SRC Meeting Minutes

SRTR Review Committee Meeting, HRSA Headquarters, Rockville, MD

October 17, 2024, 9:00 AM – 1:30 PM EDT

Voting Members:
John Magee, MD (Co-chair) ('26)
Sean Van Slyck (Co-chair) ('25)
Ginny Bumgardner, MD, PhD ('24)
Carli Lehr, MD, PhD ('26)
Deborah Maurer ('25)
Scott McPhee (HCDS) ('23)
Emily Perito, MD ('25)
David Vock, PhD (AMS) ('24)

Voting Members Absent:
Ameen Tabatabai (PFAS) ('25)

[1]New Member
[2]Virtual

Ex-Officio Members:
Adriana Alverez, MS (HRSA)[1]
Brianna Doby, MPH (HRSA)[1,2]
Shannon Dunne, JD (HRSA)
Rebecca Goff, PhD (UNOS-OPTN)
Jennifer Prinz (OPTN-POC)[2]
Jesse Schold, PhD (OPTN-DAC)

Ex-Officio Members Absent:
Jonah Odim, MD (NIH)

HRSA Guests:
Jennifer Brock[2]
Ricardo Cale
Frank Holloman
Pilar Martinez

SRTR Staff:
Earnest Davis, PhD, MHSA[2]
Tonya Eberhard[2]
Ryan Follmer[2]
Allyson Hart, MD, MS
Ryutaro Hirose, MD
Amy Ketterer[2]
Grace Lyden, PhD[2]
Warren McKinney, PhD
Jon Miller, PhD[2]
Caitlyn Nystedt, MPH, PMP[2]
Cory Schaffhausen, PhD[2]
Mona Shater, MA[2]
Jon Snyder, PhD, MS
Nicholas Wood, PhD[2]
David Zaun, MS[2]

Welcome and opening remarks

Mr. Sean Van Slyck and Dr. John Magee called the SRTR Review Committee (SRC) meeting to order. Following introductions, Dr. Jon Snyder reviewed conflict of interest management. The committee proceeded to the first agenda item.

HRSA welcome, OPTN Modernization updates, and SRTR impacts

Mr. Frank Holloman welcomed members of the committee to the Health Resources and Services Administration (HRSA) and presented an update on the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative, first noting that, for the first time in 40 years, HRSA has awarded multiple contracts to 14 vendors to apply their expertise to improve the OPTN. He noted that HRSA used an indefinite delivery, indefinite quantity (IDIQ) approach to create the pool of 14 which can then bid on certain task orders. Each contractor can only bid for tasks within the domain(s) for which they were awarded an IDIQ contract. Mr. Holloman said the board support contract was awarded to the American Institutes for Research (AIR), which is beginning to acclimate to the responsibilities of supporting the OPTN Board. HRSA is working with the United Network for Organ Sharing (UNOS) to transition the board support to AIR on January 1, 2025. UNOS will be a part of the current operations through December 31, 2024. HRSA has issued the following five research task orders as part of the IDIQ awards: General Dynamics IT for OPTN IT, Arbor Research for patient safety, Maximus Federal for policy development, Deloitte for patient-centered communication, and

Guidehouse for OPTN financial management. Vendors have 9 months to complete assigned tasks. HRSA hired Summome to run the program management office (PMO) to make sure all vendors are working together, there is no duplication of work, and there are clear distinctions between vendor functions. The PMO will be coordinating meetings between each group and making sure lines of demarcation are clear.

The committee expressed concerns with the level of communication to the transplant community during this transition period from one to multiple vendors. The committee also expressed concern with transparency about how decisions are made about prioritization and level of funding to be given to the different contractors. Mr. Holloman explained that as all vendors are contracted with HRSA, it will be working with these vendors to assess cost and funding expectations with feedback from the OPTN committees. He added that this system allows task orders to be released more quickly, leading to a more transparent environment in that HRSA is also being transparent with the public in immediately sharing which vendors have been awarded which tasks. He added that these changes to the OPTN contracts will have no immediate effect on SRTR's role.

