SRC Meeting Minutes

SRTR Review Committee Teleconference

April 19, 2023, 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)
Deborah Maurer, RN, MBA ('25)
Emily Perito, MD ('25)
Ameen Tabatabai ('25)
David Vock, PhD ('24)
Christopher Zinner ('23)

Voting Members Absent:
Kiran Khush, MD ('23)

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

HRSA:
Adriana Martinez, MS
Frank Holloman
Adrienne Goodrich-Doctor, PhD

SRTR Staff:
Tonya Eberhard
Allyson Hart, MD, MS
Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, MD, MS
Amy Ketterer
Grace Lyden, PhD
Jon Miller, PhD
Cory Schaffhausen, PhD
Mona Shater, MA
Jon Snyder, PhD, MS
Nicholas Wood, PhD
David Zaun, MS

Welcome and opening remarks

Dr. Roslyn Mannon and Mr. Sean Van Slyck called the SRTR Review Committee (SRC) meeting to order. Dr. Jon Snyder reviewed the agenda and statement of conflict of interest management.

Approval of the minutes

Dr. Snyder asked the committee to approve or suggest edits to the minutes from the SRC meeting held on February 3, 2023. Ms. Deborah Maurer made a motion to approve which was followed by a second. The minutes were unanimously approved.

Decision to postpone reporting of new Centers for Medicare & Medicaid Services organ procurement organization performance metrics

Dr. Snyder said Task 6 of the SRTR performance work statement requires SRTR to revise organ procurement organization (OPO)–specific reports (OSRs) to reflect the new Centers for Medicare & Medicaid Services (CMS) OPO regulatory framework, which was finalized by CMS in December 2020 and implemented on August 1, 2022. The previously approved timeline was to add the metrics to the July 2023 release, with the draft data going out to OPOs on April 1, 2023. On March 30, 2023, the Health Resources and Services Administration (HRSA) requested that SRTR postpone release of the new metrics to allow more time to better coordinate efforts with CMS. SRTR announced a delay for the OSR reports on March 31, 2023, rebuilt the 56 reports without the CMS metrics, and released them on April 4, 2023. CMS released its draft of the data to the OPOs on April 3, 2023. SRTR

requested a copy of the CMS results from HRSA to compare what would have been released to the OPOs with what CMS released to the OPOs. SRTR is still waiting for CMS to supply the report to SRTR.

Ms. Shannon Dunne said HRSA asked SRTR to pull the CMS metrics due to last-minute concerns of possible confusion about inconsistences between SRTR's replication of the metrics and the CMS reports. The transplant community has been advocating for CMS and HRSA to work together more collaboratively due to frustration about different requirements across the two agencies and perceived lack of alignment. Ms. Dunne noted that CMS is currently discussing sharing OPO reports with SRTR, and will be participating in the Membership and Professional Standards Committee (MPSC) meeting on May 4, 2023, for further discussion about the metrics. HRSA is working to set up meetings for SRTR and CMS to discuss OPO metrics and data needs. While Ms. Dunne did not have an answer on if there will be two places for showing CMS metrics in the future, Mr. Frank Holloman said only a subset of the CMS metrics was removed in the SRTR reports, with the hope that the metrics would be available in one location in the future.

Dr. Sumit Mohan asked if there were concerns that the results were different between the CMS ranking and the SRTR ranking. Ms. Maurer asked if there were concerns CMS would not share the reports with SRTR. Dr. Snyder said report differences included that SRTR would be able to provide a bit more information including subgroup analyses by race or age and a bit more granularity into the numbers within the donation service areas (DSAs) that the OPOs serve. Secondly, CMS provides 57 reports whereas SRTR builds the reports based on the current set of 56 OPOs (Washington, DC, and Maryland OPOs merged on January 1, 2023). This might result in minor discrepancies. In the future, SRTR will explore adding additional risk adjustment of the metrics to provide more insights as to what metrics OPOs could improve on. Lastly, SRTR has been unsuccessful in obtaining a dataset of the inpatient death counts, which is used to determine the allocation of deaths for a county that is shared by more than one OPO. SRTR has a version of the dataset a year removed from what CMS currently has. SRTR requested the updated version of the dataset from CMS. Because it has not been received, this may introduce minor discrepancies. Dr. Snyder noted there are disclaimers on the SRTR reports indicating that SRTR's replication of the metrics may be different from CMS's official results. The data have been close when compared directly to what CMS released in years past. Mr. Van Slyck added that OPOs have only seen individual data and not aggregated data thus far.

