

# **SRC-AMS** Meeting Minutes

# Analytical Methods Subcommittee Teleconference

March 26, 2024, 10:00 AM - 12:30 PM CDT

#### Voting Members:

David Vock, PhD (Co-chair) Joel Adler, MD, MPH Syed Ali Husain, MD, MPH, MA, FASN Erika Helgeson, PhD William (Bill) Irish, PhD Megan Neely, PhD William Parker, MD, MSCP, PhD **Not in Attendance:** Brent Logan, PhD Andrew Schaefer, PhD HRSA: Shannon Dunne, JD Adriana Alverez, MS SRTR Staff: Allyson Hart, MD, MS Larry Hunsicker, MD Ajay Israni, MD, MS Grace Lyden, PhD Jon Miller, PhD Cory Schaffhausen, PhD Nicholas Wood, PhD

#### Ex-Officio Members: Jon Snyder, PhD (Co-chair)

#### Welcome and opening remarks

Dr. Jon Snyder and Dr. David Vock called the Analytical Methods Subcommittee (AMS) meeting to order. Dr. Snyder reviewed the agenda and conflict of interest management and then proceeded with the first item.

#### New members and introductions

New members introduced themselves:

- Joel Adler, MD, MPH, Assistant Professor of Surgery, Dell Medical School, The University of Texas at Austin
- Syed Ali Husain, MD, MPH, MA, FASN, Assistant Professor of Medicine, Columbia University Medical Center
- William F. Parker, MD, MSCP, PhD, Assistant Professor of Medicine and Public Health Sciences, University of Chicago

#### SRTR 5-tier metric summaries

Dr. Snyder gave an overview of the layout of the Scientific Registry of Transplant Recipients (SRTR) search results page for transplant centers. Search results include evaluations for survival on the waiting list, getting a deceased donor transplant faster, and first year graft survival, all of which have 5-tier summaries based on underlying statistics. Kidney search results do not include a tier



evaluation for survival on the waiting list following feedback from the community. The 5-tier system replaced the previous 3-tier system, which was based on statistical significance tests of the hazard ratio (HR) being equal to 1. In addition to the metrics currently displayed, SRTR is considering adding two new tier evaluations based on offer acceptance rate ratios (currently being evaluated by the Membership and Professional Standards Committee [MPSC] as a program performance metric) and overall survival from listing rate ratios.

Dr. Snyder said this topic was being brought to the committee's attention as SRTR continues to be responsive to the OPTN Final Rule, which calls for disseminating accurate information on transplant program performance in a way that is easy to understand. At SRTR's 2012 and 2022 consensus conferences, it was recommended that patient understanding of the evaluations be improved. Dr. Snyder asked members to consider if it was preferred to use just a single tier evaluation based on overall survival from listing to replace the current tiers used in the initial search results, relegating the current tiers deeper within the report. A version of the offer acceptance tier evaluation is currently provided to transplant programs on the SRTR secure site, but SRTR is proposing to add a tier evaluation for offer acceptance within the main program-specific report (PSR). Dr. Snyder noted that there seems to be initial support from the Organ Procurement and Transplantation Network (OPTN) Expeditious Task Force leadership and MPSC leadership, as they think the offer acceptance and overall survival from listing better align with the OPTN goals to do more successful transplants.

Dr. Snyder gave an overview of the methodology used to calculate the tiers. First, the posterior distribution of the HR is determined from the observed (O) and expected (E) event counts using a conjugate prior Bayesian formulation. The prior distribution is given as gamma (2,2) and the posterior distribution is then gamma(O+2,E+2).

The posterior distribution of the HR is then converted into a score by applying a score function of the form:

$$S(x) = \frac{1}{1 + x^k}$$

The score is derived as the expected value of the score function, averaging over the posterior distribution of the HR. That is:

$$Score = \int S(\theta) f(\theta|y) d\theta = E[S(\theta|y)]$$

Where  $S(\theta|y)$  is the posterior distribution of the HR given the program's observed data, y.

The exponent on the *x* parameter, *k*, controls how steep the score function is around x = 0.5. The transition phase of the function between values near zero or one is, for example, between an HR of about 0.5 up to about 2.0 given k = -10 as used for creating the tier for first-year graft failure. The shape parameter, *k*, is negative when a lower HR is better (eg, graft failure or death) and positive when a higher HR is better (eg, transplant rate or offer acceptance). Further, values of *k* closer to zero allow for more distinction between programs with more extreme HRs, which could be considered in cases where there is more observed variation in program performance. For example, the current transplant rate tier evaluations use k = 3 and the offer acceptance evaluations currently use k = 5.

