors not under the center’s control. Should the CPM be adjusted for regional differences in organ availability? Should patients listed as inactive be included? Additional data and study are needed to determine whether any unintended consequences of the CPM could create a disincentive for centers to list appropriate but high-risk candidates.

III.2. Consider reporting life-years after listing.

Life-years after listing would portray pretransplant and posttransplant outcomes. Patients, payers and the general public want to know what happens after patients are registered on the deceased donor waiting list, regardless of outcome. Reporting life-years after listing would not preclude the need to report posttransplant outcomes, including life-years from transplant.

III.3. Consider reporting transplant program risk tolerance.

Patients, especially high-risk patients, need to find centers that are willing and able to perform their transplants. Similarly, payers that direct patients to transplant programs are interested in finding programs that are willing to perform transplants in high-risk patients and have good outcomes when they do.

Centers that perform transplants in high-risk patients, often using high-risk donors, have potentially definable characteristics (27). Organ acceptance rates, donor risk indexes, and other characteristics require study to increase understanding and develop metrics to identify centers willing to perform transplants in definable high-risk patients with characteristics that may match characteristics of patients who will benefit from transplant.

III.4. Improve monitoring and reporting of short-term living donor outcomes.

A consensus conference on living organ donors held in September 2010 recommended that OPTN collect follow-up information on living donors for 3 months after donation (28), reporting data on surgical complications, re-operation, re-hospitalization, kidney function, etc. Transplant centers should maintain contact with their donors during this



period, and CMS and OPTN should investigate centers that are not compliant with data reporting requirements. However, following donors long term is difficult for many centers. No mechanism covers the cost of routine, long-term, post-donation visits. Donors often prefer not to return to the transplant center if they are doing well and must travel great distances at their own expense. Therefore, the consensus conference on living donation recommended that long-term follow-up be carried out by a third party, although consent for follow-up would need to be obtained before donation.

III.5. Consider providing information on outcomes beyond 3 years posttransplant.

Patients may choose not to be followed at the center where they underwent transplant, and the argument could be made that centers should not be held accountable for outcomes of patients for whom they are no longer providing primary care. Therefore, 1-year patient and graft survival rates have been used for comparing program performance instead of longer-term outcomes. However, statistical techniques can be used to project long-term outcomes using short-term results. The most widely used technique is the calculation of graft half-life, the time to which half of patients alive with a surviving graft at a given time posttransplant (usually 1 year) can be expected to continue to have a functioning graft.

Currently, SRTR provides data on 3-year patient and graft survival, but CMS and the OPTN MPSC only flag centers with less-than-expected 1-year outcomes. Patients, payers and regulatory agencies are interested in outcomes beyond 3 years. However, reporting program-specific, long-term outcomes may require longer cohorts than are currently used.

### **Data**

IV.1. Provide standard definitions and identify source documents for all data.

The OPTN Transplant Coordinators Committee has been working to establish definitions of data elements in OPTN (UNOS Tiedi<sup>®</sup>) forms. This is an important task that should continue and perhaps be expanded. Studies have shown that OPTN data could be collected more accurately (29), and providing transplant centers with better instruction for data collection could be a cost-effective way to improve data accuracy.

IV.2. Examine whether data sources such as DonorNet<sup>®</sup> and Medicare claims can be used.

The quality and completeness of data in DonorNet<sup>®</sup> should be investigated. Medicare claims data could also often provide information. Up to half of kidney transplant patients may have primary Medicare coverage, at least for the first 3

years posttransplant. However, not all patients have Medicare as primary payer, and Medicare patients may differ from non-Medicare patients. Claims data may not accurately reflect the underlying clinical condition or problem being measured, and delays may occur between claims data collection and its availability for analysis.

IV.3. Survey transplant programs to better understand the data collection burden.

IV.4. Offer better education and data collection tools to assist programs in maintaining OPTN data.

IV.5. Use the OPTN policy development process for adding new data elements.

