

# SRC Meeting Minutes

## SRTR Review Committee Meeting, HRSA Headquarters, Rockville, MD

April 30, 2024, 9:00 AM – 3:30 PM EDT

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**Voting Members Present:**

John Magee, MD (Co-Chair) ('26)  
Sean Van Slyck (Co-Chair) ('25)  
Ginny Bumgardner, MD, PhD ('24)  
Deborah Mauer ('25)  
Emily Perito, MD ('25)  
Ameen Tabatabai (PFAS) ('25)  
Scott McPhee (HCDS) ('23)  
David Vock, PhD (AMS) ('24)  
Carli Lehr, MD, PhD ('26)

**Ex-Officio Members:**

Rebecca Goff, PhD (OPTN/UNOS)  
Shannon Dunne, JD (HRSA)  
Sumit Mohan, MD, MPH (OPTN-DAC)  
Jonah Odim, MD (NIH)  
Jennifer Prinz (OPTN-POC)

**HRSA:**

Adrienne Goodrich-Doctor, PhD  
Frank Holloman  
Adriana Alvarez, MS  
Chris McLaughlin  
Suma Nair, PhD, MS

**SRTR Staff:**

Tonya Eberhard (virtual)  
Allyson Hart, MD, MS  
Ryutaro Hirose, MD  
Larry Hunsicker, MD (virtual)  
Ajay Israni, MD, MS  
Grace Lyden, PhD (virtual)  
Jon Miller, PhD  
Cory Schaffhausen, PhD  
Mona Shater, MA (virtual)  
Jon Snyder, PhD, MS  
Nicholas Wood, PhD (virtual)  
David Zaun, MS (virtual)

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### Welcome and opening remarks

Mr. Sean Van Slyck called the SRTR Review Committee (SRC) meeting to order. Roll call for voting and ex-officio members was taken, with quorum met. Dr. Jon Snyder reviewed the agenda and conflict of interest management. He proceeded with the first item.

### Approval of the minutes

Dr. Snyder asked for a motion to approve minutes from the SRC meeting on January 16, 2024. There was a motion to approve and a second. The minutes were unanimously approved.

### Launching a preview of the patient-friendly SRTR website

Dr. Snyder gave a brief history of the SRTR website. The last major website update was in 2018, when the tier system launched. Design work for the new website began in 2021 with the newly-formed Patient and Family Affairs Subcommittee (PFAS). Seven home page design concepts were developed and narrowed down to three through PFAS and focus group review. The three revised home page design concepts were reviewed by four patient and family Zoom feedback sessions and narrowed down to a preferred design. After additional review, the design was shown to three patient and family Zoom feedback sessions. Following the 2022 consensus conference and subsequent prioritization exercises, work began to build the site. Dr. Snyder introduced Dr. Cory Schaffhausen to walk through the new site.

Dr. Schaffhausen said the new site will be launched as a new site in parallel to the current SRTR public website. He reviewed the home page and explained that the images of people rotated

randomly through a library of images that reflect the diversity of patient and professionals we serve, changing each time a page is refreshed. Dr. Schaffhausen briefly went over the Getting Started page and the sections for decision aids, videos, and frequently asked questions. He reviewed the organ transplant journey and living donor journey sections of the home page, which are simplified versions of the transplant system map built to provide an incremental reveal as users click deeper into the site. He then showed the Transplant Center Search tool, which can also provide a side-by-side comparison for up to four transplant programs.

Ms. Mona Shater, SRTR Marketing and Communications Director, said SRTR plans a press release upon launch, and will gather user feedback via email. She said that Google Analytics will be running on the site to provide geographic data for the users hitting the site, but she noted that it cannot discern which users were patients, researchers, physicians, etc. SRTR will capitalize on the launch during the summer 2024 conference circuit. SRTR is also actively pursuing connections to pretransplant organizations. Dr. Emily Perito suggested having QR codes as part of its materials to distribute to audiences at events to link directly to the site.

Dr. Schaffhausen went over the interactive system map, which can be modified by organ and journey path. Each stop on the path contains questions and answers that have gone through internal review and review by our patient groups. Answers often include links to data on the website, and links to other organizations will be added when applicable. It also includes different printable versions. He then reviewed the patient journey pages, a text version of the interactive map that allows search engines to find transplant keywords.

