

SRTR Review Committee Meeting Minutes

January 16, 2024, Via Webex, 10:00 AM – 1:00 PM CST

Voting Members Present:

John Magee, MD (Co-chair)
Sean Van Slyck (Co-chair)
Ginny Bumgardner, MD, PhD
Carli Lehr, MD, PhD
Deborah Maurer, RN, MBA
Scott McPhee
Emily Perito, MD, MAS
Ameen Tabatabai
David Vock, PhD

Ex-Officio Members:

Rebecca Goff, PhD (OPTN/UNOS)
Shannon Dunne, JD (HRSA)
Sumit Mohan, MD, MPH (OPTN-DAC)
Jennifer Prinz (OPTN-POC)
Jonah Odum (NIH)

HRSA:

Frank Holloman

SRTR Staff:

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
Bryn Thompson, MPH
Maryam Valapour, MD, MPP
Nicholas Wood, PhD

Welcome and opening remarks

Mr. Sean Van Slyck (co-chair) called the SRTR Review Committee (SRC) meeting to order. This was the first meeting of 2024, and the first for four new members. Dr. Jon Snyder went down the list to introduce everyone, for the sake of the new members. Dr. Snyder quickly mentioned the issue of conflict-of-interest management then proceeded with the first agenda item.

Approval of the minutes

Mr. Van Slyck asked for a motion to approve the minutes from the SRC meeting on October 27, 2023. There was a motion to approve and a second. The minutes were approved.

SRTR Strategic Plan

Dr. Snyder presented a high-level overview of the recently determined top-5 tasks to be completed by SRTR in 2024. These tasks follow:

1. Task 5 Recommendation Responses and Patient-Friendly Website (SRTR Contract Tasks 5 & 7)
2. Support the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative (Task 3)
3. OPTN Committee and Board Support (Task 3)
4. Improved SRTR Data Administration and Provision (Tasks 8 & 9)
5. Continued Expansion of the Living Donor Registry (Task 13)

Dr. Snyder then went into more detail on each topic.

For the Task 5 Recommendation Responses and Patient-Friendly Website, the goals are to launch the Donation and Transplant System Explorer application in response to the consensus conference

recommendation to “create a dashboard of system performance that could be reviewed (eg, at OPTN regional meetings),” and the National Academies of Sciences, Engineering, and Medicine (NASEM) report recommendation to “create a publicly available dashboard of standardized metrics to provide a complete human-centered picture of the patient experience—from patient referral for transplant evaluation, time on the waiting list, to posttransplant quality of life—managed by the Scientific Registry of Transplant Recipients (SRTR) or a similar entity.”

A second goal is to launch the Kidney Predicted Waiting Time application in response to consensus conference recommendation A1, “provide personalized predicted waiting times.”

A third goal is to launch the Long-Term Transplant Outcomes application in response to consensus conference recommendation L1, “provide posttransplant graft/patient survival metrics, adult vs pediatric, longer-term outcomes (eg, 10 y) - more important by patient characteristics than by center.”

A fourth goal is to launch the Multi-organ Transplant Explorer application in response to consensus conference recommendations 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,” and L2, “provide long-term outcomes for multiorgan recipients.”

A fifth Task 5 goal is to launch the Liver Offer Decision Aid tool in response to consensus conference recommendation H.5, “provide tools that facilitate shared decision-making between patients and providers in preparation for and at the time of organ offer.”

On the topic of supporting the OPTN Modernization Initiative, Dr. Snyder covered the specifics of the Option Period 3 task, which were to work with any/all new OPTN contractors to ensure minimal disruption to SRTR activities during any upcoming OPTN transition contracts, keeping the Health Resources and Services Administration (HRSA) and the SRC informed of any potential impacts to SRTR operations.

On the topic of OPTN Committee and Board support, Dr. Snyder covered the specifics of the Option Period 3 goals to support the OPTN Expeditious Task Force and its workgroups; to support the development of continuous distribution policies for the liver, heart, and kidney committees; to support the rapid response to the Secretary of Health and Human Services’ directive to begin capture of prelisting data and donor potential data; and to continue to support regular committee activities and requests.