Dr. Ryutaro Hirose said having transparency and data flow would be great if it happens, adding that it was important to have the most current data. He emphasized the need for CMS and SRTR to have a dialogue to discuss how to account for variances (ie, how to count donors). He said SRTR's contracted obligations of overseeing the entire field of transplantation in terms of data analysis were encumbered by lack of transparency and data transfer. Mr. Holloman said many data use agreements need to be worked out between the two agencies, and HRSA is working to improve data sharing.

Dr. Mohan was concerned that CMS decided not to provide a race adjustment in their metrics while SRTR is providing the adjustment, even if it leads to rehashing the conversation about the appropriateness of race adjustment. Dr. Hirose agreed that conflict in the tier rankings caused by adjustment discrepancies was a reason for concern. Dr. Mohan said discrepancies would raise

questions about the stability of an estimate and the metric's validity if estimates are sensitive to changes in methodology. Dr. Jon Miller said one factor to consider was SRTR's plans to include value-added reporting (eg, subgroup analyses), which could be seen as complementing the CMS reporting rather than conflicting with it since CMS does not provide these analyses.

Mr. Van Slyck added that on the OPO side, CMS has included new sub-ranking (A-E) within tiers. SRTR may want to include or consider the additional data point, since it is the new way CMS is reporting to OPOs. He also asked if SRTR knew how long it would take to add in the reporting once CMS releases it, if SRTR needed to wait one cycle release. Dr. Snyder noted this was pending further discussion with HRSA and CMS. He confirmed that once SRTR received the datasets, it would take only a day or two to run all of the updated reports.

July OSR modifications

Dr. Snyder said the removal of imminent eligible death data was approved at the February SRC meeting. Removal of imminent and eligible death reporting was also a Task 5 recommendation. SRTR is proceeding with this removal and had planned to replace these data with the new CMS metrics. With the CMS metrics reporting on hold, the entire donor donation rate area of the OSRs is being removed. This includes organ-specific eligible death donation rates, eligible death donation rate bar plots that compared OPOs with the national average, rate ratio scatter plots comparing OPOs on their overall eligible death donation rates and provided reporting by organ, eligible death counts by donor hospital and how many became donors, and deceased donor data detailing how many hospital deaths were reported as eligible, imminent, or neither. These changes will go live in July 2023.

Mr. Van Slyck suggested discussing offline a way to include total referrals and donation after brain death (DBD) and donation after circulatory death (DCD) data by donor hospital. Dr. Hirose asked what the tab would be replaced with, along with when SRTR will define the reasonable donor potential denominator since eligible deaths plus imminent will not be used. He thought this should be discussed with the MPSC, as to how to develop the denominator (based on cause of death, hospital deaths) so the MPSC can come up with a metric that measures potential donor conversion.

Research pancreata and OPO performance metrics

Dr. Miller gave background information on the new CMS metrics for OPOs. The OPO recertification cycles are based on a denominator of potential donors which is based on age, location, and cause of death consistent with donation. Patients that meet these criteria based on the Centers for Disease Control and Prevention's multiple cause of death by county are aggregated to the DSA level for the OPO, accounting for waiver hospitals within those counties. The CMS donation and transplant rates both use the same denominator, with the numerator for each calculated from the SRTR standard analysis file (SAF). For the donation rate, the numerator is donors with one or more organ transplanted, including pancreata that are recovered for research even if not transplanted. For transplant rate, the numerator is the number of organs that are transplanted from those donors, again including pancreata recovered for research.

