SRTR Review Committee Meeting Minutes

via Zoom

August 14, 2024, 12:00 PM – 3:00 PM CDT

Voting Members:
John Magee, MD (Co-chair) ('26)
Sean Van Slyck (Co-chair) ('25)
Ginny Bumgardner, MD, PhD ('24)
Deborah Mauer ('25)
Emily Perito, MD ('25)
Scott McPhee (HCDS) ('23)
David Vock, PhD (AMS) ('24)
Carli Lehr, MD, PhD ('26)

Voting Members Absent:
Ameen Tabatabai (PFAS) ('25)

Ex-Officio Members:
Rebecca Goff, PhD (UNOS-OPTN)
Shannon Dunne, JD (HRSA)
Jonah Odim, MD (NIH)
Jennifer Prinz (OPTN-POC)
Jesse Schold, PhD (OPTN-DAC)

HRSA Guests:
Adriana Alverez, MS
Jennifer Brock
Ricardo Cale
Brianna Doby, MPH
Frank Holloman

SRTR Staff:
Tonya Eberhard
Allyson Hart, MD, MS
Amy Ketterer
Grace Lyden, PhD
Warren McKinney, PhD
Jon Miller, PhD
Cory Schaffhausen, PhD
Mona Shater, MA
Jon Snyder, PhD, MS
Nicholas Wood, PhD
David Zaun, MS

Welcome and opening remarks

Mr. Sean Van Slyck and Dr. John Magee called the SRTR Review Committee (SRC) meeting to order. Roll call for voting and ex-officio members was taken, with quorum met. The co-chairs welcomed Dr. Jesse Schold to the committee as the new ex-officio member representing the Organ Procurement and Transplantation Network's (OPTN's) Data Advisory Committee. Dr. Magee reviewed the agenda, and Dr. Jon Snyder reviewed conflict of interest management.

Approval of the minutes

Dr. Magee asked for a motion to approve the minutes from the SRC meeting held on April 30, 2024. There was a motion to approve and a second. The minutes were unanimously approved.

SRTR leadership updates

Dr. Snyder announced that Dr. Ajay Israni will be transitioning to the Chief of Nephrology position at the University of Texas Medical Branch in Galveston, Texas, effective September 6, 2024. Dr. Israni will remain at SRTR as Senior Staff for Special Projects. Dr. Ryutaro Hirose will stay on as the SRTR Surgical Director. He will be joined by Dr. Roslyn (Roz) Mannon on September 1, 2024, as the SRTR Medical Director. Lastly, Dr. Allyson Hart began her role as the SRTR Deputy Director on August 12, 2024.

HRSA welcome and OPTN modernization updates

Mr. Frank Holloman of the Health Resources and Services Administration (HRSA) gave an update on the OPTN modernization efforts launched last year. The patients are the central component of these efforts, along with supporting providers and supporting robust information for the public on the transplant system's capacity, performance, and activities. Key accomplishments so far include the establishment of an independent OPTN Board of Directors. Members of the Board of Directors will not partake in any of the OPTN contractors or their boards. HRSA will be awarding a board support contract in August or September 2024. A transitions operations contract, which includes several domains, will be awarded shortly thereafter. Multiple vendors may win awards from the operational components.

HRSA recognizes the important role SRTR serves in supporting the OPTN with independent data and analysis that underpins the efforts to access and improve informal policy-making. With the current SRTR contract nearing its final year of the current award cycle, HRSA welcomes the SRC's feedback regarding lessons learned, challenges, and opportunities for improvement. These will help inform HRSA's re-competition efforts, the new contract's performance work statement, and new activities that may fall under SRTR moving forward.

As SRTR enters the final contract year, there will be a focus by HRSA on the most meaningful work and service to the OPTN strategic aims, goals, and priorities. HRSA recently announced two separate directives: collecting data from the point of candidate referral and getting standardized information on potential organ donors. The data collection requires the Office of Management and Budget (OMB) clearance process. There will be a public release for a 60-day public comment period in August and September for the directives. HRSA looks forward to working with SRTR on potential opportunities to leverage data collection instruments and data reporting and welcomes SRTR feedback on the proposals. HRSA encourages the SRC and transplant community to stay informed, participate, and share experiences in the OPTN modernization effort.