At this point, Dr. Snyder yielded to Dr. Sumit Mohan to give the committee a summary of the OPTN work to begin collecting prelisting data and potential donor data. Dr. Mohan gave a brief overview of the activities of the Data Advisory Committee (DAC) efforts in preparing to collect prelisting data and potential donor data. He said data collection for this might start as soon as September 2024.

Dr. Snyder, Dr. Mohan, and Dr. Ginny Bumgardner engaged in a conversation focusing on the collection of the data, including who is responsible for the collection and how much of a data collection burden it would be. Dr. Mohan informed the committee that they are still identifying the best stage for data collection, and they are aware of the challenges, but are still identifying the data elements. This is just the first step and other iterations will follow. OPTN is working closely with SRTR to make sure the data being collected are as useful as possible.

Frank Holloman of HRSA made a clarifying comment that not all the burden of collecting these data

is on transplant centers, some of these data will be collected by organ procurement organizations (OPOs) as well.

Dr. Snyder then continued on to the topic of Improved SRTR Data Administration and Provision goals for Option Period 3, which were to finalize design and production of a new internal database structure, transition all SRTR production code to use the new structure, and finalize design and production of a new external data structure for distribution to external researchers with approved data use agreements (DUAs). SRTR is also working with OPTN to transition incorporation of the National Technical Information Service (NTIS) Limited Access Death Master File into the OPTN data process prior to provision of the OPTN data to SRTR. A final objective for the year is to resolve data access issues to Centers for Medicare & Medicaid Services (CMS) data sources, including End Stage Renal Disease Quality Reporting System (EQRS) data and CMS claims data using the new CMS clinical data registry (CDR) data environment.

Dr. Snyder then touched on to the topic of continued expansion of the Living Donor Collective (LDC) registry, which includes working with HRSA and the OPTN Living Donor Committee to craft policy that better aligns LDC and OPTN data collection and provides more consistent, long-term follow-up for living donors. LDC leadership will be looking to enroll additional programs into the LDC in 2024. As a demonstration of outcomes ascertainment, LDC will implement merges with SRTR and the United States Renal Data System (USRDS) to assess organ failure or initiation of dialysis. The LDC will continue to issue follow-up surveys to living donor candidates in the registry while engaging the Living Donor Steering Committee for input on data collection and living donor candidate engagement. Finally, the LDC will execute deliverables and goals outlined in the 2024 LDC strategic plan.

A discussion followed involving Ms. Deborah Maurer, Dr. David Vock, Dr. John Magee (co-chair), Mr. Van Slyck, and Dr. Mohan that centered on the question of if the modernization of the database would cause difficulties for the end users and if there had ever been thoughts about integrating the data requests that go to OPTN and SRTR.

Dr. Snyder informed the committee that SRTR had some discussions with OPTN and HRSA about some ways the handling of data could be made more efficient. For example, the SRTR standard analysis files (SAFs) and the OPTN Standard Transplant Analysis and Research (STAR) files currently have differences that could be addressed by better coordination on data production (eg, OPTN integrating the Limited Access Death Master File instead of SRTR doing so on SRTR's end). He assured that SRTR would work to minimize disruption to the community of data users that modernization of the database may bring. A lot of work is being done by SRTR staff on the back-end to ensure a seamless transition.

Mr. Van Slyck asked if it was possible to keep the SRC apprised of the progress on this more frequently than just at the quarterly meetings. Dr. Snyder agreed that the committee could be informed if there were any significant issues.

The SRC Committee voted to approve the 2024 Strategic Plan as written to go to HRSA for final approval. A motion was made by Ms. Maurer and second by Dr. Emily Perito. The strategic plan was approved.

CMS metrics

Dr. Snyder covered the background of this topic. SRTR had planned to initiate reporting of the CMS metrics in the OPO-specific reports (OSRs) on July 6, 2023. HRSA requested SRTR hold this reporting

to continue to align with CMS reporting activities. CMS/Center for Clinical Standards and Quality (CCSQ) representatives presented to Membership and Professional Standards Committee (MPSC) on May 4, 2023, and noted that SRTR will provide additional reporting of metrics with additional subgroup analyses. At the July 18, 2023, meeting of the SRC, the committee voted to move ahead with developing reports that could be provided to OPOs on the SRTR secure site on December 15, 2023, while SRTR continues to await guidance from HRSA on public presentation of the data.

