

SRTR Review Committee Meeting Minutes

October 27, 2023, Via Webex, 10:00 AM – 1:00 PM CDT

Voting Members Present:

Roslyn Mannon, MD (Co-chair) ('23)
Sean Van Slyck (Co-chair) ('25)
Ginny Bumgardner, MD, PhD ('24)
Emily Perito, MD ('25)
Ameen Tabatabai ('25)
David Vock, PhD ('24)
Chris Zinner ('23)
Kiran Khush, MD ('23)

Voting Members Absent:

Deborah Maurer, RN, MBA ('25)

Ex-Officio Members:

Laura Cartwright, PhD, MPH (OPTN/UNOS)
Shannon Dunne, JD (HRSA)
Sumit Mohan, MD, MPH (OPTN-DAC)
Jennifer Prinz (OPTN-POC)

Ex-Officio Members Absent:

Jonah Odum, MD (NIH)

HRSA:

Cmdr. Adrienne Goodrich-Doctor, PhD
Frank Holloman
Adriana Martinez, MS

SRTR Staff:

Tonya Eberhard
Allyson Hart, MD, MS
Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, 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 called the SRTR Review Committee (SRC) meeting to order. He took role for voting and ex-officio members. Ms. Deborah Maurer was not present. Mr. Van Slyck reviewed the agenda and conflict-of-interest management. He proceeded with the first agenda item.

Approval of the minutes

Mr. Van Slyck ask for a motion to approve minutes from the SRC meeting on July 18, 2023. There was a motion to approve and a second. The minutes were unanimously approved.

SRC Nominations Committee

Dr. Roslyn Mannon, Chair of the SRTR Nominations Committee (SNC), walked through the candidate recommendations made by the SNC. The SNC had reviewed each candidate's application, personal statement, curriculum vitae (CV), and conflict-of-interest declaration with a scoring rubric to rank each. Dr. Mannon stressed that while many applicants were exceptional, SNC had to prioritize the best fit for the committee and subcommittees in terms of needed expertise, geographic representation, and diversity in sociodemographic representation. Dr. Mannon first reviewed candidates for the main SRC, noting Dr. Kiran Khush, Dr. Mannon, and Mr. Chris Zinner (also the Human Centered Design Subcommittee [HCDS] co-chair) would be rotating off the committee. The SRC needed a new member and co-chair, while the HCDS position would be determined through the HCDS nominating process. The SNC recommended Dr. John Magee, professor of surgery at University of Michigan Health Systems, as SRC co-chair. Dr. Magee has broad experience in clinical

transplantation and also understands SRTR's responsibilities and role in the system. The SNC thought he would serve the organization well in this. The SNC then recommended Dr. Carli Lehr from the Cleveland Clinic Respiratory Institute as an SRC general member. The SNC thought her expertise in thoracic organs was an adequate replacement for Dr. Khush. The SNC also recommended original SRC applicants Dr. Joel Adler of the University of Texas at Austin and Dr. Syed Ali Husain of Columbia University Medical Center for the Analytical Methods Subcommittee (AMS). The SNC chose the two for AMS since both have experience using SRTR data, and could provide clinical as well as analytic expertise. The voting members did not voice any dissent to these choices, and they were approved.

Dr. Mannon next addressed the SNC's recommendations for the Patient and Family Affairs Subcommittee (PFAS). She noted PFAS seeks a diverse group of individuals regarding geography, organ type, gender, etc. The SNC recommended Mr. Robert Goodman, Mr. Joseph Hillenburg, Mr. Marcus Simon, and Ms. Teresa Wasserstrom. Dr. Allyson Hart noted the other applicants, while excellent, overlapped with representation already on PFAS. She said PFAS will also look to expand the committee with targeted recruitment (living kidney and deceased donor family members in particular), as not all members will be able to attend all meetings due to illness. Mr. Ameen Tabatabai added that the selected four add more coverage across the transplant journey map, and represented different regions across the US. He said PFAS would benefit from recruiting more members to get the total number up into the teens. There were no disagreements with the decisions, and the nominations were approved. Dr. Hart and Mr. Tabatabai planned to reach out to individuals not chosen to speak with them directly.

