



SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

February 10, 2023

VIA E-MAIL

Shannon Dunne, JD
Division of Transplantation
Healthcare Systems Bureau
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane Room 11W09C
Rockville, MD 20857
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Re: SRTR CONTRACT NUMBER **75R60220C00011**
Task 4.1, D28– SRC Meeting Minutes
DUE: 2/10/2023
SUBMITTED: 2/10/2023

Dear Shannon:

Pursuant to Task 4.1, D28 of Contract No. 75R60220C00011, attached are the meeting minutes from the SRTR Review Committee, held February 3, 2023.

If you have any questions, or if I can provide any further information regarding this deliverable, please feel free to contact me.

Sincerely,

Caitlyn Nystedt, MPH, PMP
Program Manager
Organ Donation and Transplantation Research

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SRC Meeting Minutes

SRTR Review Committee Teleconference

February 3, 2023, 10:00 AM – 1:00 PM CST

Voting Members:

Roslyn Mannon, MD (Co-chair) ('23)
Sean Van Slyck (Co-chair) ('25)
Kiran Khush, MD ('23)
Deborah Maurer, RN, MBA ('25)
Emily Perito, MD ('25)
Ameen Tabatabai ('25)
David Vock, PhD ('24)

Not in Attendance:

Chris Zinner ('23)
Ginny Bumgardner, MD, PhD ('24)

Ex-Officio Members:

Shannon Dunne, JD (HRSA)
Nicole Turgeon, MD, FACS (OPTN-POC)
Jonah Odum, MD (NIH)
Laura Cartwright, PhD, MPH (OPTN/UNOS)
Sumit Mohan, MD, MPH (OPTN-DAC)

HRSA:

Adriana Martinez
Frank Holloman
Adrienne Goodrich-Doctor, PhD

SRTR Staff:

Allyson Hart, MD, MS
Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, MD, MS
Grace Lyden, PhD
Jon Miller, PhD
Cory Schaffhausen, PhD
Jon Snyder, PhD, MS
Nicholas Wood, PhD
David Zaun, MS

Welcome and opening remarks

Dr. Roslyn Mannon called the SRTR Review Committee (SRC) meeting to order. New members gave introductions:

- Sean Van Slyck, Executive Director of Sierra Donor Services
- Deborah Maurer, RN, MBA, Program Administrator of Transplant Services, University of Pittsburgh Medical Center
- Emily Perito, MD, Associate Professor, Benioff Children's Hospital
- Ameen Tabatabai, University of Washington patient advisory committee, organ procurement patient advocate, liver transplant recipient

Ex-officio members introduced themselves. Dr. Jon Snyder clarified that the new Organ Procurement and Transplantation Network (OPTN) Data Advisory Committee representative is Dr. Sumit Mohan, who transitioned from an SRC voting member to ex-officio on January 1, 2023.

Dr. Mannon reviewed the agenda and conflict of interest management, then proceeded with the first item.

Approval of the minutes

Dr. Mannon asked the committee to approve or suggest changes to the minutes from November 29, 2022. There was a motion to approve followed by a second. The minutes were unanimously approved.

SRC Charter and proposed nominating process

Dr. Snyder noted that minor edits have been made to the SRC Charter, which is typically reviewed at the first SRC meeting of each calendar year. The minor edits included updating membership numbers, as certain subcommittees have expanded their membership, and removal of specific staff names from the charter.

Dr. Snyder then introduced the concept of forming a nominating committee and process to identify and propose future members of the SRC and its subcommittees. Dr. Snyder proposed that the nominating process could take place from July to September, with the committee making recommendations at the fourth quarter meeting to SRTR leadership and the Health Resources and Services Administration (HRSA). The subcommittees could also follow a similar process.

Dr. Snyder said the current composition of the SRC has one organ procurement organization (OPO) slot, three medical/surgical positions, one transplant administrator, and three subcommittee chairs. Nominees would be considered based on expertise in organ transplantation or organ donation while accounting for diversity in gender, race, and geography. He proposed that the nominating committee would consist of one SRC co-chair and two voting members for reviewing applications and getting recommendations back to the committee by the fourth quarter.