Dr. Ginny Bumgardner asked whether there was currently a set budget per domain area. Mr. Holloman said there was no set budget per domain area. Dr. Ryutaro Hirose asked how the transition from the current UNOS Board to the new one will affect OPTN committees and their work. Mr. Holloman said none of that work is being paused or changed based on the transition. OPTN liaisons will assist with the transition, and UNOS will continue to play a role as it is one of the 14 IDIQ contractors. He wished to remind the committee that any federal contracting information is always publicly available.

Ms. Deborah Maurer said there should be more proactive efforts from HRSA to bring robust communication to the transplant community about these changes, as opposed to having to seek it out. Dr. Bumgardner agreed, adding this will lead to better communication with patients from transplant providers about these transitions. She added that the transplant community would be most interested in more specifics about vendor and task goals, as opposed to the contracting process that Mr. Holloman outlined earlier. Dr. Magee said it would be reasonable to not expect HRSA to orchestrate all communication with the community, and suggested engaging OPTN governance to help with messaging by releasing summary updates. Mr. Holloman clarified that all communication posted on the OPTN website needs HRSA clearance.

Dr. Hirose said there was no such thing as over-communication to the transplant community. More transparency, such as through reports or digests, would go a long way in reducing skepticism about HRSA's actions. Dr. Emily Perito agreed and highly encouraged more accessibility of information. Dr. Holloman agreed while noting the HRSA communications clearance process has increased dramatically recently. He also stated again that the details of these contractor Task Orders are available on sam.gov.

SRC Nominating Committee 2024

Dr. Magee noted this was the second year of the SRC nominating process and SRTR Nominating Committee (SNC), which consists of five SRC voting members with support of the subcommittee co-chairs. The SRC has put out a call for nominations for the main SRC and its three subcommittees.

The SNC met on October 8, 2024, to discuss and select nominees with the help of subcommittee co-chairs, and now brings forward the recommendations to the SRC.

Dr. Magee reminded the committee that member terms were ending for Dr. Bumgardner and Dr. David Vock (also the Analytical Methods Subcommittee [AMS] co-chair) from the SRC; for Dr. Vock, Dr. Brent Logan, and Dr. Andrew Schaefer from the AMS; and for Ms. Olivia Foss from the Human Centered Design Subcommittee (HCDS). The Patient and Family Affairs Subcommittee (PFAS) has no member terms expiring but requested to expand the committee both to increase diversity and to ensure adequate members are present during committee meetings. Dr. Magee said the SNC reviewed 15 main SRC nominations and narrowed them to three for the SRC's consideration. He reviewed the top three, and then turned the topic over to the committee for discussion, including strengths of each candidate.

Dr. Bumgardner put forth a motion for Dr. Amit Mathur, the top candidate recommended by the SNC, to be selected to join the SRC. Ms. Maurer seconded the motion. The SRC members voted unanimously to invite Dr. Mathur, while noting that one SRC voting member, Mr. Ameen Tabatabai, was absent.

Dr. Magee moved on to AMS nominations, reporting that AMS co-chairs Dr. Snyder and Dr. Vock selected Dr. Jonathan Daw and Dr. Yong-Fang Kuo. Current AMS member Dr. William Parker was also put forward to become the new co-chair. Dr. Vock made a motion to approve, followed by a second. The SRC members voted unanimously to approve the recommended candidates.

HCDS co-chairs Dr. Cory Schaffhausen and Mr. Scott McPhee selected Ms. Devika Patel, with Mr. McPhee making a motion to approve, seconded by Ms. Maurer. The members voted unanimously to approve Ms. Patel.