After the score is determined, it is converted to a tier using the following function:

*Tier*  $1: 0 \le score < 0.125$  *Tier*  $2: 0.125 \le score < 0.375$  *Tier*  $3: 0.375 \le score < 0.625$  *Tier*  $4: 0.625 \le score < 0.875$ *Tier*  $5: 0.875 \le score \le 1$ 

The methodology was published in a 2018 paper "A Five-Tier System for Improving the Categorization of Transplant Program Performance" in the journal *Health Services Research*<sup>1</sup>. Dr. Snyder highlighted the differences between the 5-tier system and the previous 3-tier system as highlighted in the paper, noting that the previous 3-tier system put most programs in the middle tier with very few programs placed in tiers 1 or 3. Many in the transplant community said this was not very helpful to patients since all programs were lumped into the middle performance tier despite a range of observed first-year graft failure HRs from approximately 0.5 to 2.0. Dr. Snyder also reviewed results presented in the paper for how well the 5-tier system accurately places better programs in higher tiers based on a simulation study.

Next, Dr. Snyder went over Dr. Cory Schaffhausen's earlier work on which icons should be used to present the 5 tiers. Of the icon choices of bars, circles, color circles, dials, donuts, and pies, 37% of participants preferred the bars, while the dial (also referred to as speedometer or gauge) was found to yield the most accurate interpretation of the data. Dr. Snyder asked the committee to consider whether SRTR should switch from the current bar design, which was preferred by patients, to the gauge, and broke down its design. The example gauge presents tier 1 in red, tier 2 in yellow, and tier 3 and higher in shades of green. This would hopefully better convey that tier 3 is good, as being commensurate with national average outcomes. The gauge would contain a pointer that indicates the exact location of the program's score, better delineating where the program falls within its tier. Dr. Snyder also presented for consideration a bullet graph, where bullet placement marks the center's score overlaid on a bar of colors indicating the 5 tiers, similar to the gauge. The SRTR team prefers the gauge icon. A credible interval could also be added to the icon.

Dr. Ajay Israni said cognitive interviews had not been done with patients for the icons, and credible intervals could confuse patients, noting that previous publications by the Agency for Healthcare Research and Quality (AHRQ) on best practices for public reporting of health care performance recommended against presenting confidence/credible intervals. Dr. Allyson Hart said that cognitive interviews were not the best for answering the question of which icon results in the best understanding.

Dr. Snyder then presented an application that contained current PSR data with the four metrics to demonstrate how the tier methodology works and how program distribution within tiers changes with choice of the score function's shape parameter *k*. Dr. Larry Hunsicker was opposed to the

<sup>&</sup>lt;sup>1</sup> Wey A, Salkowski N, Kasiske BL, Israni AK, Snyder JJ. A Five-Tier System for Improving the Categorization of Transplant Program Performance. Health Serv Res. 2018 Jun;53(3):1979-1991. doi: 10.1111/1475-6773.12726. Epub 2017 Jun 13. PMID: 28608369; PMCID: PMC5980219.



credible interval being displayed as one solid gray area, suggesting rather a shaded gray region that is more intense near the calculated score and fading to the edge of the credible interval. He also said it was important to remember that this tool is for the patients, not the centers. Dr. Vock pointed out that with this rating system, it would be hard for patients to discern if listing at a tier 1 or 2 program was more favorable to not being listed at all. Dr. Israni agreed, noting that patients often see the metric 1-year survival as most important, when they usually should focus on getting a transplant faster, which is why the current SRTR website indicates the metric of most importance to patient outcomes.

Dr. Adler and Dr. Parker agreed on the importance of determining how influential the shape of the score function is. They discussed if SRTR should focus on functions generally between 0.5 and 2.0, or allow for flatter functions for metrics with more program variation.

The committee briefly returned to discussing icons. Dr. Schaffhausen said one part of the study he conducted pointed participants to a 3-tier program to see if they understood what a 3 meant. He asked members for ideas on what to expect a user to come away with when viewing the bars, and how to measure if they are achieving the desired interpretation. Dr. Israni said one-on-one interviews with patients regarding the icon would be the best way to understand its representation. Dr. Hunsicker pointed out that for kidney transplant centers, there is not a lot of variation in 1-year graft survival, but there is wide variation in the likelihood of getting a transplant; showing patients the distribution would be helpful. Dr. Schaffhausen said presenting the numerical values behind the tiers was difficult to do, and noted that switching from 1-year to 3- or 5-year graft survival would elucidate wider variation in program outcomes.

Dr. Snyder said the main takeaways from the discussion included considering the shape score function and its overarching effects, support for presenting the overall survival from listing metric, and replacing the bars with the speedometer/gauge-style icon. Dr. Israni added showing variation across the tiers for survival after listing, and Dr. Hunsicker added introducing patients to helpful information prior to viewing data, such as variability for 1-year graft survival.

## Offer acceptance CUSUMs

Dr. Nick Wood went over potential issues with the current custom methodology for offer acceptance, starting with background information. PSRs are published every 6 months, containing a description of the program offer acceptance practices using a 12-month cohort. They show the number of offers, the number of accepted offers, and offer acceptance rate ratios.

Every month SRTR also publishes cumulative sum (CUSUM) charts, which show the cumulative difference between a program's expected (E) and observed (O) number of acceptances over a 4month period using the most recent PSR models. Centers also have access to a table detailing the number of offers, expected acceptances, and actual acceptances for different subgroups of offers. Programs often use these data to get an indication of if their program will be flagged in the next PSR cycle.