Dr. John Magee and Mr. Van Slyck called for a motion to approve the site. There was a motion for approval. The committee voted, and the motion passed with 9 yays, 0 nays, 0 abstentions, and 0 absent. SRTR plans to launch the website prior to the Transplant Management Forum (TMF) conference in early May 2024.

### **Donation and Transplantation System Explorer application updates**

Dr. Nick Wood went over new metrics and stratifications added to this application since it launched. One stratification includes donation after circulatory death (DCD) stratification by whether normothermic regional perfusion was used. Another stratification is kidney transplants performed under the kidney-after-liver safety net policy.

Two new metrics were recently added to the application: waitlist size (point-prevalent) and sequence number at the start of expedited placement. Dr. Wood showed two trends on waitlist size: the average waitlist size on any given day and, for days in the past year, how many candidates were ever on the waiting list. Dr. Wood's method for defining these counts was to use match-run data to count the number of candidates on the match run and the number of candidates who were screened off the match run, the sum of which gives the size of the waiting list at the time the match run was generated. The metric of proportion of accepted offers via expedited placement was briefly reviewed.

Dr. Snyder asked the committee if SRTR should identify the trends in the application that could be applied to the OPO level or transplant program level and whether SRTR should make the information public or provide it on the SRTR secure site. Members advocated for transparency to

understand trends over time. Ms. Jennifer Prinz said transparency was needed but was unsure about the timing of accessibility and transparency, since there is a lot of variability in the process. It was also important to consider the decision from an ethics perspective, as expedited placement in the United States is being scrutinized. Dr. Sumit Mohan added that program-filtered offers are not as nuanced as thought, which poses an operational challenge. Dr. Wood pointed out the number of filters used is high, and Dr. Mohan said one concern is that the total number of offers is also growing almost at an exponential speed.

There was general support for making OPO-level and program-level data available publicly. In addition, Dr. Allyson Hart suggested considering the application in a larger context and whom the data are for, and consider how data could be relevant to patients. Dr. Wood planned to look into what metrics made the most sense at the OPO and program level, which SRTR will bring back to the committee for consideration at the next meeting.

### **OPO metrics**

Dr. Snyder reviewed the OPO metrics background. In March 2023, donation and transplant rates with the eligible death denominator were removed from OPO-specific reports (OSRs) per the Task 5 recommendation and the SRC's prior vote. SRTR explored including the newly-developed Centers for Medicare & Medicaid Services (CMS) metrics as called for in the SRTR performance work statement and contract, replicating the CMS donation and transplant rates to add to the public OSRs. The Health Resources and Services Administration (HRSA) subsequently directed SRTR to not include these in the public reports. In July 2023, the SRC voted for SRTR to create secure site reports for OPOs with a replication of the CMS metrics which included several subgroup analyses. These reports were approved by the SRC on October 10, 2023, for the December 2023 release. In December 2023, HRSA instructed SRTR to not release these reports. Subsequently, in January 2024, the SRC approved SRTR constructing new OPO donation rate and transplant rate measures that further refine the denominators per Organ Procurement and Transplantation Network (OPTN) policy 1, refine the definition of donor per OPTN policy 1, and supply risk-adjusted metrics of donation rates, recovery rates, and transplant rates. These new metrics were prepared between January and March 2024. On April 3, 2024, SRTR reviewed the metrics with HRSA, and again with CMS/Center for Clinical Standards and Quality (CCSQ) representatives on April 19, 2024. After further discussion, HRSA decided not to have SRTR proceed with these metrics. Therefore, SRC will not be voting today to launch these new metrics.

Various members of the SRC expressed concern and asked HRSA for further explanation of this decision. Ms. Shannon Dunne of HRSA said CMS is concerned that the potential supplemental metrics could conflict with CMS metrics, potentially causing disagreement between HRSA and CMS reports of OPO performance. HRSA is still working to provide this information by communicating with CMS through the Organ Transplantation Affinity Group (OTAG), a HRSA and CMS collaboration. SRTR may present to the group about the issue in the near future.

