SRTR Review Committee Meeting Minutes

Teleconference

August 13, 2021, 12:00 PM – 3:00 PM CDT

Voting Members:	**Ex-Officio Members:**	**SRTR Staff:**
Roslyn Mannon, MD (Co-Chair)	Shannon Dunne, JD (HRSA)	Ryutaro Hirose, MD
Jeffrey Orlowski, MS, CPTC (Co-Chair)	Nicole Turgeon, MD, FACS (OPTN-POC)	Larry Hunsicker, MD
Kiran Khush, MD, MA, MAS	Jonah Odim, MD (NIH)	Ajay Israni, MD, MS
Chris Zinner	Darren Stewart, MS (OPTN/UNOS)	Bertram Kasiske, MD, FACP
Richard Knight, MBA	Rachel Patzer, PhD (OPTN-DAC)	Caitlyn Nystedt, MPH, PMP
Brent Logan, PhD		Nicholas Salkowski, PhD
James Markmann, MD, PhD	**HRSA:**	Cory Schaffhausen, PhD
Sumit Mohan, MD, MPH	Chris McLaughlin	Jon Snyder, PhD, MS
James Pittman, RN, MSN	Adriana Martinez	Andrew Wey, PhD
	Shannon Tait	

Welcome and opening remarks

Co-Chair Dr. Roslyn Mannon called the SRTR Review Committee (SRC) to order. She said a new ex-officio member, Dr. Nicole Turgeon, was taking the place of Alexandria Glazier as the Organ Procurement and Transplantation Network (OPTN) policy oversight committee representative:

- Nicole Turgeon, MD, FACS (OPTN-POC), transplant surgeon, University of Texas at Austin

After reviewing the agenda and reminding everyone of conflict-of-interest management, Dr. Mannon proceeded with the agenda.

Approval of the minutes

Dr. Mannon requested an approval of the SRC April 2021 meeting minutes. Mr. Richard Knight made a motion to accept the minutes as presented, followed by a second. There were no disapprovals.

Reports from the subcommittees

In the last meeting, co-chair Mr. Knight said that the Patient and Family Affairs Subcommittee (PFAS) discussed the importance of focus groups and the process of creating them. Members agreed there should be a sufficient number of patients in all focus groups. The number of patients invited to the consensus conference should be estimated on the high side, as some patients might not be able to attend. The subcommittee said that engagement before the conference is necessary to allow time for patients to review the educational materials. Mr. Knight also suggested expanding the subcommittee because there could be absences due to illness. In a discussion about multiorgan transplant, Dr. Allyson Hart said that members felt the information should be presented separately from single-organ transplant data.

Chris Zinner, co-chair of the Human-Centered Design Subcommittee (HCDS), said its June meeting was the first robust design criticism/critique (CRIT) discussion on the interactive data query tool. The new tool takes national data report PDFs and displays them on the SRTR website in an interactive format. The subcommittee reviewed the data structure that formed the report and gave advice on ways to improve the tool for intuitive use. Mr. Zinner said that the subcommittee also reviewed Task 5, emphasizing the importance of ensuring that metrics are human-centric. In addition, one member said that their expertise was not very useful and was replaced by Olivia Foss, a Mayo Clinic service designer.

Dr. Cory Schaffhausen said that past feedback was used to revise some user interface concepts. The mock-ups of that interface were sent to the SRTR internal teams that are building the tool. The next HCD subcommittee meeting will focus on new versions of the SRTR individual risk calculator and patient decision aid. Currently, HCD is helping SRTR redesign individual tools like the kidney decision aid tool and the liver waitlist calculator. Dr. Rachel Patzer asked how patients and stakeholders will know about these tools and how this knowledge would be measured. Mr. Zinner said that with the evolution of the SRTR website into a patient-engagement platform, the HCD subcommittee would create an outreach campaign to draw awareness to these tools and measure the campaign's success.

Co-Chair Dr. Brent Logan of the Analytical Methods Subcommittee (AMS) said that the June meeting focused on selecting risk factors for the model adjustments used in program- and organ-specific reports (PSRs and OSRs). In this process, SRTR has a two-step build in the fit-model cycle. The build stage consists of gathering information on a large number of predictors, or recipient and donor factors. The final model is produced in the fit stage, which involves 15 to 20 predictors instead of the 100 identified in the build stage. The subcommittee proposed combining the two stages into a single step. This would require defining a list of covariates for the model to consider, which would come with the possibility of missing covariates or an arbitrary selection. The subcommittee's feedback was to include more factors and encourage discussion with clinicians about which factors should be considered and which variables should be included in the model.