Dr. Mannon then addressed the SNC's recommendations for the HCDS, noting HCDS needs a new co-chair and two general members. The SNC recommended Ms. Bridgette Huff for a general position, as she has expertise in United Network for Organ Sharing (UNOS) design initiatives, and would aid in collaboration and coordination between the Organ Procurement and Transplantation Network (OPTN) and SRTR. As other candidates were not identified with the required experience/skillset, Dr. Cory Schaffhausen and Mr. Zinner reached out to two additional candidates who had missed the initial deadline for applications. Both candidates had supplied their applications to the SNC prior to today's SRC meeting. Those applicants were presented to the SRC by Mr. Zinner for consideration. The first was Ms. Bree Fouss of Accenture, and the second was Mr. Scott McPhee of Afflo Transplant Solutions, who has transplant technical software expertise helping with organ allocation in Canada. The SNC recommended Mr. McPhee for the co-chair role and Ms. Fouss as a new general member. Mr. Zinner acknowledged his conflict with Ms. Fouss as an Accenture employee, but said she has been working in transplant for four years, has experience in clinical work and consulting, along with human-centered design and behavioral science. Mr. Zinner said Mr. McPhee has knowledge of all aspects of the transplant system from transplant centers to organ procurement organizations (OPOs) and allocation systems. He is familiar with human-centered design techniques, research, and usability testing. Voting members had no objections to these decisions, and they were approved.

Dr. Mannon next addressed the SNC recommendations for the AMS, noting two members were rotating off the subcommittee. SNC recommended Dr. William Parker of the University of Chicago, as he has both clinical experience and experience in health services research and analytics using

SRTR data. As mentioned earlier, Dr. Mannon also noted SNC's recommendation of Dr. Adler and Dr. Husain. Dr. David Vock expressed some concern if clinicians would be an optimal fit for the AMS, which is currently made up of PhD-level biostatisticians and operations researchers, but noted having the clinical representation would likely benefit the discussions. Dr. Mannon noted that the clinicians were not solely recommended because they were clinicians, but because their research strategies used analytical tools and techniques that are relevant to the work of SRTR. The change was an opportunity to grow the subcommittee in terms of expertise and ability. Dr. Grace Lyden and Dr. Nick Wood expressed support for the selection of the clinicians and noted their prior research collaborations with them. Similarly, Dr. Sumit Mohan, while noting his conflict as faculty at Columbia, expressed his support for Dr. Husain as a qualified clinician-researcher. Voting members approved the recommendations.

Dr. Mannon summarized recommended changes to the nomination process for next year. She said candidate interviews would not be required, but planned in a timely manner if needed. Dr. Emily Perito said interviews could be useful for candidates no one on the SNC knew, and could be done for those lesser known to give them a fair chance to be selected. Dr. Mannon said it was important for SRTR staff to communicate if there were insufficient applications for the committees so that targeted recruitment could also be done. She also suggested allowing 60 days for submissions, and that each (sub)committee(s) member and chairs be notified when the submissions period is open and when it ends. Dr. Khush said it would be helpful to remind SNC members which members' terms are expiring and what seats need to be filled before the submission period. Dr. Mannon said the applications needed to be obtained well in advance of the final SRC meeting of the year to allow adequate time for review and recommended changing the procedures to allow for targeted recruitment if not all seats are filled.

Dr. Jon Snyder said SRTR will craft invitation letters to the recommended new members and will confirm if Dr. Adler and Dr. Husain will accept joining AMS. Formal invitations will go out next week. Dr. Mannon said nominees should be ready by January, and to notify those who were not selected with the appropriate response. Dr. Snyder said the letters will likely come from Dr. Mannon and Mr. Van Slyck, in addition to being co-signed by the subcommittee co-chairs.

OPO metrics secure site report

Dr. Snyder reminded the SRC that, in July 2023, SRTR had planned to publicly release replications of Centers for Medicare & Medicaid Services (CMS) metrics in the OPO-specific reports as requested in the SRTR contract. However, the Health Resources and Services Administration (HRSA) instructed SRTR to not release the metrics. In May 2023, members of the CMS/Center for Clinical Standards and Quality (CCSQ) presented to the Membership and Professional Standards Committee (MPSC) noting SRTR would be providing additional reporting of the metrics and subgroup analyses. At the July 2023 SRC meeting, members voted to develop a report for the OPOs to be provided on the SRTR secure site. SRTR would then continue to work with HRSA on an acceptable public presentation of these metrics. Dr. Jon Miller developed the report following the July recommendation to be reviewed and approved today. Dr. Snyder said if the committee agrees that these reports should be posted to the SRTR secure site, they will be posted for the preview release of OPO-specific reports on December 15, 2023.