Dr. Miller said research pancreata are defined by three recovery codes from the Organ Procurement and Transplantation Network (OPTN): recovered for transplant but submitted for research,

recovered for research (majority of pancreata included in the numerator), and recovered for pancreas islet cells. In each case, the recovery code would not be included in the numerator except that research pancreata are included.

Dr. Miller reviewed the timeline for the new CMS metrics. The publication of the CMS Final Rule in the *Federal Register* was December 2, 2020, effective February 2021 and implemented August 2022. As mentioned, there are two separate rates: 1) donation rate being donors over potential donors unadjusted and 2) transplant rate being transplants over potential donors adjusted for age through standardization. OPOs are sorted into three tiers based on these criteria. Tier 1 is the upper 95% confidence interval of those rates being above the 75th percentile of the rate for all OPOs. Tier 2 is the upper 95% confidence interval above the median but below the 75th percentile. Tier 3 is the upper 95th percentile below the median rate.

Dr. Miller explained that for the analysis, SRTR looked at trends in recovery of pancreata for research in the cohort of donors from January 1, 2009, to February 2, 2023. February 2 was the latest date that data were available when the analysis was executed. The first trend analyzed was a backwards looking, rolling 1-year window for each day, with each time point on the trend plot reflecting the average over the previous year from that day of pancreata recovered for research as a proportion of all organs transplanted. SRTR also looked at donors whose only success under these metrics was a pancreas recovered for research as a proportion of all donors.

The second comparison was looking at a pre-post Final Rule comparison of the percent of research pancreata recovered as a percent of all organs transplanted (including pancreata recovered for research) by OPO. SRTR compared the 791 days prepublication and postpublication of the Final Rule. The last comparison examined the impact of excluding research pancreata from the numerator of both metrics on the overall tiers calculated with the method used by CMS for evaluation, and how OPOs move among the tiers if research pancreata were not included in those metrics.

Results showed that the rolling average had some variation but generally stayed around the 2% to 3% mark prior to publication of the Final Rule. There was a dip after the COVID-19 pandemic to about 1.5%, with a dramatic increase to 7% following publication of the Final Rule. For the pre-post comparison, Dr. Miller showed a graph with the percent of research pancreata as a percent of total organs recovered before the Final Rule (x-axis) and percent after the Final Rule (y-axis). The clustering of dots above the diagonal line indicated a number of OPOs recovering more pancreata for research as a percent of all organs after the Final Rule compared with before, including some that had increased from less than 5% up to 10% or 20%. Dr. Miller said the trend was similar for donors whose only organ recovered was a pancreas for research.

Regarding tier comparisons without research pancreata included in the numerator, Dr. Miller said that SRTR identified four OPOs whose tier decreased when research pancreata were excluded, and two OPOs whose tier increased. Both of the OPOs with lower tier when including research pancreata would move from tier 3 to tier 2 if research pancreata were excluded from the numerator. If these OPOs were to be in tier 3 in the fourth year of the cycle (which is the recertification year), the OPOs would be decertified without the ability to recompete, while excluding the research pancreata would move these OPOs into tier 2, in which they would be able to compete to retain their DSA.

Dr. Miller concluded the procurement of research pancreata has increased substantially. Some OPOs are procuring more research pancreata than others, and the inclusion of the research pancreata can affect the tier rating for each OPO. He added SRTR has considered research pancreata as a subgroup analysis that could be included in the OSRs. He showed an example of what some of this subgroup analysis would look like, which indicates there are a handful of OPOs that are recovering research pancreata at a higher rate. Dr. Miller added SRTR is working to put together a manuscript on these findings.