Members agreed with the proposal, as it would improve transparency and be more likely to identify the necessary expertise needed by SRTR. Dr. Mohan questioned if the size of the SRC was adequate. He suggested determining the committee's main roles, as well as expertise and representation sought, as this would affect the committee's size and composition. Dr. David Vock advised having a separate nominating committee for each subcommittee. Dr. Perito asked if SRTR staff would be members on the committee. Dr. Snyder confirmed staff would be involved and assist with the process, but not be a voting member of the nominating committee. Nominations would eventually be vetted by SRTR leadership and HRSA for a final determination and invitation.

The committee agreed to proceed and work offline between now and April to modify the SRC Charter to include a nominating process and committee. Both Ms. Maurer and Dr. Kiran Khush expressed willingness to participate on the nominating committee, and Dr. Ryutaro Hirose volunteered to help advise from SRTR staff with his previous experience with nominating committees. Mr. Van Slyck asked about the potential to form workgroups to tackle ad hoc projects of interest to the SRC. Dr. Snyder clarified that the SRC can form ad hoc workgroups and those workgroups do not need to comprise members of the SRC. These details could be added to the SRC Charter.

Task 5: Progress on prioritization of recommendations

Dr. Snyder gave an update on the Task 5 Initiative. In November 2022, SRTR went through the process used to enumerate 160 recommendations collected from the consensus conference, and is distilling these priorities to determine what implementation projects can be launched. Priorities were broken into three levels: level 1, data available and easy to implement; level 2, data available but need work; and level 3, data are not available and data collection would be needed. Discussion focused on level-1 and level-2 recommendations that were also prioritized by conference breakout

session groups. SRTR continues to focus on distilling information to understand what it is people want to know, and how to respond to these recommendations.

Dr. Snyder updated the committee on the meeting report manuscript that was submitted to the *American Journal of Transplantation* (AJT). AJT invited a resubmission of the meeting report. Editorial feedback suggested more prioritization and targeted distillation of the 160 recommendations. SRTR has delayed manuscript resubmission for further committee discussion. Dr. Snyder noted that today's discussion would present the results of the prioritization survey SRTR implemented following the prior SRC meeting on November 29, 2022. The goal of today's discussion is to arrive at a final "top priority" list for initial focus by SRTR.

Task 5 conference prioritization

Dr. Cory Schaffhausen reviewed that the goal was to take the 160 recommendations and funnel them down into a manageable group that could be addressed in the future. The prioritization process involved reviewing data from the conference, specifically the data sources of flip-board sheets used in the breakout sessions when groups discussed recommendations. Each breakout group participant voted on the group's listed priorities with stickers to mark the flip sheets. These data were digitized; the process was a "first pass" at funneling the 160 recommendations into a smaller number. The resulting 26 recommendations were a combination of what was voted on in the conference breakout sessions and data implementation levels 1 or 2. This list of 26 was discussed in detail in November 2022 and was used in the online survey sent after the meeting. Dr. Schaffhausen said narrowing down the 26 recommendations would be a focus of today.

Dr. Hirose commented that level-3 items should not be delayed, especially if they are a high priority for the transplant community. Rather, they should be seen as a long-term goal that can be done in parallel with other priorities. Dr. Schaffhausen said some new data collection activities may be initiated by level-2 recommendations that do not have existing data for all parts of the recommendation. Following the November 2022 SRC meeting, members (10 voting, 3 ex officio, and 2 Patient and Family Affairs Subcommittee [PFAS], HRSA aggregate response) completed a survey to rank the top 5 out of the 26 recommendations. Results showed close alignment between SRC voting and ex-officio members, and partial alignment between SRC and HRSA members.