Dr. Miller gave some background information. SRTR has been working on metrics for the OPOs using the cause of death, age, location consistent with transplantation (CALC) potential donor denominator as used by CMS. SRTR removed eligible-death donation rates from the OPO-specific reports following previous recommendations of the SRC and the Task 5 Consensus Conference due to concerns surrounding subjectivity of the metric. Dr. Miller reviewed the draft report, highlighting significant aspects of 1) predicting potential donors in the years in which the CDC data are not yet available, and 2) presentation of subgroup analyses to allow OPOs to assess performance within various subpopulations.

Dr. Miller said SRTR has considered a variety of subgroups, some of which SRTR is able to stratify the denominator and the numerator (eg, donation rates by sex, race, ethnicity), while in other cases, SRTR cannot stratify the potential donors denominator and instead presents the total number of potential donors as the denominator (eg, donation after brain death and donation after circulatory death donation and transplant rates).

Mr. Van Slyck said the report would be very beneficial to OPOs and gives additional perspective beyond what is available within the CMS reports. Mr. Frank Holloman said that CMS is fine with extrapolating data for OPOs, but it has to have 100% fidelity with the CMS data reports and methodology. Dr. Miller noted that there are actually few places in our report that attempt to report the exact same numbers as those contained in the CMS reports, and Dr. Snyder added that SRTR is using the exact methodology and definitions used by CMS but differences may be introduced by 1) using updated data sources available to the SRTR at the time the reports are generated, and 2) constructing the reports and metrics based on the current set of 56 OPOs rather than the 57 or 58 contained within the CMS reports depending on the evaluation year.

Mr. Holloman said HRSA and CMS needed to review the report to address any concerns before it is approved for release to the OPOs. He said concern exists due to potential discrepancies between the SRTR and CMS reports. Another potential concern raised by CMS was the predictive component in the SRTR report of predicting potential donors in years that the CDC data are not yet available. Mr. Van Slyck said that many OPOs are already making these predictions, and the predicting component of the report would really help OPOs understand areas it needs to improve, even knowing there is a little bit of uncertainty in the predictions. Because the OPO is already employing their own predictions, he believed it would be preferable to get the predictions from SRTR, which is deemed reliable and trustworthy.

Ms. Shannon Dunne said SRTR report might cause OPOs to view themselves as performing a certain way, but if actual CMS reporting period shows they do not do as well as expected, they may voice complaints. Ms. Adriana Martinez added it could lead to a false sense of security. While Mr. Holloman said discussions with CMS on this issue were ongoing, Dr. Ryutaro Hirose disagreed with CMS's current stance on this report. He said the insistence to not risk adjust goes against the principles of any health care metric, and it clearly affects the performance assessment of an OPO.

Dr. Miller suggested triangulating on the predicted years by using both SRTR reports and CDC's WONDER, which contains more recent data many OPOs are trying to use. OPOs could consult the SRTR with questions, if these two methods for trying to understand what the potential donors are in 2022 and 2023 in the more recent years resulted in discrepancies. Dr. Miller said no one method is

going to have 100% accuracy, and having more information available leads to better decisions. Dr. Ginny Bumgardner suggested adding regional and national benchmark analyses. Dr. Miller said this could not be done for the December release, but could be incorporated in the next cycle. Ms. Jennifer Prinz said she did not understand why CMS had reservations about predictive modeling when it would benefit the nation's donation and transplantation system. She requested communicating with CMS on why predictive modeling would help to increase donation and transplantation performance across the country.

Dr. Mohan suggested distinguishing between predictions and observed data in the report to avoid confusion. Dr. Snyder acknowledged this could be made clearer. He posited SRC members meeting with CMS representatives to discuss the report, with a decision made well in advance of the December 15 reporting deadline. The committee voted on whether to proceed with the report as is, with the caveat to discuss any lingering issues with CMS and HRSA, and secondly, if the Excel workbooks Dr. Miller created containing collective data of all OPOs should be on the secure website blinded or unblinded. Members voted yes to the first item. Members agreed to present the Excel workbook as unblinded, citing transparency and the need for open discussions with OPOs about the data.

Predicted waiting times app demonstration

Dr. Lyden demonstrated a personalized risk prediction calculator currently available on the last tab of the kidney transplant decision aid tool on the public SRTR website. The tool allows patients to view likely outcomes for patients like them on a kidney-alone waiting list. Users input demographic information on a left panel, and select a point in time into the future for prediction. On a right panel, the tool shows the probability of having different outcomes on the waiting list by that point in time. Dr. Lyden explained that the tool predicts cumulative incidence for patients with these characteristics based on models that were fit using data from 2020 and 2021.