Dr. Snyder added that SRTR had removed donor hospital data from the OSRs when SRTR removed the eligible death data; however SRTR has received many queries from OPOs asking for the data. He showed a table SRTR has created that includes total referrals and donors, stratified by donation after brain death (DBD) and DCD donors, by donor hospital. He proposed putting the table back up

on the secure site for OPOs in June 2024, and subsequently add them to public OSRs in January 2025.

There was a motion to add in the donor hospital table for secure release in June 2024 followed by a second. There were eight yays and zero nays, with one member absent. The eight members also voted yes to providing OPOs stratification of their data to facilitate quality assurance. Ms. Dunne noted that HRSA would provide the donor hospital table to colleagues at CMS to make them aware and would look for further opportunities for SRTR to meet with OTAG about the OPO metrics.

### **SRTR 5-Tier metric summaries**

Dr. Snyder presented four questions to members regarding the 5-tier metrics: 1) Should there be consistent score functions regardless of which metric is being evaluated? 2) Should SRTR create a tier for overall survival from listing and replace the initial search results with this tier? 3) Should SRTR create a tier for organ offer acceptance? 4) Should SRTR change to a gauge display rather than the current five-bar icons?

For question one, Dr. Snyder briefly reviewed the current methodology to convert Bayesian posterior distributions of a hazard ratio to a score using a scoring function. The resultant score is between zero and one.

Scores are then converted to a tier using the following function:

*Tier 1:*  $0 \leq score < 0.125$

*Tier 2:*  $0.125 \leq score < 0.375$

*Tier 3:*  $0.375 \leq score < 0.625$

*Tier 4:*  $0.625 \leq score < 0.875$

*Tier 5:*  $0.875 \leq score \leq 1$

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> At the Analytical Methods Subcommittee (AMS) discussion in March 2024, members expressed a preference to use the same score function across all metrics, with the shape parameter ( $k$ ) chosen to express the value SRTR places on various values of the hazard ratio.

Dr. Snyder explained that absolute values of  $k$  closer to zero result in larger tails of the scoring function, resulting in lower bounds outside of which more extreme hazard ratios are not given additional penalty or benefit, and that negative values of  $k$  are used when the outcome is a negative event (e.g., graft loss or death) vs. positive values that are used for positive events (e.g., offer acceptance and transplants events). For example, the current score function for graft loss uses  $K = -10$ , resulting in a score function differentiating hazard ratios between approximately 0.58 and 1.70, whereas  $K = 5$  values offer rate ratios between 0.34 and 2.89. Historically, different values of  $K$  have

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<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.

been used based on the observed variability in program performance, with metrics with broader ranges (e.g., offer acceptance) having lower values of  $K$ .

Dr. David Vock said it seemed that deciding how to split up the centers into tiers mattered more than deciding on what to pick for  $K$ . Dr. Mohan said it was important to spend more time thinking about how these thresholds should be set, and the data need to be interpreted correctly by nonstatisticians. Members agreed there needed to be clearer communication on what was trying to be conveyed by the data. Dr. Hart said first there needed to be consensus on how data are calculated, followed by properly communicating the information. Dr. Vock added that while it may look like the tiers are driven solely by math, they were driven more so by a value judgment that could be clinically relevant.

Members suggested other ways to display the data. Dr. Magee suggested presenting the data as actual survival or chance of getting a transplant. Dr. Ginny Bumgardner suggested showing actual data instead of using the tier system (which patients often interpret differently). Dr. Hart added that with the 5-tier system, there needed to be better communication with patients that a 3-tier program does not mean it is a bad program.

Dr. Snyder went on to the second question, if SRTR should create a tier for overall survival from listing and replace the initial search results with this tier. He noted the OPTN Final Rule, which stated data should include "...risk adjusted overall survival following listing...". He briefly explained the methods SRTR uses to estimate overall survival from listing, which presents an intent-to-treat-style metric out to 5 years postlisting (7 years for kidney listings). The methodology was published in the 2019 paper "Piecewise exponential models with time-varying effects: Estimating mortality after listing for solid organ transplant" in the journal *Stat*.<sup>2</sup>

Dr. Snyder then showed examples of overall survival from listing tiers, demonstrating that higher overall survival from listing is correlated with higher waitlist mortality tier, a higher transplant rate tier, and a higher graft failure tier. Dr. Snyder asked members if they supported moving toward an overall survival from listing tier to replace the current search results tiers.