Dr. Schaffhausen reviewed the survey format, which included an open-ended question about the general rationale for assigning priorities. Rationales for general implementation goals included 1) continuing momentum on existing projects, 2) increasing focus on drivers of racial disparities, 3) prioritizing recommendations that influence clinician behavior, and 4) prioritizing recommendations to inform patient decisions. HRSA's response prioritized rationales 2 and 4. He moved on to survey results from SRC voting members and PFAS members for which recommendations had the most votes, including a list of the top seven recommendations and notations for recommendations also prioritized by HRSA:

- A.1: Provide personalized predicted waiting times
- A.2: Provide survival benefit of transplant vs alternative therapies
- B.1: Provide data on which centers are most likely to refer, to evaluate, to list, and to perform transplant for a patient like me or my loved one

- E.6: Provide data on timing of referral, listing, and transplant process (eg, time from end-organ failure to referral, time from referral to evaluation, time from evaluation to [active] listing). Data presented with stratification/adjustment for underserved communities.
- H.5: Provide tools that facilitate shared decision-making between patients and providers in preparation for and at time of organ offer
- I.1: Provide transplant rates; considerations include: organ-specific, breakout living donor and overall transplant rates, include breakdowns by medical urgency status, apply a consistent start time (eg, dialysis start)
- Q.1: Provide data on acceptance and decline patterns by program, stratified by organ quality, organ type, and candidate characteristics; specific information tailored for pediatric candidates

Ms. Maurer said in regard to E.6, a lot of variables are out of transplant centers' control, specifically how payers may affect the program's ability to see the patient while awaiting insurance authorization. Dr. Hirose said although he understood, that does not mean a task can't be addressed in small increments. Ms. Maurer agreed that such information should be worked on to be transparent. She also suggested the possibility of partnerships with entities such as Cerner and Epic for data collection. Dr. Mohan remarked that in a recent Data Advisory Committee (DAC) meeting it was found OPTN has legal authority to collect prelisting data, and the process to potentially collect data was moving forward. Mr. Tabatabai said there was value in running data analyses to determine what questions can be answered by which data before a wider data collection was done. Also, partnering with other organizations to see what data are available would be helpful.

Dr. Hirose stated that currently, there was not compliance with the clause in the US Department of Health and Human Services (HHS) Final Rule: 'Such data shall include the following measures of inter-transplant program variation: risk-adjusted total life-years pre-and post-transplant, risk-adjusted patient and graft survival rates following transplantation, risk-adjusted waiting time and risk-adjusted transplantation rates, as well as data regarding patients whose status or medical urgency was misclassified and patients who were inappropriately kept off a waiting list or retained on a waiting list.' Dr. Ajay Israni agreed, and that the rule allowed OPTN to collect such data.

Dr. Schaffhausen said this compiled list may be what SRTR ends up putting into print for what future implementing recommendations will be. Dr. Snyder said that some of the chosen priorities have data available and just needed to be reported more effectively, such as Q.1: providing data on acceptance and decline patterns by program, stratified by organ quality, organ type and candidate characteristics; specific information tailored to pediatric candidates. Perhaps SRTR could work to make offer acceptance data more understandable, and include reporting for offers to pediatric candidates. Mr. Tabatabai pointed out that children may not be asking for data but their parents may be seeking the information. Family members of pediatric patients also requested longer-term outcomes data.

Dr. Schaffhausen then summarized three HRSA recommendations that were nonoverlapping with SRC/PFAS top priorities:

1. E.1: Information about potential for and benefits of listing at multiple centers,
2. H.2: Data about the risks/benefits of willingness to accept clinically complex donor types, and

3. L.1: Posttransplant graft/patient survival metrics, adults vs pediatric, longer-term outcomes (possible implementation strategy that combines L.1 and L.2 [multiorgan specific]).

Ms. Shannon Dunne said some were chosen due to being more general and overlapping with other prioritizations. Dr. Mannon added that there was an OPTN public comment proposal about multilisting policy. Potential implementation of a policy may affect the ability to provide information, making E.1 less informative. Dr. Perito added that it would not change policy but was meant to give guidance. Dr. Nicole Turgeon agreed and said it was important to determine where these priorities intersect with policy needed to implement the priorities, and getting these recommendations to OPTN so each goes through proper policy.