Dr. Hirose said this was why there needs to be a dialogue between SRTR and CMS. CMS is required to count research pancreata as actual donors for transplantation, though it is important for the committee to understand the grave effect it could have on certain OPOs because of this nuance. Dr. Emily Perito said it was important to consider how patients and transplant centers might see this issue in a negative light (eg, OPOs trying to game the metrics), rather than trying to minimize deaths on the waiting list or improve long-term patient outcomes. Dr. Jonah Odim asked if transplant centers are reimbursed through organ acquisition fees for the research pancreata procured. If so, another incentive was how research is done, such as sponsoring islets research if being paid. Mr. Van Slyck said this varies, as research pancreata go to transplant centers and private researchers, and often they reimburse a small amount of money back to the OPO for supplying the research pancreata.

Members thought OPOs should not be penalized for the way research pancreata are accounted for in the CMS metrics. Dr. Ginny Bumgardner added it was important to not lose sight of the value of procuring pancreata for research, and perhaps represent it differently. Dr. Mannon thought the perspective of OPOs gaming the system did not necessarily represent OPO intent at all, since OPOs are simply responding to incentives in the CMS Final Rule. She thought it was best to leave conclusions more balanced as opposed to negative. Mr. Van Slyck agreed.

Dr. Snyder said SRTR planned to add some of these data into future public reports to increase transparency and further public discussion. SRTR will continue to work with HSRA and CMS on these issues and will keep the committee informed.

SRC proposed nominating process

Dr. Mannon said at the last SRC meeting members voted to create a nominating committee with the goal of increasing transparency around the selection of committee members. She said it was important to develop a fair and equitable nominating process while making sure to have unique abilities and perspectives within the SRC and each of its subcommittees.

Every January approximately three voting members rotate off and are replaced. Dr. Mannon said the goal was to have a nomination process between July and September. In the fourth quarter, the SRC nominating committee can make recommendations to SRTR leadership and HRSA, who will make the final decisions and issue invitations. The subcommittees will have a similar process, while keeping in mind the unique needs and missions that may be different from the main SRC.

Dr. Mannon briefly reviewed the main SRC structure: two co-chairs, one OPO representative, three medical/surgical representatives, one chair of each subcommittee (3 total). Dr. Mannon said representation is needed across various organ types, and it was important to recognize potential

conflicts of interest. Having representation in terms of sex, race, ethnicity, and geography was also important.

Dr. Mannon said it was important to develop guiding principles for this process. A call for nominations would take place in the summer followed by an internal ballot and review. Then a set of candidates would be ready by the fourth quarter. Dr. Mannon noted the nominating committee would include one of the SRTR co-chairs and two voting members. Ms. Maurer, Dr. Kiran Khush, Dr. Perito, and Dr. Hirose would initially serve on the nominating committee. Members agreed the nomination process and bylaws for each committee would vary in order to cater to the specific needs of each. Dr. David Vock added that the level of expertise in and outside of the transplantation field would also vary depending on subcommittee needs. Members agreed the call for nominations would go out in July. Dr. Mannon will continue to lead the development of the process.

Task 5 conference prioritization

Dr. Snyder and Dr. Cory Schaffhausen gave updates on Task 5 web development and Task 5 recommendations. Dr. Schaffhausen shared that custom versions of the patient journey transplant map are being created for researchers who want to align specific data collection to points on the map. He also noted the possibility of reaching out to OPO professionals on the SRC to get feedback about OPO data collection and metrics.