Next, Dr. Allyson Hart said she as the outgoing co-chair, along with co-chair Mr. Tabatabai and SRTR Senior Staff for Patient and Family Affairs (and incoming co-chair) Dr. Earnest Davis, recommended that the following nominees be invited to join PFAS: heart recipients Mr. Matthew Greenberg and Mr. Calvin Henry, liver recipient Ms. Morgan Lorenz, and lung recipient Mr. Akshai Patel. These new members would add diversity of perspectives to the committee from different organ types, geographic regions, gender, race, and ethnicity. Dr. Carli Lehr made a motion to approve, seconded by Mr. Van Slyck. The committee voted unanimously to approve the slate of four PFAS candidates.

Dr. Magee asked if the SRC wanted to restructure term years for a more consistent cadence of members rolling off. Dr. Snyder agreed that if the SNC or SRC wanted to alter some terms so they are staggered, this was acceptable. Dr. Hirose commented that other organizations, including the OPTN, should take the lead in including more patient voices. Mr. Van Slyck suggested expanding SRC membership to include additional organ procurement organization (OPO) participants. Dr. Snyder added the possibility of having more than nine SRC voting members. Dr. Magee said it would be worthwhile to devote some time next year to considering these suggestions.

As next steps, Dr. Snyder said invitations will be extended to new members. Assuming they accept, notices will be sent to all other applicants thanking them for applying.

The 2025 Task 5 SRTR follow-up consensus conference

Dr. Snyder noted that the SRTR contract includes a follow-up conference to the 2022 consensus conference to be held in 2025, and the SRTR had been planning the event with some initial feedback from the SRC and subcommittees. Mr. Holloman informed the committee that, in light of the uncertainties with potential new task orders being produced at the time of the April 2025 event, and concerns over the possibility of not being able to implement feedback from the community (due to any potential plans to go in a different direction with the OPTN tasks or potential constraints from the US government), HRSA requests SRTR pause the planned consensus conference. Instead, updating the community on consensus conference accomplishments in a town hall or webinar was potentially acceptable but would need to be discussed further.

Dr. Snyder said SRTR had planned to show the SRC some potential marketing material and discuss the current agenda and state of planning. Prior to the news from HRSA yesterday about the conference being put on pause, the conference had been envisioned as three half-day virtual meetings including the use of an interactive online webinar system to demonstrate tools developed in response to the 2022 consensus conference, discuss current projects underway, and asking what patients and the professionals would like to see prioritized next.

The committee thought it was important for patients to have a platform to have their voices heard. Dr. Hirose said it was important to get patient feedback on what SRTR has accomplished since 2022. Dr. Vock said many people may not want to participate if there is no forum for feedback. Dr. Lehr added that this may be damaging in terms of building patient trust. Dr. Davis said asking for patient feedback despite not using it was better than marginalizing patients completely. There needed to be transparency and utility, which he felt neither a webinar nor town hall were sufficient in providing. Dr. Perito and Dr. Bumgardner agreed new OPTN vendors should attend the town hall or webinar, if possible, to hear from the community and make sure that what they are working on aligns with the work done in the past 2 years in response to this diverse stakeholder feedback.

Dr. Snyder moved on to discussing potential next steps. Mr. Holloman suggested HRSA review the SRTR plan to determine what concepts align with the direction they would like to take, and further discussions between HRSA and SRTR leadership. Mr. McPhee proposed going through the slides about the 2025 conference anyway, as it would be worthwhile to review the content. SRTR Communications Director Ms. Mona Shater then gave a condensed version of the marketing materials. She said for the 2022 consensus conference, SRTR pivoted its tagline “data driven” to “people driven transplant metrics” to highlight SRTR’s focus on the people it serves: patients, professionals, OPOs, payers, and all members of the transplant community. The conference focused on how people are more than just numbers, facts and figures are human based, and individual voices form a community of feedback.

