

SRTR Review Committee Meeting Minutes

Teleconference

November 2, 2021, 10:00 AM – 2:30 PM CDT

Voting Members:

Roslyn Mannon, MD (Co-Chair)
Jeffrey Orlowski, MS, CPTC (Co-Chair)
Kiran Khush, MD, MA, MAS
Chris Zinner
Richard Knight, MBA
Brent Logan, PhD
James Markmann, MD, PhD
Sumit Mohan, MD, MPH
James Pittman, RN, MSN

Ex-Officio Members:

Shannon Dunne, JD (HRSA)
Nicole Turgeon, MD, FACS (OPTN-POC)
Jonah Odum, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)
Rachel Patzer, PhD (OPTN-DAC)

HRSA:

Adriana Martinez

SRTR Staff:

Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, MD, MS
Bertram Kasiske, MD, FACP
Caitlyn Nystedt, MPH, PMP
Cory Schaffhausen, PhD
Jon Snyder, PhD, MS

Welcome and opening remarks

Mr. Jeffrey Orlowski called the SRTR Review Committee (SRC) meeting to order. All voting members were present. He reviewed the agenda and conflict of interest management.

Approval of minutes

With no suggested changes to the meeting minutes from August 13, 2021, the vote to approve the minutes was unanimous.

SRC membership

Dr. Jon Snyder discussed modifying voting membership terms in the SRC and each subcommittee: the Analytical Methods Subcommittee (AMS), Human-Centered Design Subcommittee (HCDS), and Patient and Family Affairs Subcommittee (PFAS). Subcommittee chairs also have a seat on the SRC to liaise between each. To avoid subcommittee cochair memberships ending simultaneously, some memberships will be extended. Current co-chair positions end in December 2021 for Dr. Brent Logan (AMS) and Mr. Richard Knight (PFAS). Dr. David Vock agreed to co-chair AMS for the next 3 years, and Mr. Knight agreed to extend his term to 2022. The term for Mr. Chris Zinner (HCDS) will go through 2023. In the SRC, Dr. James Markmann's term ends in December 2021, and an invitation to Dr. Ginny Bumgardner of Ohio State University as replacement is in progress.

Reports from the subcommittees

SRTR staff co-chair Dr. Allyson Hart had no updates for PFAS. SRC co-chair Mr. Knight reported progress for forming focus groups to support the SRTR's Task 5 initiative. Dr. Hart said there was a need for heart and lung patients, and other members gave contact suggestions. SRC co-chair Mr.

Zinner said that HCDS completed a design critique for the interactive data query tool and discussed Task 5 and the consensus conference. SRTR staff co-chair Dr. Cory Schaffhausen said that Olivia Foss from Mayo Clinic replaced a former member. He added that the planning process for Task 5 was discussed with design-centric language, specifically identifying problems to address, brainstorming, and prioritizing solutions. The subcommittee said it was important to think in aspirational ways when planning significant changes. The next meeting will focus on patient-centered tools.

Co-chair Dr. Logan of the AMS said the subcommittee discussed the process of developing risk-adjustment models and COVID-19's impact on program-specific reports (PSRs) and organ procurement organization (OPO)-specific reports (OSRs). Despite transplant program inquiries addressed to AMS to reconsider adjusting the original carve-out period (March 13 to June 12, 2020), the subcommittee decided not to revisit it at this time. Members agreed to update the COVID-19 monitoring application and asked the SRTR staff to assess their available resources to resume updating the application. Dr. Logan drafted a response to these requests, which is being reviewed by AMS members. Mr. James Pittman noted that one of his programs in Texas also asked SRTR to consider programs that were unaffected during the carve-out period but affected at a later time. The program was concerned about the carve-out period, because the program completed nine successful heart transplants during this period that would not be counted.

Members discussed how to address the disagreement transplant centers had about the carve-out period. Dr. Markmann suggesting adding to the draft response that the carve-out decision was based on disruption to transplant and donation activity. Dr. Roslyn Mannon said the issue wasn't necessarily programs being disrupted by COVID-19 but transplant recipients dying after the carve-out period. Dr. Snyder clarified that patients who received transplants before the carve-out do not resume follow-up after the carve-out period. Mr. Darren Stewart suggested adding the Organ Procurement and Transplantation Network (OPTN) Membership and Professional Standards Committee (MPSC) perspective to the SRTR response that outcomes that don't meet OPTN requirements will be assessed on the basis of individual circumstances during COVID-19. Mr. Stewart also brought up the possibility of censoring by death due to COVID-19 within a certain time limit. Dr. Snyder suggested adding information to the reports on reported COVID-19 deaths within the evaluation cohort, potentially presenting two different hazard ratios for each program. The members noted that presenting two different hazard ratios could cause more confusion than it would resolve. Dr. Sumit Mohan said that adding information on COVID deaths could be done for a defined period.