Dr. Ginny Bumgardner asked questions on how the funds for the modernization initiative will be allocated within the multivendor model, if the transplant community will have general access to the new data collection, and if the nominating procedure for the new board elections has been determined. Mr. Holloman said fund allocation had not been determined yet, data and new data elements will continue to be open and available for new researchers and requestors that want to perform research studies, and there will soon be a plan from the contractor on how new elections will be handled. Dr. Magee asked if the SRC would have a formal role in providing feedback and comments, and Mr. Holloman said it will be a more informal feedback loop. Dr. Snyder thanked HRSA for its willingness to get feedback from the SRC.

Discussion on future of SRTR and OPO quality improvement data

Mr. Van Slyck began dialogue on SRTR involvement in organ procurement organization (OPO) metrics given recent developments and holds on SRTR work on the metrics going forward. While he was aware of work on future data collection at the end of 2023 or early 2024, Mr. Van Slyck advocated for SRTR to be able to provide more granular data and analyses to the OPO community so that OPOs can better assess and benchmark their progress and support quality improvement. He

emphasized the urgency of this work, given 2024 is the evaluation year that will determine the upcoming recertification of OPOs.

Ms. Brianna Doby of HRSA said the data directive is moving toward providing benchmarkable data, and proposed having a separate meeting with the SRC on this topic. Mr. Van Slyck proposed that HRSA put forth a statement stating it is fully committed to providing analytics with the help of SRTR to ensure OPOs have the appropriate data and analytics to support process improvement.

Members discussed what type of data analysis was being done and who could do it. Dr. Jonah Odim said there should be nothing that prevents any organization or entity from doing sensitivity analysis of looking at data multiple ways. He questioned if the same federal body, i.e., the Centers for Medicare & Medicaid Services (CMS), needed to do the sensitivity analysis. Mr. Van Slyck said SRTR had the ability to do these analyses, which was preferable to all 56 OPOs having to do their own analyses. However, Ms. Doby said SRTR has thus far been unable to exactly replicate the CMS calculations, and all subanalysis and sensitivity analysis would require replication of the regulatory metric. She noted a separate meeting could be held to discuss the barriers and how to overcome those barriers.

Members agreed to schedule a separate call for this topic.

SRC 2024 nominating process

Dr. Snyder opened the discussion of the SRC nominating process by noting that about one-third of members' terms expire every year. Dr. Snyder said Dr. Bumgardner's and Dr. David Vock's terms expire on December 31, 2024. Dr. Vock's, Dr. Brent Logan's, and Dr. Andrew Schaefer's terms on the Analytical Methods Subcommittee (AMS) expire, Ms. Olivia Foss's term on the Human Centered Design Subcommittee (HCDS) expires, and three new positions on the Patient and Family Affairs Subcommittee (PFAS) will be added with no members rolling off. Dr. Snyder reviewed the 2024 application materials and nominating committee policies and procedures document. All correspondence and all communications will be available on the SRC landing page on the SRTR website for people to apply. Materials will also be included in SRTR e-mail correspondence and on the SRTR social media platforms. SRTR will also be using its distribution list for communication with professional organizations and societies (e.g., Donate Life America, the Association of Organ Procurement Organizations [AOPO], the American Society of Transplantation [AST], the American Society of Transplant Surgeons [ASTS], the National Kidney Foundation [NKF], and the American Association of Kidney Patients [AAKP]).

Dr. McGee will be the co-chair for the SRC nominating committee, with Ms. Deborah Mauer, Dr. Emily Perito, Dr. Bumgardner, and Dr. Vock as additional members. Subcommittee co-chairs will work to help replace members who are leaving. All members agreed with the process and having the nominations period be August 14, 2024, through September 30, 2024th. The nominating committee will then have 2 weeks to review the nominees and make recommendations for selection at the next SRC meeting on October 17, 2024. A motion to launch the nominating process was made, seconded, and unanimously approved.

Donation and Transplantation System Explorer application updates

Dr. Snyder summarized utilization data on the Donation and Transplantation System Explorer tool. In the past 90 days, the tool had 1,400 views from almost 558 unique users. The tool is currently the eleventh most popular page on the SRTR website.

Dr. Nick Wood said an update was made to the waitlist size (point prevalent) trends showing the size of the waiting list on any given day, allowing for numerous stratifications of the waiting list. The other addition to the application was utilization of liver and heart offer filters. Dr. Wood is developing the tool's ability to select program-specific and OPO-specific trends.