Ms. Shater said the 2025 consensus conference plan was to focus on how together we can achieve anything, especially with the change happening in the transplant community. The conference would focus on five cornerstones under “together, we achieve: collaboration driven, community driven, connection driven, innovation driven, and growth driven.” The conference would showcase all the feedback SRTR has received and incorporated into its current projects, with a focus on how to achieve future goals. The conference would have live contributions during the event that relate back

to the five cornerstones. Ms. Shater said SRTR planned to create a visual representation of that each day to share with attendees and on social media platforms. The planned virtual platform was RingCentral events.

Dr. Schaffhausen reviewed the agenda, which spanned 3 days of 3 hours per day. The content was broken out across different groups of recommendations that are aligned with areas on the transplant system map. Each 45-minute session would include updates being given for each group, with the opportunity for discussion and feedback. Day 1 would discuss prelisting; day 2, waitlist sessions and posttransplant; and day 3, deceased donor metrics and future work. He added that the first 2 days would be primarily reporting back summaries of work since 2022, with day 3 including greater focus on future priorities. Dr. Snyder said the format could be condensed further, given HRSA feedback.

Members thought the structure was well done. Mr. McPhee suggested adding a chat where HRSA could answer questions in real time. Dr. Perito asked how HRSA could arrange for SRTR to share this work with OPTN vendors, and Mr. Holloman said PMO would help with coordination. Ms. Pilar Martinez from Summome, which holds the PMO contract, explained they were meeting with the vendors to discuss management efforts, and SRTR would be part of its integration efforts. Ms. Martinez said she would need to confirm with HRSA if it was possible to share with the SRC the information Summome prepared for vendors and collected from stakeholder engagement. The committee agreed community and patient input should be integrated moving forward, and Dr. Hart said going forward it was important for HRSA to develop specific plans on how to get ongoing feedback from the patient community through this transition.

Approval of the minutes

Ms. Shannon Dunne said HRSA wanted to add a statement to the August 2024 minutes noting that a representative from HRSA stated that HRSA cannot advocate that SRTR produce OPO metrics that are in conflict with current Centers for Medicare & Medicaid Services (CMS) regulations. There was uncertainty about the exact statement that was made as well as the context, and the committee noted that there are different OPO metrics that can be developed that are in addition to, not in conflict with, CMS metrics. The committee agreed to a review of the recording to determine accurate wording. The minutes would be circulated by email with the specific edit highlighted, and the committee could vote on the edited version.

Donation and Transplant System Explorer application updates

Dr. Nick Wood said that the current Donation and Transplant System Explorer application on srtr.org only shows trends at the national level. In response to feedback, SRTR is proposing a version of the application that looks at trends for specific OPOs and for specific transplant centers. Dr. Wood showed a beta version of the application in a live demo. This version allows for examining OPO- and center-specific trends. He demonstrated a few specific trends as well as how the application handles instances where OPOs have merged. Following previous SRC recommendations, Dr. Wood noted that the application only allows for 365-day rolling windows when viewing trends by center or OPO to avoid issues introduced by small numbers if choosing 30- or 90-day rolling windows. Lastly, Dr.

Wood said SRTR is continuing to build out more metrics over time and would welcome feedback on what would be useful to the community.

Dr. Bumgardner suggested adding a note in the application explaining which OPOs have merged or programs that have shut down. Dr. Vock agreed. Dr. Hirose proposed looking at multiple different trends overlaid for the same program, and Mr. Van Slyck suggested having the application look at one trend overlaid from multiple programs/OPOs.

Dr. Wood reviewed a few examples of out-of-sequence allocations, which could be made available for transparency. Dr. Hirose said it was important that users of the tool did not use one metric to judge any particular part of the transplant system, or even a transplant center or OPO. For example, out-of-sequence allocation is one facet but placement of organs from medically complex donors is another. Dr. Hart suggested adding pop-ups to guide the user through specific metrics, and Dr. Rebecca Goff agreed saying the language could also be clarified to help the user understand what the metrics mean and what other metrics complement the current metric.