New data elements can be suggested by OPTN organ-specific committees, subjected to public comment, reviewed by the Policy Oversight Committee and ultimately approved by the Board of Directors. New data elements should be carefully considered to ensure that collection is feasible and anticipated benefits are realized. Each data element requires reasons for its collection, clear definitions, careful source documentation and an understanding of cost implications. Unproductive elements such as "other" or "unknown" should be avoided.

IV.6. OPTN should explore the feasibility of building data collection interfaces with electronic medical records.

IV.7. Consider allowing the cost of mandated data entry to be added to the Medicare Cost Report for reimbursement, and not limiting this option to the Candidate Registration Form.

Currently, no mechanisms allow transplant centers to be reimbursed for the cost of collecting data, and the cost of any additional data collection must be borne by the center. The cost is not inconsequential. One large, multi-organ, transplant program estimated that it had submitted a total of 5245 forms to OPTN over a period of 3 years, requiring 2.5 full-time equivalent positions dedicated to collecting the data and submitting the forms, at an estimated cost per form of \$27 (30). Current costs are probably higher.

IV.8. Consider providing information about paired exchange.

The OPTN kidney paired living donor exchange pilot program has been successful, and is being proposed as OPTN policy. As part of the implementation process for this policy, data collection should be included and reported on the PSRs. The PSRs could be used to encourage centers to participate in this important program and could allow patients to locate centers that offer this option.

## Discussion

Several potentially useful recommendations resulted from this consensus conference. Many of these recommendations are not new. In 2009, the STAC formed a subcommittee to examine the PSRs. This subcommittee's recommendations included: (1) alternative approaches to the PSRs should be studied; (2) methodologies should be reviewed every 3 to 5 years; (3) steps should be taken to improve data reporting and reduce the number of missing values; (4) subjective variables (such as patient "functionality") should be audited more carefully or dropped; (5) factors that may improve the predictive power of models should be sought; (6) continuous versus categorical variables should be studied; (7) the ability to answer questions with nonspecific responses such as "unknown" should be restricted; (8) a process to prospectively exempt (or adjust for) pre-defined high-risk transplant candidates should be developed; (9) a more coherent process to add or remove data elements should be developed; (10) minimum standards for outcomes that trigger administrative review should be developed; (11) an alternative method for flagging small programs should be considered and (12) public concerns should be addressed with educational programs.

The recommendations made by the participants in this consensus conference vary greatly regarding the resources that would be needed to implement them. Some changes in statistical methodologies would be relatively inexpensive. Other changes, such as additional data collection, could be very costly. Adequate financial support for any changes would play a key role in successful implementation.

The STAC reviewed the recommendations of the consensus conference at its regularly scheduled meeting February 23, 2012. The STAC generally concurred with most recommendations and is in the process of helping SRTR and HRSA prioritize the recommendations. Many potential changes, if adopted by HRSA, will take time to implement. Nevertheless, the consensus conference was an important step in what will no doubt be an ongoing process of improvement in the oversight and quality assurance of solid organ transplant programs in the United States. This process is unique in many ways, and it may ultimately serve as a model for other areas of the health care system.

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## Disclosure

By virtue of employment at or affiliation with a transplant program or an organization with an interest in the assessment of transplant program quality, any author of this manuscript could be perceived to have a conflict of interest.

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## Topics and Speakers

Introduction (Maureen A. McBride), background (Bertram L. Kasiske), current uses and future needs of the SRTR PSRs from the perspectives of OPTN (Alan I. Reed), CMS (Thomas E. Hamilton), transplant programs (Barry S. Friedman), private insurers (Richard Migliori), and patients (David H. Howard), unintended consequences of PSRs (Jesse D. Schold), analysis of the effects of flagging on subsequent center volume (Jon J. Snyder), the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS, David Naftel), the Center for International Blood and Bone Marrow Transplant Research (CIBMTR, J. Douglas Rizzo), the CUSUM method (David A. Axelrod), other analytical techniques (Nicholas Salkowski), limitations of different methods (Ajay K. Israni), breakout group topics on methods (Nicholas Salkowski), risk adjustment (Michael Abecassis), outcomes (Lawrence G. Hunsicker) and data (Stuart C. Sweet).

## Meeting Participants

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