Dr. Perito and Dr. Allyson Hart agreed that some of HRSA's recommendations overlapped with other priorities, such as multiple listing with predicted time to transplant, and risk and benefits of clinically complex donor types with offer acceptance criteria. Both agreed that the pediatric perspective of longer-term outcomes of interest was also important. Dr. Vock pointed out the need to determine the overall goal with these recommendations, and what metrics will be used to gauge what are the right priorities. Dr. Hirose said caution was best with E.1, as patients with wealth and resources are more likely to be able to list at multiple centers. In the interest of promoting equity, it was important to acknowledge that access to list at multiple centers was not equitable. Dr. Hirose also asked HRSA to inform the committee on what the Centers for Medicare & Medicaid Services (CMS)/HRSA Organ Transplantation Affinity Group (OTAG) discusses, as H.2 is consistent with a priority of OTAG. Ms. Dunne said that, regarding E.1, multilisting may not be as beneficial when continuous distribution becomes more prominent. Mr. Frank Holloman explained that the End-Stage Renal Disease Treatment Choices Learning Collaborative (ETCLC) is a project that strives to make progress in increasing transplants and reducing nonuse rates, particularly among high-kidney donor profile index (KDPI) kidneys. OTAG is more of a higher-level collaborative effort between HRSA and CMS. These items are not ready for public dissemination yet, and they are currently working internally with their federal partners.

Multiple members agreed with Dr. Hirose's comments. Dr. Mohan said that multiple listings would not be needed if there was a level playing field in terms of access to transplant and transplant rates. Ms. Maurer said that some insurance companies do not pay for multiple listing. Dr. Vock worried that some of these metrics in isolation (ie, without looking at the entire process) may lead to unintended consequences. For example, long-term survival of adult kidney transplant recipients can often be maximized by just avoiding candidates with cardiac comorbidities. Dr. Perito said it would be interesting to have SRTR modeling/analysis on which patients actually benefit from multilisting for patient education purposes. Mr. Tabatabai said, from a patient perspective, it was important to address what the best option is for that patient, as everyone has a different experience.

Dr. Schaffhausen reviewed recommendations rated as the #1 top priority by SRC and PFAS members, but not commonly voted as a top priority in the survey. These included:

- A.4: Information on any absolute contraindications to transplant,
- G.1: Waitlist management tools to help programs manage and understand their waiting list, and
- K.2: Metrics of tailored outcomes relevant to organ types beyond graft failure and death.

Ex-officio recommendations that were indicated as top priorities included:

- H.1: Predicted survival benefit to accept or decline an offer, and
- H.4: Estimated time to a “better” offer if declining current offer.

Dr. Schaffhausen said that next steps would be to communicate the prioritized recommendation list in the AJT manuscript and to identify the top two or three within the list to give immediate attention in the current calendar year. Dr. Mannon suggested highlighting the methodology used to get these results in the manuscript or supplemental methods section. Dr. Hart proposed describing the voting exercise and the group discussed as both informing the final recommendations list without calling out one (sub)group.

Dr. Snyder asked if the HRSA recommendations should be presented as separate from the SRC and PFAS ones in the manuscript. Ms. Dunne said the HRSA rationale could be left out. She questioned if it was necessary to include the asterisks denoting HRSA overlap, and instead mention that HRSA was also surveyed. The committee agreed to present their top seven priorities along with the additional three HRSA priorities as the initial top 10 priorities for SRTR to focus on. Dr. Snyder suggested adding that HRSA agreed with the top priorities. Ms. Dunne agreed with noting HRSA’s approval of the top priorities.

Dr. Schaffhausen discussed the next item, which was creating a new design for the SRTR website. A project that entailed working with an external contractor who was an expert in web design ended in September 2022. The project involved updating the SRTR homepage, and creating separate homepages for professionals and patients, as well as other features. Dr. Schaffhausen said the new website design is a foundation for work described in the Task 5 recommendations. Because these recommendations depend on having a user-friendly website, the website being built is a main focus in 2023, as are tools for long-term transplant outcomes, pediatric patients, and multiorgan candidates in particular.