Dr. Wood explained that because the CUSUM charts present a more contemporaneous 4-month period than the 12-month period the underlying models are based on, this creates a situation where the predictions in the CUSUM charts are almost always completely out-of-sample. This can create



situations whereby we see "drift" in the overall O/E if significant changes occur that affect national acceptance practices (eg, the lung continuous distribution policy).

Dr. Wood showed a figure that demonstrated drift in pancreas and lung acceptance practices over time. SRTR is concerned that this drift can lead to inaccurate inferences by programs and can cause "jumps" in the program's CUSUM charts every 6 months when the PSR models are updated.

Dr. Wood also investigated the 2020 liver policy change, rerunning the PSR cohort from that time, and running the CUSUM charts that would have followed. He found that the low offer acceptance ratios (OARs) were due to the COVID-19 pandemic. External factors like these change offer acceptance behaviors, leading to a difference in a center's OAR in its CUSUM charts and PSR. This could give centers a false sense of their performance. Looking into kidney policy change showed that pancreas, kidney, and kidney-pancreas were all affected. Dr. Wood said a main takeaway of this is that CUSUM charts for offer acceptance are applying a model to derive mostly/completely out-of-sample predictions with no guarantee that the O-to-E values overall are going to be around 1.

Dr. Wood's proposed solution was to refit the models using the most recent 12 months of data every month. The last 4 months of the cohort would continue to be presented on the CUSUM chart, or the CUSUM chart could be modified to present a full 12 months of performance. He found that applying this solution to the CUSUM charts following the June 2023 PSR release led to overall acceptance ratios closer to 1.

The committee did not express any concerns on implementing a process to try to keep the models more current with the offer acceptance evaluations. Dr. Vock asked if the effects of a big policy change would be slow to cause changes to CUSUM charts. Dr. Wood said these changes happen quickly, and regardless of how methodology is implemented, CUSUM charts help programs get a sense of changes in their center's processes.

Going forward, Dr. Wood plans to investigate the two possibilities of expanding the offer acceptance cohort out to a year rather than just 4 months and rolling the model forward monthly.

## New donation and transplant rates for OPO-specific reports

Dr. Jon Miller said the current OPO-specific reports (OSRs) evaluate 56 OPOs. In July 2023, SRTR removed information on eligible deaths from the OSRs given concerns expressed in the community about the self-reported nature of these data by OPOs. At the same time, SRTR was working on replications of the Centers for Medicare & Medicaid Services (CMS) metrics for donation and transplant rates to be included in the OSRs per Task 6.2 of the SRTR contract; however, the Health Resources and Services Administration (HRSA) recommended withholding release of the SRTR replication of the CMS metrics to allow more time to better coordinate with CMS. Following this delay, SRTR created a report of the metrics to be released to the OPOs on the SRTR secure site in December 2023; however, HRSA again recommended withholding these reports to allow more time for coordination with CMS. Following this development, SRTR voted for SRTR to develop a new version of these metrics for possible inclusion in the OSRs that does not attempt to exactly replicate the CMS metrics. This is responsive to recommendation 3.2 of the 2022 SRTR Consensus Conference: "Develop a new donor potential definition and metric, leverage existing OPO data

captured within OPO electronic medical records, present metrics at OPO and donor hospital levels, and include risk adjustment."

Following this recommendation, SRTR has made refinements to the denominator, using both inclusionary and exclusionary *International Classification of Diseases, 10th Revision (ICD-10)* codes based on OPTN policy 1 indicating several conditions that, if present, preclude organ donation.

SRTR is also using the OPTN definition of a donor as a decedent who has at least one organ recovered for the purpose of transplant.

For risk adjustment, SRTR included all of the categories that are reported in both the OPTN data and the CDC death certificate data, including age, sex, race, ethnicity. The posterior distribution of the donation rate ratio is then calculated using the gamma (2,2) prior as gamma (O+2,E+2), with the mean of the posterior yielding the observed donation rate ratio as (O+2)/(E+2). In addition to the overall donation rates provided by substratum, SRTR also plans to include 5-year trends. Recovery rate ratios and transplant rate ratios are calculated in a similar way with indirect standardization using organ-specific exclusion codes.

Dr. Israni said getting an organ transplant was more important than recovery, and said that adding an organ transplant rate ratio would be beneficial. Dr. Hunsicker was uncertain on how to go about organs transplanted as opposed to recovery, as OPOs are incentivized to recover every organ that has a reasonable chance of being used. Organ use is determined by the transplant centers as much as, or potentially more than, it is determined by the OPO. There is the risk of penalizing OPOs if they are associated with transplant centers that have low acceptance rate ratios.

Dr. Miller also presented a new version of a table SRTR plans to include in the July 2024secure release that presents referrals and donors at the donor hospital level, replacing a table that was based on eligible death referrals that was removed from the reports in July 2023. This is to address Consensus Conference recommendation 3.2 to present information at the level of the donor hospital.

The committee was supportive of the direction and methods the OPO metrics were taking and supported bringing this draft to the main SRTR Review Committee at their meeting on April 30, 2024, for consideration.

## **Closing business**

With no other business being heard, the meeting concluded. The next meeting date is to be determined.