Members agreed transparency was important, even if the data could be misused. Mr. Van Slyck asked if this information would be available on the public or secure site. Ms. Maurer advocated for placing the tool on the secure site so transplant centers can understand the data before it is made publicly available. The general sentiment was the committee was not opposed to this tool ending up on the public site, and agreed with placing it on the secure site for a period of time when programs and OPOs could view it and submit feedback. Dr. Snyder said the committee could review these comments and then decide if/when to recommend making the functionality publicly available.

Dr. Hirose said that most patients are not going to use this type of tool, and there needs to be a more patient-friendly ability to look at the US transplant system. Dr. Davis mostly agreed but said there are many different types of patients. If SRTR decided to not make this data available to the patient population, there should be a back-end process for making this data available for someone if requested.

Personalized predicted kidney waiting times

Dr. Schaffhausen gave an update on the personalized predicted wait-times application for kidney patients. The functioning prototype does a personalized breakdown, providing the amount of time until predetermined percentages of patients have had a transplant, done in a timeline visual display. He displayed an example where the waiting time was a wide range from several months to 10 years.

Dr Schaffhausen gave an overview of user feedback that was incorporated into the current tool. Twelve participants gave feedback over six Zoom sessions, with a mix of transplant candidates, recipients, and family members. This feedback showed a preference for showing the full and potentially wide range of waiting times. Per the feedback, vertical and horizontal styles are available on the interface to work with either mobile or desktop viewing. There was an interest in having a pop-up or user guide explaining wait-time variance, and also for features to provide the ability to compare centers. Dr. Schaffhausen showed a mock-up that included explanatory language and center comparison at the bottom.

Dr. Vock suggested adding in other factors, such as kidney donor profile index (KDPI), to help patients see if they can receive transplant faster if they are willing to consider different offers. Dr. Schaffhausen noted that these kinds of offer acceptance tools are in development with independent funding. Dr. Jesse Schold said waitlist removals in addition to mortality should be considered, and Dr. Hart clarified that these models include those competing events. Dr. Warren McKinney asked if this tool would replace the current kidney calculator, or if similar education would be built around the tool. Dr. Hart clarified that these tools are designed to complement each other and show information in different ways to be used for different reasons. Dr. Schaffhausen said SRTR plans to develop content to introduce the tool and explain how it can be used, and the patient-friendly website is the framework to help guide patients and families to the information they need when they need it.

Long-term posttransplant outcomes

Dr. Jon Miller reviewed the long-term outcomes calculator, which has been shown to PFAS for feedback. The calculator presented a survival curve with separate tabs for heart, kidney, liver, and lung transplant. Variables included age, gender, primary diagnosis, and living/deceased donor for kidney and liver.

Dr. Schold said the tool was problematic in its current state because SRTR cannot accurately estimate long-term kidney graft/patient survival without access to all available data on graft losses and deaths, as CMS and HRSA have not finalized agreements to share the data. This fact makes these tools very limited in how they are interpreted, and potentially overly optimistic. He said it would be irresponsible to share misleading data with patients. Dr. Schold emphasized the urgency for HRSA and CMS to finalized the data sharing agreements. Dr. Hirose agreed, saying that the public would be upset if they knew all the agencies under one department were not sharing data with one another. Ms. Dunne thanked them for their feedback and acknowledged the concerns.

Dr. Schaffhausen reviewed feedback received on the calculator from patients. He intends to have a second round to feedback to include more patients, especially kidney patients, as the project evolves. When a live demo and mock-ups were reviewed, he noted a preference to have a survival curve included with simple text explanations and a data table as shown on mock-ups. Dr. Miller demonstrated an updated version, which included the original layout of a survival curve but with survival at each year from 1-10 years and also grouped characteristics in the left data entry section to improve organization.

Members asked whether error bars should be added but discussed how error bars have been shown to reduce understanding and actually decrease trust in the estimates rather than improving it, and so are not recommended. Members also discussed how all of these tools need to fit into the framework that the patient-friendly website provides, having additional shared decision-making tools to help them understand trade-offs and provide more guidance. For example, long-term survival after transplant needs to be weighed against the benefit of getting an organ faster. Dr. Perito suggested some clarifying language in the calculator.