Members inquired if SRTR could launch the tool for SRC access under a password-protected application so that members could explore the program- and OPO-specific functionality prior to public launch. Dr. Wood and Dr. Snyder noted that the tool can be made available under a password-protected application for SRC preview. Dr. Schold pointed out that SRTR should be cognizant of the potential for small sample sizes for certain strata. Dr. Perito and Dr. Carli Lehr discussed the possibility of limiting strata in the tool or adjusting the window period to avoid small samples. Dr. Hart suggested if there is too small of a group in the data, a message should appear to alert the user and the tool should not give any output. Dr. Wood agreed to further explore possible mitigation of small sample size issues.

SRTR will continue development on the tool and will update the committee during the October 2024 meeting.

Launch of the preview of the patient-friendly SRTR website

Dr. Snyder gave an update on the patient-friendly SRTR website since its preview launch in April 2024. Weekly usage statistics through the end of July show a substantial fraction of new users, with a total of 100-200 users (sometimes 300 when new reports are launched). The United States is the main country using the website. Top pages include the Compare Transplant Programs and transplant search results pages.

Dr. Snyder reviewed the feedback for the patient-friendly website, which has been mostly positive. Critiques include use of medical jargon and need for more focus on the living donation component. SRTR has addressed a number of these suggestions already. In terms of next steps, HRSA is planning to fund accelerated development of the site by adding more tools and functionality, and making a clear distinction between patient and professional content. The preview site will eventually be merged with the srtr.org site.

Ms. Maurer advocated for all transplant centers to be promoting this site. Dr. Perito said naming the website preview.srtr.org caused confusion as to whether it was meant for public use. She also thought preview.srtr.org could serve as a good entry point to OPTN and HRSA data dashboards. Mr. Scott McPhee suggested finding ways to better ascertain the kinds of users hitting the site, and noted that this could be a part of the HCDS agenda. Dr. Snyder said srtr.org previously had a pop-up survey to the kinds of users hitting the site, but the categories were not granular enough given SRTR had to use a pre-OMB-approved survey that had user categories predetermined and was nonspecific to transplantation. Setting up a new user survey may require OMB review and approval.

The committee expressed thanks for the updates on the patient-friendly website and looked forward to continued reports at upcoming meetings.

2025 Task 5 follow-up conference

Dr. Snyder said Task 5 of the SRTR's performance work statement requires SRTR to do a follow-up conference every 3 years with the goal of assessing progress on recommendations stemming from the 2022 consensus conference. SRTR is planning a virtual 2-day conference for the first week of April 2025, with hopes of capitalizing on Donate Life month.

Dr. Cory Schaffhausen said the overall agenda structure would follow the transplant map. The tentative agenda for day 1 includes opening remarks and reviewing recommendations from the 2022 conference, which include general SRTR recommendations, prelisting recommendations (referral and center selection), prelisting data collection recommendations, and waitlist and posttransplant recommendations. Day 2 will consist of topics connected to the transplant map, including deceased donation recommendations, living donor recommendations, and research. There are also recommendations aligned with OPTN and Organ Transplantation Affinity Group (OTAG) work. The agenda will transition to future priorities. Dr. Schaffhausen added the conference will include active data collection (live polling) among participants. Each day will be about 7 hours long. Dr. Hart said the agenda and conference structure will be run by PFAS for input.

Members discussed if the conference should be a consolidated 2-day event, or shorter events over a longer period of days. Dr. Snyder thanked members for the feedback and would keep the committee updated as planning continues.

[Dr. Bumgardner had to leave the meeting following this topic.]

SRTR 5-tier metric summaries

Dr. Snyder said SRTR has been in the process of improving the methodology and exploring ways to enhance the interpretation of SRTR's 5-tier summary metrics.

The AMS reviewed the topic at its July meeting and was generally supportive of standardizing the score function, such that SRTR uses a consistent approach across all of the metrics. The AMS supported standardizing the score function shape parameter to ±4.82. Also, the SRC recommended that the AMS explore ways to provide additional context as to what the tiers mean in terms of actual patient outcomes and event rates and the range of performance across tiers. The SRC supported adding a tier for offer acceptance, although it is currently not publicly available until possibly the January 2025 program-specific report (PSR) release.