Dr. Vock said it was important to consider the unintended consequence of centers not listing more acute patients. Dr. Bumgardner expressed concern over the overall survival data and unintended consequences of making the suggested change. Dr. Snyder said SRTR would not eliminate the other tiers, and the tiers could be changed depending on the committee's suggestion.

Next, Dr. Ajay Israni and Dr. Warren McKinney presented their Agency for Healthcare Research and Quality (AHRQ)-funded project investigating patient perspectives on the survival after listing metrics. The previous AHRQ-funded R01 collected data (2015 to 2020) from local Minnesota transplant candidates at two centers, their family members, and national transplant recipients as well (about 170 people, mostly patients). Organs of focus were lung, liver, kidney, and heart. Patients had a strong interest in longer term outcomes beyond 1 year.

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<sup>2</sup> Wey A, Salkowski N, Kremers W, Ahn YS, Snyder J. Piecewise exponential models with time varying effects: Estimating mortality after listing for solid organ transplant. *Stat*. 2020;9:e264.

Dr. McKinney discussed some of the mock-ups showing new metric with hypothetical data that Dr. Schaffhausen and Dr. Cinthia Lozano created. Mock-ups included a search results page from [www.transplantcentersearch.org](http://www.transplantcentersearch.org) where information about the user can be entered. A survival after listing metric was included, and other metrics are going to be built on the basic search results. Labels and definitions (such as different definitions for survival after listing) included in the mock-up received generally positive feedback. In addition to definitions, the study is looking at a number of alternative labels: survival listing, overall survival, and survival expectancy after listing.

Dr. McKinney shared primary themes found from the recent two kidney focus groups and three interviews of local Minnesota transplant candidates, who saw various mock-ups of data with survival after listing metric. These included patients finding the new metric useful, and patients want information to help them make decisions. Dr. Israni said interviews and focus groups are planned for liver, heart, and lung, and will be conducted in Spanish also. Pediatrics are not included in the studies since these low numbers are not rate risk adjusted.

Members found the study useful, and Dr. Snyder noted general support for creating a tier for overall survival from listing. The committee supported further exploration on this concept with PFAS at its May 2024 meeting.

Dr. Snyder went on to the third question, if SRTR should create a tier for organ offer acceptance. He noted these tier ratings were available on the secure site in a table format with qualitative labels instead of icons for the “history of acceptance” column. The Membership and Professional Standards Committee (MPSC) started using offer acceptance practices as a quality metric this year, and the Expeditious Task Force is trying to draw more attention to it. Dr. Snyder asked members if SRTR should publicly display the “overall” table row on the SRTR website.

Members discussed if the information was more appropriate for professionals or patients. Dr. Perito and Dr. Mohan said it seemed more for professionals, and Dr. Mohan said converting the information into probability would be more beneficial to patients. Dr. Hart said it was important to disclose the program offer and acceptance counts to patients. Mr. Ameen Tabatabai agreed it would be a good idea to display these in percentages by organ for patients. Dr. Schaffhausen said he was currently involved in a parallel research study on shared decision-making for organ offers and how to communicate the risks and benefits of accepting different organ types—a center will call a patient with an offer and they can decide to accept or not. Dr. Hart said this could be tied to how SRTR decides to communicate this information to centers and patients. Overall, there was a lukewarm response to this proposal; while making the suggested row public may not have a huge impact on patients, it would be helpful for professionals.

Dr. Snyder moved on to the fourth question, if the 5-tier bar icons should be replaced with color-coded gauges. Dr. Schaffhausen said a randomized survey was conducted a few years ago to the general public (over 1,000 people), testing the comprehension of different icons. Those taking the survey saw one randomly selection version of the icon and answered questions. Afterward, all icon versions were shown. The methodology was published in the 2021 paper “Design of a patient-

centered decision support tool when selecting an organ transplant center” in the journal *PLoS One*<sup>3</sup>. The study found that while participants selected the bars as the easiest icon to interpret, the gauge led to the most accurate interpretation of the data.