Dr. Rachel Patzer said the carve-out was appropriate but worried that any additional carve-outs would be driven by center rather than patient perspectives. Ms. Amy Ketterer, who fields questions from the public about SRTR reports, added that the SRC needed to be concerned about programs not understanding the effects of the carve-out and that modifying the carve-out may cause additional confusion. Dr. Mannon and Dr. Ryutaro Hirose agreed. Final recommendations from the committee included no additional carve-outs, analyzing past data to assess sensitivity levels of patient deaths and outcomes, and consulting the PFAS for feedback and guidance.

Sociodemographic adjustment

Dr. Snyder discussed a recent controversy in the use of race in medical equations such as glomerular filtration rate (GFR) estimating equations and deceased donor quality estimates. The

National Kidney Foundation (NKF) has released statements stating that using race in GFR equations is no longer an acceptable approach, while recent literature has argued against the use of race in OPO performance metrics. Dr. Snyder said that SRTR believes that adjusting for race brings to light potential problems rather than obscures disparities. SRTR cited its analysis demonstrating examples of Simpson's paradox, in which OPOs, for example, may be deemed lower performers when not adjusting for ethnicity; however, after adjustment, the lower-performing OPO would be shown to indeed be the higher-performing OPO (Snyder et. al. *Am J Transplant*, 2020). The Centers for Medicare & Medicaid Services (CMS) decided against using race as a risk adjustment in OPO performance metrics. Also, the National Quality Forum (NQF) in 2014 published a position statement arguing that adjustment for race is appropriate when 1) there is a conceptual relationship between race and outcomes, 2) there is empirical evidence that race impacts the evaluations, and 3) a standardized process is followed for building the risk-adjustment models. This was discussed with the AMS at its meeting on November 2, 2021, and the majority of the subcommittee supported this recommendation. Dr. Hirose supported adjustment for race. Mr. Orlowski agreed. Dr. Hirose said it is necessary to stratify and risk-adjust for race.

Dr. Snyder said that SRTR's analysis of the NQF's second criterion found empirical evidence that race is associated with outcome. Race is often selected using the Least Absolute Shrinkage and Selection Operator (LASSO) as a predictor in models of posttransplant graft and patient survival. This also addressed NQF's third criterion that race is often kept using SRTR's standardized model-building procedures. For the first criterion of identifying a conceptual relationship between race and outcomes, Dr. Snyder cited three plausible reasons for this association: race has been associated with the ability to identify suitable donor matches, which has resulted in historic changes to allocation policy to mitigate this risk, race being associated with unmeasured social risk factors, and potential bias within transplant programs or the healthcare system.

SRTR also rebuilt models without the option to include race. The discriminatory ability of the models decreased slightly when race was not offered as a potential risk predictor. When race was removed, patient-level predictions changed in predictable ways, depending on the relationship between the predictor and outcome. On a program level, evaluations did not change, on average. Dr. Snyder said that AMS discussed these topics, and a majority of the subcommittee agreed with SRTR's approach to adjusting for sociodemographic factors, including race.

The committee agreed that race is important in some discussions but should be approached carefully. Mr. Orlowski and Dr. Kiran Khush supported the subcommittee's recommendation. Dr. Mohan said that the difference in models was very small. He didn't think that the average transplant provider understood the model well enough for it to be driving clinical behavior. Drs. Mohan and Patzer noted that because race is a proxy for socioeconomic status and sociodemographic factors, it is important to consider the unintended consequences of risk-adjusting for race. Dr. Patzer added that race should be defined as a social construct, and the decision to race adjust depends on the goal. Mr. Knight liked SRTR's analysis and said that further analysis would be beneficial, stressing that the objective should be to increase patient quality of life. Mr. Pittman added that there is a need to take a more sophisticated look at the complexities of race to help mitigate potential disparities. Mr. Orlowski said that knowing when race is important to address requires further analysis. Dr. Mannon and Mr. Zinner agreed that simplicity is key in presenting data to patients and physicians for accurate decision making. Dr. Hart said the conversation highlighted that racial equity as a

potential quality metric should continue to be examined and that using race in a model should be a conscious decision that can be justified beyond statistical significance.

The discussion concluded with most members supporting SRTR's current approach to adjusting for race in risk-prediction models used to evaluate transplant program and OPO performance.

Development of decision aids

Dr. Schaffhausen reviewed the SRTR website update timeline. Year 1 of the current 5-year contract cycle focused on rebuilding existing online tools, and the second year will focus on adding functionality to the SRTR secure site. The timeline for additional website rebuilding has yet to be determined. In addition, the planning effort for Task 5 started in year 1 and continued into year 2. The Task 5 conference will also take place in year 2, with implementation in the following years guiding future website development.