SRTR 5-tier metric summaries: **Score function shape and parameter**

Dr. Snyder explained that SRTR has historically used score functions with a shape parameter of -10 for posttransplant outcomes and waitlist mortality, +5 for offer acceptance, and +3 for transplant rate. When the functions were created, the shape parameters were influenced by the variance in observed evaluations across programs, meaning if a metric was more highly dispersed, values closer to 0 are used. However, SRTR is proposing to standardize the score parameters across different metrics, such that relative deviations from expected are all scored similarly regardless of the metric.

SRTR now proposes, with the support of the AMS, using a score function shape parameter of ±4.82. The effect on posttransplant outcomes and waitlist mortality is fewer programs in Tier 1 and Tier 5 and more in Tier 3. For transplant rate, more programs will be seen in Tiers 1 and 5 and fewer in the middle tiers, given the move from a score parameter of 3 to 4.82. Dr. Snyder showed a few example plots of the expected outcomes within each tier under the different score functions, and he noted these ranges can be used to add additional context to the tiers as SRTR continues to enhance the website.

Dr. Vock pointed out the fewer number of transplants means a wider confidence band, resulting in more centers pulled towards Tier 3. Giving the internal metrics or markers of where the tiers are may upset centers. Dr. Grace Lyden added that in this case, it was better to have a philosophical norm than use a data-dependent method. Dr. Schold supported the rationale behind having homogeneous score functions, while also noting that the tiers have limited ability to predict future outcomes for patients considering them as a decision aid for where to list. He further noted that while they offer perspective on historical performance, they are less predictive of what will happen for a prospective patient. Dr. Magee agreed with Dr. Schold, and Dr. Snyder said this will also be reviewed by patients at an upcoming PFAS meeting in September.

Mr. McPhee motioned to approve standardizing the score function parameters to ±4.82, with the friendly amendment that this should continue to be brought before patients and the HCDS as the SRC continues to develop the presentation of these 5-tier summaries. Dr. Lehr seconded the motion. The motion was unanimously approved.

SRTR 5-tier metric summaries: Updating the icons to improve understanding

Dr. Schaffhausen highlighted the article "Design of a Patient-Centered Support Tool when Selecting an Organ Transplant Center" in the journal *PLoS One*.[1] The publication was about work through an external research grant that analyzed the design of a website that used SRTR data to evaluate what type of icon would be best to increase interpretability by the user. There were six different icon variations in a randomized survey. Participants were shown one of the six icons, and answered a few questions. Users were then shown all images, and asked which was preferred. The bars were the most preferred, but the dial was the icon interpreted most accurately. Dr. Schaffhausen said PFAS and the HCDS showed a lot of interest in the dial concept at their recent meetings.

SRTR has created a survey to get additional data to help reach a decision about which icon to pursue for future improvements to the website. Like the previous survey, participants would see a single randomly selected variation and answer questions based off their interpretation, followed by a preference choice with all the icons. There is a third added section addressing how multiple icons or multiple metrics compares to having a summary of initial search results that shows a single composite, like overall survival from listing.

Dr. Schaffhausen reviewed the different icon variations, with option A reflecting the current website, option B maintaining the use of the three separate metrics and replacing the icon with a dial, and options C, D, and E containing only the single overall survival from listing metric. These also evaluate

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

a few different color schemes for a dial. Option F includes numeric content, which may have additional options itself for future study. Dr. Schaffhausen said part three of the survey will look at different ways to use combined metrics.

Dr. Magee suggested including numerical anchors with the mock-ups, questioned whether displaying a lot of granularity was useful to patients, and wondered if the icons are really only differentiating within "grade A" programs. Dr. Hart said SRTR has worked with patients over many years and patients, donors, and their families support presenting these differences; she also noted that this was supported in the recommendations from the Task 5 consensus conference. Patients advocate for transparency and insight into even small differences. Patients having access to such data allows them to advocate for themselves.

Reports from the subcommittees

Dr. Snyder noted that much of the recent discussion by the AMS was already covered at an earlier meeting and the next AMS meeting is being scheduled for the autumn. Dr. Schaffhausen noted for the HCDS there will be meeting in September that will include discussions of the ongoing project for estimating waiting times. PFAS will also be meeting in September and will continue to provide insights into the development of the Task 5 conference in 2025 and the presentation of the tiers and transplant program search results.

Closing business

The next meeting is scheduled for October 17, 2024, at HRSA headquarters in Rockville, MD. Hearing no other business, Ms. Shannon Dunne thanked the members for their service to HRSA and the SRTR and Dr. Magee and Mr. Van Slyck adjourned the meeting.