Dr. Snyder showed how the gauge was divided into different color wedges (green, yellow, and red) to reflect the five tiers. SRTR is also exploring adding a confidence band to the gauge. Dr. Hart liked this addition, as it could be explained to patients who wanted to go a step further in understanding the icon. Members agreed the gauge showed more granularity, whereas the tiers were more fixed. Dr. Hart said the gauge communicated that a three was a good score through the use of the green color. Mr. Tabatabai said the gauge helped get away from the five-star mentality and encouraged patients to do more data interpretation for themselves.

Dr. Bumgardner suggested adding actual values into the gray confidence band, and was concerned the number zero on the gauge might be misleading. Members discussed how zero might be misinterpreted by patients. It was agreed legend placement would be important. There was general support for the gauge icon. Dr. Snyder said SRTR can design more studies to analyze interpretations and work on improving it. There was a motion to move to a continuous gauge distribution that conveys both broad concepts and specificity with the arrow, moving away from the five-bar icons. All members were in favor. The second vote was for continue investigating and moving towards a tier for overall survival from listing to replace the three. A majority of members voted in favor of this. There was one oppose from Dr. Bumgardner, who disagreed with combining the survival of transplanted patients off the waiting list with the survival of patients. Mr. Scott McPhee abstained from voting.

### **HRSA data directive**

Dr. Snyder explained that HRSA directed the OPTN to expand data collection in February 2024 to include data on prewaitlist patient referral and evaluation and referral of potential deceased donors. Dr. Mohan explained that there are two new data collection efforts: an OPO-specific data collection effort to get more granular information about potential donors, and a focus on data elements in the transplant center process about referral and potential donor deaths. As these were HRSA-directed, there will be a 60-day public comment period in the *Federal Register* rather than through the OPTN public comment process. There will also be an additional 30-day comment period following revisions based on the comments received during the 60-day comment period. The goal is to start data collection by September 1, 2024. For the transplant center process, little information will be collected at the referral phase, with more collection for the time of evaluation. This will be new data SRTR will have to work with.

### **SRTR access to CMS data**

Dr. Snyder said there are ongoing discussions between HRSA and CMS on an information exchange agreement to try to gain better access for SRTR to end-stage renal disease program data, Medicare and Medicaid claims data, and death data. Easier exchange of information between federal agencies will hopefully result in better alignment of all transplant registry data across SRTR, OPTN, and the

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<sup>3</sup> Chu S, Bruin MJ, McKinney WT, Israni AK, Schaffhausen CR (2021) Design of a patient- centered decision support tool when selecting an organ transplant center. *PLoS One*. 16(5): e0251102. <https://doi.org/10.1371/journal.pone.0251102>

United States Renal Data System. Dr. Snyder will keep the committee apprised of developments in this area.

### **Report from the subcommittees**

Mr. Tabatabai said PFAS is working with the SRTR communications team to make patients and transplant organizations aware of the SRTR data. New members have joined PFAS, expanding the inclusion of different organs, ages, genders, and races. There are plans to expand the PFAS numbers into the teens. The next PFAS meeting is scheduled for May 17, 2024.

Dr. Schaffhausen said a specific agenda has not been drafted for the Human Centered Design Subcommittee (HCDS) meeting on May 22, 2024. However, the meeting will discuss the new website launch, the Task 5 project, user testing for kidney transplant estimated waiting time, and design of the tier gauges.

Dr. Vock said the last AMS meeting in March 2024 discussed the 5-tier system methodology, the new OPO metrics, organ acceptance, and cumulative sum (CUSUM) methodologies. Three new members joined the subcommittee. Dr. Snyder added the next meeting is scheduled for July 11, 2024. The agenda may include a focus on the tiering methodology and translation to the gauge icon, specifically methods for the confidence bands and how to convert scores back to a scale with a more patient-friendly interpretation.

### **Closing business**

The next meeting will be virtual and is scheduled for August 8, 2024. The fall 2024 meeting will be in-person in Washington, DC.