After CMS/CCSQ review, CMS requested that SRTR remove figures detailing research pancreata from the report and remove predictions of donation rates and transplant rates for years not yet observed. SRTR complied with this request on December 11, 2023, and supplied updated reports to HRSA. On December 14, 2023, citing continued concerns, HRSA asked SRTR not to post the secure site report on December 15, 2023.

Dr. Snyder then detailed remaining discrepancies between the SRTR and CMS reports. SRTR reports on the current set of OPOs (56) and, for the sake of consistency, back-calculates all metrics back to 2019 assuming 56 OPOs. This causes discrepancies with the CMS reports given that CMS reports historically contain 57 or 58 OPOs.

Additionally, SRTR does not have nonrounded sharing fractions for counties that are shared. The public CMS report provides the fractions rounded to the integer. SRTR believes this is causing slight discrepancies. SRTR has requested the nonrounded fractions from CMS, but they have not been provided. Finally, SRTR uses the most recent data cut available when producing the reports. Due to data changes over time, this may introduce slight discrepancies to the numbers reports by CMS.

Dr. Snyder further expounded on the efforts to date. He showed sample reports as examples of how the results could be reported.

Dr. Jon Miller took control of the presentation to provide an update of what he has been working on. He defined four focus areas, the first being to refine the denominator of a “potential donor” per OPTN Policy 1. He further broke the refining process down to:

- a. Refine the denominator from CALC (Cause of death, Age, and Location Consistent with transplantation) deaths to a denominator that also removes deaths with specific exclusionary codes based on exclusionary comorbidities listed in OPTN Policy 1 within the Eligible Death definition.
- b. SRTR will look at in *all* diagnostic codes on the death certificate, not just the primary code that CMS considers.
 - Dr. Miller showed a slide with all the codes.
- c. SRTR will consider “donor-level” exclusions (for the donation rate) as well as “organ-level” exclusions (for the transplant rate).
 - Dr. Miller showed a slide with all the OPTN exclusions.
- d. In addition to the things enumerated in the eligible death definition, SRTR will assess other common *International Classification of Diseases, 10th Revision* (ICD-10) codes on the death certificates to look for other potential exclusions.

Dr. Miller continued with the other three focus areas: 1) to report research pancreata separately, 2) to use the definition of a “donor” per OPTN policy, and 3) to explore a different “transplant rate” metric counting as a success recovering/offering an organ for the purpose of transplant. Dr. Miller showed slides outlining the numerators and denominators for this metric.

- a. Organ-specific numerators:
 - i. Kidney: kidneys recovered for the purpose of transplant
 - ii. Livers: liver offered for transplant

- iii. Heart: heart offered for transplant
- iv. Lung: lungs offered for transplant
- b. Organ-specific denominators:
 - Dr. Miller showed a slide noting the organ-specific denominator exclusions:
 - i. Removing decedents with organ-specific exclusions found in OPTN Policy 1.

Dr. Vock, Mr. Van Slyck, Ms. Jennifer Prinz, Dr. Magee, Dr. Snyder, and Dr. Miller were involved in a discussion after the main topic's presentation. The key issue raised during that discussion was if SRTR is also going to show organs actually transplanted instead of just procured. The SRTR plans to have in the reports a complete accounting of both the numerator and the denominator and will include the number of transplanted organs.

A secondary question raised was about the reporting of research pancreata: whether this should simply be removed from SRTR reporting altogether. SRTR proposes to report it separately for pancreata that are not transplanted from a donor.

When SRTR removed the eligible death donation rate from our reports, which had been a long-standing component of our OPO reporting, SRTR did so to replace it with the CMS metrics as specified in the SRTR contract Task 6. SRTR is now trying to find a path forward to put a metric of potential donor conversion in those reports that helps the OPOs. SRTR will continue to refine going forward and as OPTN collects additional data on potential donors in the future. SRTR does not anticipate any new data coming to SRTR for at least a year.