Dr. Snyder reviewed a list of projects prioritized by the SRC that are being initiated or underway. These include:

- Patient-friendly website rebuild
- Personalized predicted waiting times and transplant rates
- A comparison of survival with kidney transplant versus dialysis (partnership with the United States Renal Data System [USRDS]). Dr. Snyder noted that the recommendation was broader than kidney, but SRTR would begin with kidney given the readily available data on all patients with end-stage kidney disease maintained by the USRDS.
- Patient-specific program search capability, with the goal of incorporating this into the new SRTR website. Dr. Ajay Israni, who had done part of the work for developing the Agency for Healthcare Research and Quality website, will present data on the new webtool preferred by patients at the July meeting of the SRC.
- Information on the potential for and benefits of listing at multiple centers, which may be tied in to the project on personalized predicted waiting times and transplant rates.
- Providing data on timing of referral evaluation listing and transplant. Dr. Snyder said there was dialogue between Kaiser Permanente and SRTR about partnering to explore data on referral, evaluation, and listing for patients with end-stage kidney and liver disease.
- Benefits/risks of using complex donor organs
- Providing tools that facilitate shared decision-making in preparation for and at the time of organ offer. Dr. Schaffhausen is currently working on a patient-centered tool for considering liver and kidney offers that will be part of the new website. Providing long-term outcomes nationally and with drill down for specific patient populations. SRTR can start to provide and improve information on longer-term outcomes.

- Providing data on offer acceptance patterns by program. SRTR is working on pediatric versus adult splits in the offer acceptance reporting and planning to add a granular data review sheet for programs to look at on the secure site.
- Developing a new donor potential conversion metric. This will be discussed with the MPSC at the May 4 meeting.
- Keeping SRTR risk-adjustment models current. SRTR has been working with the Analytical Methods Subcommittee (AMS) on this, with a target release date of updated posttransplant outcomes models in January 2024.
- Create an OPO or deceased donation–specific system map.
- Creating a dashboard of OPTN system performance metrics (also a National Academies of Sciences, Engineering, and Medicine [NASEM] report recommendation). Dr. Nicholas Wood will present on a beta version, which is next on the agenda.
- Improving the calculation of the kidney donor risk index (KDRI) and the kidney donor profile index (KDPI) by potentially eliminating the use of a percentile mapping and developing a race-free version of the KDRI. There are ongoing discussions between SRTR and the kidney committee, and one paper was already published on this topic.

Dr. Snyder noted that other high-priority projects center on long-term living donor follow-up and eliminating use of the term “discard” when describing nonuse of donated organs.

Dr. Schaffhausen reviewed progress for the new SRTR website. Patients gave feedback via Zoom sessions on the initial design. The overall direction of the website was decided and included patient and professional sections. This work is in the early stages of implementation. Dr. Schaffhausen said the new website will become a much easier foundation or platform to integrate the new data and tools from Task 5. A main goal for this project is providing easier navigation for patients to the most sought-after types of information. The website will also include or link to broader transplant education.

Dr. Schaffhausen mentioned the ongoing discussion with SRTR IT and Communications staff, and the contractors who are helping with the technology and the development. It was initially assumed that the new website would be an update of the existing one; however, it has become apparent in recent discussions that some of the legacy software does not have a feasible upgrade path. The strategy going forward is to build the new website from scratch. There will be a period when the current website is still live with the new website running in parallel, eventually transitioning fully to the new website and retiring the legacy site.

Dr. Wood then presented a beta version of a system performance dashboard, a Task 5 and NASEM report recommendation. Dr. Snyder noted that SRTR has a broader goal in mind for a systems performance dashboard and asked the committee to consider how SRTR could play a role in setting national target goals.

Dr. Wood reviewed the beta application built for monitoring trends in transplantation by presenting rolling average trends over time with key policy initiatives or other major dates (eg, COVID-19 emergency) noted on the plot. He showed various examples and noted how users can spot changes over time. Dr. Wood noted users can also choose to view data by 30-, 90-, or 365-day rolling averages.

Dr. Wood said this tool could be useful for the community to better understand the impact of policy changes on the system. Voicing the need for caution when interpreting these graphs, he cited the *post hoc, ergo propter hoc* fallacy, which means "after this, therefore because of this." The fallacy means that a change after an event does not necessarily mean that specific event caused the change. All of the trends are currently presented as unadjusted trends. However, in some cases causal conclusions can be drawn. Other times a nuanced look may be better such as with risk adjustment.