The other topic was whether to implement offer-acceptance models as part of the simulated allocation model (SAM) process, which is done to predict the number and distribution of transplants under different allocation systems to understand effective policy proposals. The subcommittee discussed how SAMs implement the ad-hoc discard process by truncating match-runs after a certain number of offers and discarding the remaining ones. The cutoff number is calibrated to the baseline scenario. A concern was that the ad-hoc process may not align with how the discard and acceptance rates naturally occur. In particular, differences between allocation schemes can change depending on the cutoff number used. SRTR felt that SAMs should not model this discard process due to concerns over sensitivity to the cutoff number. The subcommittee agreed.

Mr. Darren Stewart said he understood that for the fit-model cycle, organ-specific committees decide which factors to include in a 3-year cadence. Dr. Jon Snyder said that although this was the original structure, it was difficult for organ-specific committees at the United Network for Organ Sharing (UNOS) to give feedback on what wasn't in the models but should be. With 160 models being refitted every six months, it's a challenge to construct a strong implementation process. Dr. Ryutaro Hirose suggested having UNOS consider which subcommittee had the clinical and statistical

expertise to look at risk stratifications. Dr. Jonah Odim suggested having a covariate evaluation assessment committee. Mr. Logan said that it might help to always have a base set of variables in the models that establishes minimal validity for physicians and clinicians, followed by another set of variables if it is important in the model-building process. Dr. Sumit Mohan agreed with the idea, but said it may lead to a situation in which a coefficient becomes zero. Dr. Mannon pointed out that transplant faculty do not understand the intricacies of biostatistics and suggested offering training programs or webinars.

Website updates in response to COVID

Dr. Snyder reviewed modifications to the SRTR public website regarding COVID-19 in the form of disclaimers that COVID-19 is affecting analyses. A yellow banner appears at the top of the search results page, with a "click here" option to learn about these changes. A first-level pop-up appears that gives users more information and provides links to an SRTR news release on the changes. An FAQ page is available as well. The warning banner is also present on PSR pages, including the new interactive reports. Page 1 of the PDF reports also contains information on changes made in response to COVID-19. The footer of each page says to see the "COVID-19 guide for pandemic-related follow-up limits." The same warning banner appears when searching for organ procurement organization (OPO) reports and when viewing OPO data.

Update on period-prevalent posttransplant outcomes

Dr. Snyder said that at the April 2020 meeting, members approved the transition to a 5-year period-prevalent cohort. SRTR wanted to finalize these decisions immediately. In case of a 2.5-year incident cohort window for 1-year outcomes, SRTR can take a 2.5 years of transplant events and follow them for one year posttransplant to evaluate their outcomes. The idea of moving to a period-prevalent window is that SRTR can evaluate a two-year period. Any patient alive with graft function who was given a transplant by that program in that window would be followed for that time. These models could be used for outcomes from one month to five years. The OPTN Membership and Professional Standards Committee (MPSC) expressed interest in seeing these five-year outcomes. Dr. Snyder highlighted the main takeaways from Dr. Andrew Wey's published findings showing that posttransplant outcome assessments that extended follow-up to five years with a period-prevalent approach improved the usefulness of the assessments at listing. While the committee agreed to add five-year outcomes to the one-month, one-year, and three-year outcomes, there was still the question of including MPSC's proposed metrics of 90-day graft survival and conditional one-year evaluation (ie, up to one year if a patient survives the first 90 days).

Dr. Kiran Khush asked how a center would be affected if a patient was transferred to another center for care before the evaluation window. Dr. Larry Hunsicker pointed out that it is important to distinguish between two different perspectives on the topic. While the issue of transfers is relevant to the evaluation of center issues, patients are more interested in longer-term outcomes. Members agreed that transfer practices vary by center and organ. Mr. Stewart suggested a two-fold approach: an intent-to-treat approach for patient-friendly metrics and adjustment for transfers as a time-varying center effect for MPSC metrics. Dr. Khush agreed that this approach was reasonable. Mr. Knight proposed a stakeholder analysis to understand the goals of each group. Dr. Sumit Mohan suggested having transplant centers partner with community professionals, because transplant

centers don't have the ability to manage all transplant recipients. Dr. Odim agreed. Mr. Jeffrey Orlowski said that the 30- and 90-day outcomes were no longer useful.