A question was raised about whether SRTR would be using a risk-adjusted approach. Dr. Miller clarified that SRTR would be pursuing risk adjustment. At the moment, SRTR is able to adjust for age, sex race, and ethnicity. These elements are collected in the data sources for both the numerator and the denominator. As additional data collection gets rolled out, SRTR should be able to do a lot more.

Finally, Dr. Snyder was asked about the intended timeline for rollout. SRTR's goal is to bring this back to the SRC at the next in-person meeting to present data and then the committee can decide if this is something to move forward with.

After the discussion, a vote was called for on the question, "Does the committee support SRTR pursuing these new measures of potential donor conversion, both a new donation rate and a new organ-specific recovery/offer rate for transplant?"

Mr. Van Slyck called for a motion. Dr. Bumgardner motioned and Dr. Magee seconded. The motion carried. The action was approved.

Task 5 projects update

Mr. Ameen Tabatabai joined the meeting and introduced himself.

Dr. Snyder began by giving an overview of one of the recommendations from the consensus conference and two suggestions from the NASEM report. From the SRTR consensus conference, suggestion 6.4 was to "create a dashboard of system performance that could be reviewed (eg, at OPTN regional meetings)". NASEM recommendation 1 was to "develop national performance goals for the U.S. organ transplantation system" and recommendation 12 was to, "create a dashboard of standardized metrics to track performance and evaluate results in the U.S. organ transplantation system."

Dr. Nick Wood presented the application he had been working on to highlight some of the improvements made since it was previously presented to the committee, which included some

additional metrics, some minor layout changes, such as the drop-down order matching the “subway map” flow, and a “bug” fix.

The committee was receptive to the updates. Dr. Snyder mentioned that this application has also been presented to the former NASEM writing committee, as recommended by Dennis Wagner, and also to the OPTN’s Expeditious Task Force, and received positively.

Dr. Rebecca Goff gave some positive feedback, specifically on the inclusion of the definitions for each metric.

Dr. Wood then presented an outline of steps needed to be taken to complete the application for a public launch scheduled for January 24, 2024.

The committee was asked to vote on approving the Donation and Transplant System Explorer application to launch as described in the outlined plan.

Mr. Van Slyck called for a motion. Ms. Maurer offered the motion, Mr. Scott McPhee seconded, and the launch plan was approved.

There was a brief final discussion. Mr. Van Slyck asked about how the committee would be apprised of the updates to the application going forward. Dr. Perito asked about how to give feedback on it when they test it.

The committee was informed that they would be kept up to date and feedback could be emailed to Dr. Wood.

Patient-friendly website update

Dr. Cory Schaffhausen briefly updated the committee on the status of the patient-friendly website rebuild process and the relative tasks to be completed in 2024.

SRTR is looking forward to doing demonstrations and sharing more detailed tours of this site, likely in the next SRC meeting. Dr. Schaffhausen showed screenshots of the Patient Facing Portal webpage. This is what SRTR is calling phase one. Upon launch of this site, the existing srtr.org website will continue as-is as the primary homepage and will be the access point for existing reports; however, on that homepage there will be a prominent link to view the new patient-friendly preview site, and upon clicking that link, users would be taken to a new page. That new page includes a lot of new content that has been developed with the focus on patients, donors, and caregivers. It is going to include a lot of additional patient information about the patient journey. So, there would be some relation to the subway map, but there will also be additional sorts of enhancements to prominently feature any existing decision aids and calculators.

SRTR will expand it as those offerings or new offerings are created. There is a focus on making the site mobile friendly and providing guides along with access to existing video libraries and infographics.

Then Dr. Schaffhausen reviewed the current status. SRTR is continuing to work with a web development subcontractor. All pages and most of the key functionality have now been programmed, and SRTR is in a phase of initial internal review, documenting any potential bugs or any potential things we want to clarify in terms of matching the functionality to anything that has been planned in our initial requirements. SRTR is capturing that, and the team is checking all of those requirements off and making any changes. The communications team is ramping up their training so that they can manage ongoing content changes. SRTR is hoping to have an opportunity to give a demonstration to HRSA in the coming weeks with a public launch tentatively planned for

March or April 2024.