OPO-specific report including CMS Metrics

Dr. Jon Miller said SRTR was tasked with adding the new CMS metrics of OPO performance into the OPO-specific reports (OSRs). These new metrics for the OPO recertification process consist of using Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics (NCHS) detailed multiple cause of death data as the denominator in the donation and transplant rates for each OPO. Aggregated at county level, this included the number of inpatient deaths, age 75 years and younger, cause of death consistent with transplant determined by *International Classification of Diseases (ICD)* death codes. There is a list of *ICD* cause of death codes used to determine who has a cause of death consistent with transplant. The numerator consists of donors defined as having one or more organs transplanted. The numerator for the transplant rate is the total number of organs transplanted from those donors. Mr. Van Slyck clarified that pancreata used for research purposes are also considered a transplant. Dr. Hirose pointed out that there are no exclusionary criteria in the CMS definition.

Dr. Miller said CMS metrics included the donation rate, or numbers of donors divided by number of potential donors, and transplant rate, the number of transplants divided by potential donors. He also noted that the transplant rate is age adjusted using standardization. These metrics are used to

place OPOs into one of three tiers, and the overall tier is the lowest of the donation or transplant tier, with tier 1 having a 95% confidence interval (CI) around the transplant and donor rate above the 75th percentile. Tier 2 means both rates have their CI above the median (50th percentile), and tier 3 means having one CI below the median. Dr. Snyder added that in terms of CMS consequences, OPOs in tier 1 would have their contracts renewed with CMS, tier 2 OPOs would have contracts recompeted but would be allowed to compete for their donation service area (DSA), and tier 3 OPOs would not be allowed to recompile for their DSA.

Dr. Miller said these metrics would be added to the OSRs for the July 2023 release. Once all the information is rolled out into OSRs, it will be updated once a year for the summer release, and duplicated for the winter release, as there will only be updated CDC denominator data once per year. SRTR has been able to replicate the CMS-published rates and CIs almost but not quite exactly. SRTR is continuing to work with CMS in an attempt to resolve any minor discrepancies.

Dr. Miller showed examples of figures that what would be added to the summer OSR release. The first figure showed donation rates of each OPO along with 95% upper CIs. The two lines running across the figure represented the 50th and 75th percentile rates used to define the tiers. There was a table below the figure, showing potential donors, actual donors, and rates. The next figure had subgroup analyses that showed donation rate in an OPO compared with national donation within any given strata for age, race, Hispanic ethnicity, and general demographics consistent between CDC denominator data and SRTR staff numerator data—and, if possible, stratification by cause of death if category classification within CDC data.

Dr. Miller asked the committee if rates and subgroup analyses should be added to the summer OSR. Members thought this was a good idea, as was being transparent about how many donors and/or transplants were solely due to pancreata being sent for research. Members discussed data limitations, such as not being able to stratify the CMS denominator by donor hospital, but able to stratify by county, and complying with stratification rules in the CDC's data use agreement. Dr. Hirose also suggested creating an observed-to-expected (O:E) ratio and risk stratifying race and ethnicity. Going back to the figures, Dr. Mohan suggested a visualization that shows how OPOs are moving between the tiers, as seeing the change over time may be informative. Also, because the Center for Medicare & Medicaid Innovation (CMMI) has the learning collaborative, the OPO measure there is organ utilization above a KDPI of 60%. Having some sort of visualization that helps them understand how they are performing on the ETCLC would be valuable. Dr. Mohan said it might be beneficial to make it visually obvious that the OPO measure also penalizes larger OPOs due to the manner in which the tier boundaries are constructed.

The committee did not vote on whether SRTR should add the CMS overall donation and transplant figures and tables to the OSRs, as this is a contractual requirement of SRTR. Members were overall in support of the proposal. Dr. Perito commented that in a tier system, if the median is continuously raised, a percentage of OPOs will always be decertified. With the members giving a number of suggestions, there were no concerns with proceeding as planned to incorporate the SRTR's best possible re-creation of CMS metrics as well as subgroup analyses in the summer 2023 OSRs.