Mr. Chris McLaughlin asked why the SRC was acting on this item now instead of discussing it during the 2022 consensus conference. Dr. Snyder said that it was urgent to discuss the topic in light of MPSC expressing interest in seeing 5-year outcomes. However, the committee agreed to table the discussion and save it for the conference.

Developing presentations of new CMS metrics in OPO reports

Dr. Snyder said that the Centers for Medicare & Medicaid Services (CMS) decided to implement new metrics and standards for OPOs in November 2020. These two new performance metrics are donation rate (donations per potential donor) and transplant rate (transplanted organs per donor). Because Task 6.2 charges SRTR to publish these metrics in OPO reports, Dr. Snyder asked for the committee's opinions on how to apply the metrics. The CMS rule implementation date is August 1, 2022.

Dr. Snyder shared a few formatting ideas for the OPO report pages on the SRTR website. Along with the current tabs on the page (eg, donor data, donation rates, organ yield), Dr. Snyder proposed adding a new tab, "eligible death donation rates," under "donation rates." It would be titled "donor per death consistent with organ donation," consistent with CMS final rule language. Dr. Snyder also proposed a scatter plot similar to one in the current report. Because CMS is not proposing risk adjustment of this metric, the raw rate, rather than adjusted rate ratio, would be plotted.

Dr. Hunsicker said that the approach would be fine for professionals, but confusing for the general public to see two different definitions of donor and organ yields. Mr. Orlowski favored having a tab for new CMS metrics but not deleting historical OPO data. He said that if SRTR presented multiple metrics, it would need to delineate which metrics related to which timeframes, as death rate data is two years old, and donor data is one year old by the time it's released.

The committee discussed working under the constraints of the new CMS metrics and which data should be included on the public website versus the secure website. Dr. Hirose pointed out that CMS decided not to risk-adjust for factors like age and race, which may not help OPOs improve their performance. Chris McLaughlin said that the committee should consider, independent of CMS metric status, how the reports would help the community.

Mr. Orlowski said that seeing OPO data other than his own helps define performance metric goals. He said that it is important to consider which data to present privately and publicly and how to present it. The public site needs to be as straightforward as possible. Mr. Zinner discussed reformatting these reports for the public, and Dr. Hart said it was important to challenge the assumption that if patients don't understand the data, it shouldn't be shown to them.

Modifications to treatment of heart-lung candidates in pretransplant metrics

Dr. Snyder reminded the committee that in September 2020, the SRC supported a program's request to remove heart-lung candidates from pretransplant evaluation of mortality and transplant

rate for heart and lung waitlists. SRTR has been delayed in doing the programming due to COVID-19–related changes.

The program brought up another issue regarding heart-lung candidates. It received guidance from the OPTN that heart-lung recipients should be removed from heart and lung waitlists with a removal code of "other" (if the patient receives a transplant), writing in the text explanation field that the patients received a heart-lung transplant. This is significant because SRTR methodology continues to look beyond removal from the list due to deaths, unless the patient is removed for a transplant, transfer, or 60 days post-recovery. Patients removed for "other" continue to be followed, which may result in SRTR counting a death immediately posttransplant as a pretransplant waitlist death. In addition, allocation handles kidney-pancreas candidates differently because they can opt into receiving kidney-alone offers without a separate kidney registration. OPTN does not provide any guidance for kidney-pancreas candidates registering on the pancreas or kidney lists. Dr. Nicole Turgeon suggested discussing this topic with the OPTN multiorgan committee.

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

Dr. Snyder said that SRTR is meeting monthly with the Task 5 Steering Committee in preparation for the July 2022 consensus conference. The meetings are for hearing targeted perspectives from key stakeholders and transplant metrics. Because the Health Resources and Services Administration (HRSA) and CMS delayed their upcoming presentation, the committee will use that time to discuss metric frameworks and prepare a draft agenda. The committee will hear perspectives from the American Society of Transplant Surgeons (ASTS) and private payers in the coming months. SRTR plans to send speaker invitations later this year and attendee invitations early next year. SRTR is also scheduling a public comment period in November that will be open for six months. Requests for speakers and attendees will be circulated in the near future.

Closing business

Hearing no other business, the meeting concluded. The next teleconference is scheduled for November 2, 2021, at 10:00 AM CDT.