Being purely informational, there was nothing to vote on regarding this topic.

Lung modeling error

Dr. Snyder gave an overview of the history of this issue.

. On May 28, 2021, the Lung Simulation Modeling was supplied by SRTR. In March 2023, the first lung continuous distribution allocation policy was implemented, In July 2023, following review of the 3-month results of the continuous distribution policy, the lung committee identified that the policy was not performing as expected with respect to the rate of lung transplants performed in candidates with blood type O. It was discovered that an error was made in how donor-candidate pairs were being screened within the simulation with respect to blood type compatibility. This error resulted in simulated rates of transplant to blood type O candidates that were higher than observed when the policy was implemented.

Dr. Snyder presented a slide showing two figures indicating the decline in type O transplants despite the SRTR simulations having shown an increase in the rate of those transplants.

Dr. Snyder noted that the blood type screening error in the 2021 simulation study could be traced to limitations in the simulator in use at the time, TSAM (thoracic simulated allocation model), which was not updated correctly to handle both blood type scoring and screening

He assured the committee that since 2021, SRTR has developed and put into production a rebuilt simulator, the Organ Allocation Simulator (OASim), which, by design, addresses these issues. The OASim was architected to handle screening and scoring explicitly in separate modules and makes screening rules explicit and separate from scoring rules.

He further detailed when the issue was caught and how quickly SRTR responded and corrected the issue by showing a slide illustrating a timeline of the events.

Finally, Dr. Snyder showed a series of slides, using Dr. Wood's previously demonstrated application, that showed the overall increase in lung transplant rates since continuous distribution was enacted. He further showed that the AB blood type increased in transplants while the O type remained steady. Additionally, there were less type O deaths on the waiting list during the period between when continuous distribution was implemented and the error in simulation was corrected (the ABO Modification).

There was a discussion involving Dr. Maryam Valapour, SRTR Senior Staff for Lung Transplantation, and Drs. Magee, Snyder, Bumgardner, Wood, Mohan, and Perito. The main topic of concern was how changes in policy such as this are being monitored and how issues like this are being communicated. SRTR received feedback from the leadership of the American Society of Transplant Surgeons that transparency around this error was lacking. The committee was assured that lung allocation was being monitored per the predetermined monitoring plant, and that is why it was caught quickly and corrected. OPTN put notice out to the community that noted the error in modeling, and issued a new policy for public comment. Dr. Valapour assured that the thoracic community was aware of this issue. It was unclear if SRTR should lead in communicating the issue given OPTN was communicating through policy announcements. It was suggested that SRTR should also provide the simulation models and analyses to the public to ensure transparency. Finally, the question was raised about how this could have been avoided. The committee was assured that SRTR has learned from this and taken steps to enhance the modeling process with additional predetermined quality and consistency checks.

There was nothing to vote on regarding this topic. The intent was to bring this to the attention of the committee and get feedback.

Three-year posttransplant estimate issue—letter from NY Presbyterian

Dr. Snyder referred to a letter that had been circulated to the SRC in the materials for the meeting. He explained the reason for the concern and the history of how the COVID-19 carve-out had affected 1-year outcomes in the past, and that this had been brought to the attention of the SRC previously and discussed at length in a few SRC meetings, before the SRC voted to keep the COVID-19 carve-out in the metrics. The issue is not affecting the 3-year outcomes evaluations and has caused unexpected results for the unadjusted Kaplan-Meier estimated survival percentage. SRTR has modified the reports to include 95% confidence intervals with the Kaplan-Meier survival estimates.

The overall consensus was that SRTR should remain consistent. It was agreed the committee would more closely review the issue and the letter to determine the best response, and draft a response letter. It was agreed upon to address this offline following the meeting.

Closing business

Dr. Snyder thanked the SRC members for their participation and informed them the next meeting is scheduled for April 30, 2024, to be held in-person in Rockville, MD. The meeting adjourned at 1:03 PM CST.