Program metric icon survey update

Dr. Schaffhausen gave a recap of previous SRC discussions on this topic. SRTR has done numerous surveys that explored different icon designs and ways to arrange metrics on the page. He referred to a 2021 randomized study along with the current study, which was done as an externally approved research study through Hennepin Healthcare and approved by their institutional review board (IRB). The SRC previously reviewed an icon variation consisting of the gauge icon representing a metric of overall survival after listing and combined with a number to assist with patient interpretation. Prior to the survey, the icon design was changed to also include another column labeled "estimated survival," with a number out of 100 instead of a percentage as a concept. The purpose of the survey was to determine whether there is enough evidence to support continuing on this path prior to spending time developing all the statistical methods to calculate those numbers. The dial is used to explain whether an outcome is good or not, and the number helps patients understand if the difference between two or more programs is big or small.

Dr. Schaffhausen showed six images included in the survey. These images are randomized to show only one image for questions about decision-making and interpretation. Later, all six images are shown for questions about preferences. Option A is the control (current SRTR website with "bar" icons); option B is the same metrics with gauge icons; option C, D, and E have one gauge based on overall survival after listing but varying the color scheme; and option F adds the numerical metric in addition to the gauge.

There were 96 patient participants in the survey. When seeing all six designs, most preferred option F. Regarding layout preference, most preferred the option with the overall survival on the main page, with a button to click for more details.

Dr. Schaffhausen then showed how participants made decisions about a transplant center using a mock-up. The hypothetical "Lake Hospital" was the best choice, having the best overall survival probability due to having the highest transplant rate. However, when presented with the current multiple metrics at once, many patients chose "Meadow Hospital," which has the best 1-year survival. It was also unclear if patients understand that 1-year survival for kidney may only be different by a couple percentage points. Participants who were shown the overall survival from listing metric first using the gauge had the best rate of accurate understanding.

Dr. Schaffhausen also asked how each participant interpreted an icon that was three out of five bars. Patients commonly misinterpreted this as "three out of five patients survived." He pointed out how this most recent survey revealed that the current legend is not clear enough and likely resulted in a high percentage saying that the mock-up does not provide enough information. A few things Dr. Schaffhausen gleaned from open-ended responses were that the terminology "deceased donor transplant" is unfamiliar to non-kidney patients and it is unclear to some that metrics are adjusted to reflect different patient and donor mixes. One of the biggest feedback takeaways was the need to make the legend more understandable. The legend was changed so that one icon to the left means "worse than national rate," one pointing to the middle means "similar to national rates," and the one on the right side means "better than national rates."

Dr. Davis said it was important to make sure language was not too technical for patients, but to keep in mind that not everyone will understand no matter how it is explained and some might need help from additional sources to understand the material. Dr. Snyder said it was important they come up with a method to get the number in the right column, and come back to the SRC with the actual working prototypes.

Report from the subcommittees

Dr. Davis has yet to attend a PFAS meeting but has helped Dr. Hart and Mr. Tabatabai select new PFAS members. He will become more involved. Members discussed the possibility of PFAS collaborating with the HCDS on keeping PFAS applicants in the loop for their additional feedback. Mr. McPhee and Dr. Schaffhausen from the HCDS said the next meeting Is planned for December. Dr. Schaffhausen added that the subcommittee will focus on consensus conference planning. Dr. Snyder said an AMS meeting was hosted last Friday. Dr. Vock said the AMS discussed how to handle multiorgan transplants in system monitoring with pretransplant mortality metrics.

Closing business

Hearing no other business, Dr. Snyder thanked Dr. Vock and Dr. Bumgardner for their leadership and participation in the SRC. Ms. Dunne thanked the members for their service to HRSA and the SRTR. The next meeting scheduled is a virtual meeting in winter 2025.