CMS-OPO metric race-adjustment analysis

Dr. Miller gave an update on race-adjustment analyses, which involved comparing the unadjusted donation and age-adjusted transplant rates to a hypothetical adjustment for race using that same standardization approach within the racial categories mentioned. He noted that nationally, the rate of donation for White potential donors is 3% points higher than that for the next highest racial subgroup, and 6% points higher for transplant rates.

Dr. Miller moved on to OPOs that change tier when race adjusted. When the race adjustment was added on top of the OPO metrics as calculated, eight OPOs changed tiers. He focused on OPO1, which was in tier 3. With 44% of potential donors being non-White, OPO1 overperformed the national experience among non-White potential donors in transplant and donation rates, and overperformed among White potential donors in terms of transplant rates. Adjusting for race would move OPO1 from tier 3 to tier 2, which statistically is an example of Simpson's paradox, where the overall rate can be moving in a different direction than the stratified rates. Dr. Miller said this was one of the OPOs with the largest proportion of non-White potential donors in the country. A high proportion of non-White potential donors, coupled with national experience among non-White potential donors where fewer become actual donors, drives this OPO down to tier 3 even though it outperforms the national rates for non-White donors and outperforms the national transplant rate for White donors.

Dr. Miller asked if SRTR should add the metric for the adjusted donation and transplant rates, and the variables that could be adjusted for (age, sex, race, Hispanic ethnicity, and cause of death) to the PDF and website OSRs as soon as possible. Dr. Hirose said he disagreed with the notion that race should not be risk adjusted for. To ignore that there are different populations in different DSAs and not acknowledge medical mistreatment of certain groups was a mistake. He thought that CMS metrics as non-risk adjusted were currently mislabeling OPOs in the tier system, when in fact this process should be as accurate as possible since OPO certification is critical. Dr. Snyder agreed the adjusted metric should be reported and suggested providing the CMS metrics as defined along with the adjusted version to the public as soon as methodology and coding are finalized, which may not be for the summer 2023 release. Mr. Van Slyck recommended engaging the OPO community around the provision of adjusted metrics within the reports. The committee agreed this was a reasonable approach before adding the adjusted results into the reports. There were no dissenting opinions or additional suggestions.

Dr. Miller then discussed the donation rates tab on the SRTR OSR, which has donation rates per eligible death. He asked the committee if SRTR should retain or remove from the OSR metrics for eligible death donation rates. Mr. Van Slyck thought it should be removed, as it is an incomplete assessment of donation. Dr. Snyder said that SRTR will add CMS metrics to the July reports, and simultaneously remove eligible death donation rates from the reports. A targeted messaging campaign will be done by the SRTR Communications department. The committee had no objections.

Reports from the subcommittees

Dr. Hart said PFAS also discussed prioritizing recommendations in the December meeting, with this topic being a part of future meetings. Dr. Schaffhausen mentioned the focus from the previous Human Centered Design Subcommittee meeting in January was the SRTR website redesign, which

will continue to be a priority. Dr. Snyder stated the Analytical Methods Subcommittee has a meeting in early March 2023. The committee has not met since SRC last met, as SRTR staff has been working to design a new risk-adjustment model building process with a focus on the posttransplant metrics. SRTR has developed what we believe to be a viable process to build models during each program-specific report (PSR) cycle that will result in more robust risk-adjustment models going forward. If the process is approved, SRTR will implement it into the PSRs for transplant program evaluations.

Closing business

A brief announcement by Dr. Snyder was made about the potential to return to in-person meetings when the COVID public health emergency is lifted, which is currently scheduled to happen in May 2023; the summer SRC meeting may be in person in the Washington, DC, area. A poll with potential dates will be sent out to all. With no other business being heard, the meeting concluded. The next meeting is scheduled for April 19, 2023, 10:00 AM–1:00 PM CDT.