Dr. Schaffhausen reviewed the available SRTR online tools. For waitlist outcome tools, there is an updated version of the liver waiting list calculator and a kidney transplant decision aid with an integrated calculator. The patient decision aid for liver offer acceptance focuses on candidates already on the list and provides guidance on organ offers. It also includes a section on personalized risks that will use the same modeling as the liver waiting list calculator. Dr. Schaffhausen said a version for kidney candidates is also being created. He reviewed the offer acceptance calculator tool. Members commented on the importance of patients and clinicians being aware of the decision aid tool.

He showed additional mock-ups for potential tools meant to track past offers (declined offers and predicted future outcomes if a patient continues to wait). Mr. Pittman asked if SRTR was considering a partnership with the United Network for Organ Sharing (UNOS), which is developing similar resources. Mr. Stewart said that OPTN will soon pilot new predictive analytics in DonorNet and that ensuring that information was not misaligned across multiple organizations is a priority. Despite new tools that highlight patient preference for organ offers, many said the offer acceptance process was not explained to patients. Mr. Orłowski said the patient community may assume that a transplant center is actively working with the patient to evaluate every organ offer, which is not necessarily true. Mr. Knight said the term "offer and acceptance" was misleading because it falsely suggests that a patient is always aware when they have been offered an organ. Numerous members stressed the need to educate patients on the organ offer process and said that the process itself needs improvement. Last, Dr. Schaffhausen said the upcoming year will focus on improving website navigation to access these tools.

Development of the SRTR DATA tool

Dr. Schaffhausen showed the committee screenshots of the SRTR Donation and Transplantation Analytics (DATA) tool that is under development. It reformats data in the Annual Data Report (ADR) into an interactive platform in which users can customize maps, time trends, survival curves, and plots. The tool is complementary to the ADR and enhances data for the transplant community.

MPSC proposal and implications for SRTR public reporting

Dr. Snyder highlighted the new Membership and Professional Standards Committee (MPSC) proposal that will go to the OPTN board in December. The proposal discusses including two pretransplant metrics. The first is the pretransplant mortality rate ratio, which addresses the rate at which people die before receiving a transplant. It evaluates a 2-year calendar that rolls forward every six months. The rule the MPSC put forward to the UNOS/OPTN board is that there is at least a 50% probability that the waitlist mortality ratio is greater than 1.75, or, in other words, there is more than 50% probability that the program's mortality rate is at least 75% higher than expected.

The second metric is the offer acceptance rate ratio, which addresses whether a program accepts offers at a rate higher or lower than national experience for similar offers to similar candidates using a 1-year evaluation window.

This proposal includes two proposed new outcome metrics, 90-day graft survival and conditional 1-year graft survival (conditional on the graft functioning for the first 90 days). Dr. Snyder asked the committee if SRTR should include these metrics on the SRTR website if it receives OPTN board approval. Members supported inclusion of the new metrics and said that the 1-month metric was important to retain. Dr. Larry Hunsicker suggested a tabular structure of adding 90-day and conditional 1-year survival as a tab underneath 1 year to avoid confusion.

Dr. Snyder said that if the OPTN board approves the proposal on December 6, 2021, SRTR will plan to include 90-day and conditional 1-year outcomes in the public reports, in addition to current 1-month, 1-year, and 3-year outcomes. The 90-day and conditional 1-year survival is tentatively scheduled to be included in the July 2022 public reports. Offer acceptance would begin to be monitored by the MPSC in July 2023, and waitlist mortality would follow in July 2024. SRTR does not plan to alter 1-year CUSUM charts on the secure site. SRTR also plans to modify the MPSC flagging reports currently available to programs on the secure site. SRTR will explore modification to expected survival workbooks for 1-year posttransplant outcomes to include the 90-day and conditional 1-year outcomes. The committee agreed with this plan and suggested seeking the patient perspective on these changes.

Identifying metrics to assess transplant system performance and support informed decision making

Dr. Snyder said the Consensus Conference is slated for July 18 to 22, 2022, at the Radisson Blu at the Mall of America in Bloomington, Minnesota. SRTR will open a public comment period from November 9, 2021, to April 8, 2022, for the public to submit comments on transplant metrics. SRTR will also host patient focus groups and launch a call for attendees in mid-November 2021.

Last, Dr. Snyder gave an OPO metrics update. CMS has publicly released the OPO performance report. SRTR is currently finalizing and coordinating with CMS so its methodology matches the results, which will be available on the SRTR website in the future.

Closing business

Hearing no other business, the meeting concluded at 2:30 PM CDT. The next meeting date is yet to be determined.