Members liked the layout and simplicity of the dashboard. Dr. Vock asked how the tool would be cited when used, and suggested replicating the cohort and doing a more advanced multivariable analysis. Dr. Snyder said if this were to launch on the public website, there is guidance on the site on how to cite SRTR products. Dr. Vock suggested adding the SRTR logo to the dashboard.

Dr. Hirose noted that attributing causality can be difficult, but the graphs help dispel the general statement that the entire organ system is broken by showing context of long- and short-term. Dr. Perito suggested having the red line that demonstrates policy change on the graph have a clickable "on-off" feature. Dr. Wood agreed and said other lines representing additional policy changes could be added in, depending on relevancy.

Dr. Snyder asked the committee if it thought the application met the expectations of the NASEM recommendation of creating dashboard that monitors system metrics over time. Dr. Mannon thought it met the requirements and did not have any recommendations on refining it in terms of more specificity. She said it was a good idea to make the dashboard public and have the public draw their own conclusions from the data. Dr. Laura Cartwright suggested scheduling a follow-up call with OPTN to ensure coordination, as OPTN has some similar goals and efforts ongoing with new allocation-focused dashboards.

Dr. Snyder reviewed the NASEM recommendations for system monitoring. He added that one way to structure the performance dashboard is presenting variation across key metrics. Currently, Dr. Warren McKinney and the SRTR team are working to present data within a dashboard that trends health disparities and inequities across certain populations. The NASEM goals include reducing the nonuse rates to 5% or less, increasing organs procured from DCD donors to at least 45% (2022 rate was 32%), improving organ acceptance rates to that achieved by the 90th percentile program, and increase transplants to 50,000 by 2026. Dr. Snyder said SRTR could create additional goals. Mr. Van Slyck suggested adding to the dashboard application nonuse rates by OPO. Dr. Snyder noted that SRTR tools could complement already existing tools (eg, the United Network for Organ Sharing [UNOS] kidney equity dashboard) rather than present the same data. Dr. Mannon said it would be great if there was a guidebook or sitemap for all of these transplant tools, since many in the field of transplantation are unaware of this information.

Reports from the subcommittees

Dr. Allyson Hart said that the Patient and Family Affairs Subcommittee (PFAS) started reviewing top Task 5 prioritized recommendations in the last meeting. Members also thought it was more important to make patients aware of SRTR instead of focusing solely on Task 5. PFAS will continue to work on how to develop and respond to the prioritized recommendations. Dr. Hart shared that,

unfortunately, PFAS member Ms. Amy Silverstein was recently diagnosed with terminal lung cancer. She wrote a guest essay that was published in the *New York Times*. Members discussed having a public recognition for all of Ms. Silverstein's contributions to SRTR.

Dr. Schaffhausen said the last Human Centered Design Subcommittee (HCDS) meeting in March focused on hearing recommendations from members about the different processes used by the members to execute large-scale website redesign projects. Mr. Christopher Zinner added that HCDS has gone from giving direct feedback on particular designs (human-centered design [HCD] coaching) to focusing on how HCD fits into the broader team and solving for certain constraints given how emotion and politics play into design. He agreed that having members with a breadth of experience has helped immensely with projects. Dr. Perito suggested having HCDS do a design critique of the system performance dashboard created by Dr. Wood. Dr. Mannon suggested a directory of all websites and access points for patients and providers to help everyone understand the available resources.

Dr. Snyder said the AMS meeting in March focused on continued development of a new process to build risk-adjustment models from scratch every 6 months to allow for greater flexibility. A second component AMS has been working on is implementing a relaxed least absolute shrinkage and selection operator (LASSO) fit and overcoming computational hurdles.

Closing business

The meeting concluded at 1:00 PM with no other business being brought forward. The next meeting will be in-person on July 18, 2023, 9:00 AM-3:30 PM EDT, at HRSA Headquarters in Rockville, Maryland.