Dr. Lyden then presented a new tool under development that translates these cumulative incidence predictions into actual predictions of waiting time using a timeline visualization. The model ends at 10 years post-listing, at which point the app will tell the user the percentage of similar candidates who will have received a transplant, still waiting, or died before transplant, which includes removal from the waiting list due to too sick. Dr. Lyden said that while the tool is for adults waiting for kidney transplant, the methods can be extended to include other organs and pediatric patients.

Dr. Khush preferred the results displayed as a horizontal timeline instead of a vertical timeline. Dr. Lyden said an advantage to a vertical layout was easy viewing on mobile devices. Mr. Tabatabai said that regardless of orientation, scrolling is helpful since patients often have a timeline perspective. He added that balance between the device and data visualization was important, and suggested horizontal for desktops and vertical for mobile.

Dr. Bumgardner suggested adding visuals like icon arrays to help patients understand probabilities. However, Dr. Hart said icon arrays were best for incremental differences, whereas bar charts are the best for demonstrating contrast. Dr. Bumgardner said a cylinder filling up over time might be the best visual. She also advocated for using more precise language on probability in the tool. Dr. Hart suggested doing more patient testing to make sure patients understood the concepts presented in

the tool, in particular the probability of dying or becoming too sick to transplant. Dr. Perito proposed adding an acknowledgement that it did not include pediatric predictions. Mr. Zinner cited how UNOS has a similar tool on waiting time predictions that Ms. Huff was a part of building, leaving an opportunity to discuss in the future lessons learned, and forming consistency in how OPTN and SRTR coordinate on projects within the contracts.

System performance monitoring application

Dr. Snyder said SRTR has accelerated the development of its system performance monitoring application in anticipation of the new Expedious Task Force constituted by the OPTN Board. As the task force is looking at many areas of system performance, SRTR believes the monitoring application will be instrumental in national discussions around system performance. SRTR created a password-protected website to host the application to facilitate user testing, which Dr. Wood reviewed. Dr. Snyder added that the application was a recommendation of the Task 5 conference and the National Academies of Sciences, Engineering, and Medicine (NASEM) report.

Dr. Wood said the primary purpose of the application was to monitor aspects of the transplant system, focusing on efficiency metrics and allocation policy changes that affect the transplant system. He demonstrated the tool by reviewing various trend plots and subgroup analyses, highlighting the built-in functionality to change the look-back window, toggle subgroups on/off, and zoom in on specific time periods.

Mr. Zinner said the user experience created was easy to understand. He said the idea is these allocation changes introduced inefficiencies in the system, leading to nonuse, and allocations out of sequence. He said SRTR had the unique opportunity to help answer if the allocation changes were “worth it,” meaning that while inefficiencies may have been introduced by policy changes, did the change also deliver the intended benefit? He asked if there was a way to more directly show this tension using the tool (ie, comparing an efficiency metric with an outcome metric more directly). Dr. Wood noted that he would think of ways to perhaps incorporate this idea in future iterations of the tool. Mr. Zinner suggested, in the future, displaying two trends together with scales on each side to help understand if they are having the intended outcomes.

Dr. Wood provided the login credentials to the members and instructed the committee to send any feedback to him via email within the next month.

Patient-friendly website update

Dr. Cory Schaffhausen gave a brief update on patient-friendly website development. SRTR is in the process of building and coding the live patient-friendly website. A public launch is scheduled for early 2024 (internally referred to as phase one), which will consist of a series of patient-focused webpages that will exist alongside the current srtr.org. These webpages will be presented as a preview of the new patient site.

Informational items

Dr. Snyder skipped the updates from the SRC subcommittees due to time constraints.

Dr. Snyder briefly noted that SRTR received a request to provide a stratification of offer acceptance rate ratios by kidney donor profile index (KDPI) > 60 kidney offers to support a CMS initiative as part of the End-Stage Renal Disease Treatment Choices Learning Collaborative (ETCLC) program to increase the acceptance of these kidneys. The stratification will be launched on the secure site, where programs should see it next month. It will also be added to the public reports in 2024.

Closing business

Dr. Snyder thanked the outgoing SRC members for their commitment to SRTR. The next meeting date is to be determined and will be virtual. The winter and summer 2024 meetings will be virtual, and the spring and fall 2024 meetings will be in-person in Rockville, MD. The meeting adjourned at 1:00 PM CDT.