SRTR Review Committee Meeting Minutes

Teleconference

January 20, 2021, 10:00 AM - 1:00 PM CST

Voting Members Present:	**Ex-Officio Members Present:**	**SRTR Staff Present:**
Roslyn Mannon, MD (Co-Chair)	Shannon Dunne, JD (HRSA)	Tonya Eberhard
Jeffrey Orlowski, MS, CPTC (Co-Chair)	Alexandra Glazier, JD, MPH (OPTN-POC)	Ryutaro Hirose, MD
Chris Zinner	Jonah Odim, MD (NIH)	Larry Hunsicker, MD
Richard Knight, MBA	Darren Stewart, MS (OPTN/UNOS)	Ajay Israni, MD, MS
Brent Logan, PhD	Rachel Patzer, PhD (OPTN-DAC)	Bertram Kasiske, MD, FACP
James Markmann, MD, PhD		Amy Ketterer
Sumit Mohan, MD, MPH	**HRSA:**	Donald Musgrove, PhD
James Pittman, RN, MSN	Chris McLaughlin	Caitlyn Nystedt, MPH, PMP
	Adriana Martinez	Nicholas Salkowski, PhD
Voting Members Absent:	Shannon Tait	Jon Snyder, PhD, MS
Kiran Khush, MD		Andrew Wey, PhD

Welcome and Opening Remarks

Mr. Jeffrey Orlowski called the SRTR Review Committee (SRC) to order at 10:00 AM CST. Voting and ex-officio members gave their introductions, with special recognition to new SRC members present:

- Roslyn Mannon, MD, Transplant Nephrologist, University of Nebraska Medical Center, Vice Chair of Medicine for Academic Development
- Chris Zinner, Managing Director, Accenture Federal Services
- Rachel Patzer, PhD, Epidemiologist, Health Services Research, Emory University, Organ Procurement and Transplantation Network (OPTN) Data Advisory Committee Chair

Dr. Jon Snyder noted that Dr. Kiran Khush, cardiologist at Stanford Medicine, is the other new voting member. Dr. Khush was unable to attend this meeting but looks forward to contributing to the SRC.

Mr. Orlowski gave an overview of the agenda. Dr. Snyder reminded members about the new conflict of interest management requirement, in which members must sign a conflict of interest attestation annually. All attestations are current and have been returned to SRTR. The last meeting minutes were circulated, offering members the opportunity for edits or objections. Hearing no objections, the committee approved the minutes.

New SRC Structure and Subcommittees

Dr. Snyder informed the committee of various changes to the committee operations and structure with the new SRTR contract, including changing the committee name from SRTR Visiting Committee

to SRTR Review Committee. HRSA also requested that the SRC have representation from various areas of expertise, which Dr. Snyder categorized as Transplant Professional, Methodological, Patient and Family Concerns, and Human-Centered Design. SRTR proposed to HRSA a broadening of the committee to include the main SRC and three subcommittees, which would allow more direct engagement with the different areas of expertise. With HRSA's approval, SRTR has formed the following standing subcommittees: Analytic Methods, Human-Centered Design, and Patient & Family Affairs. Recruiting for each subcommittee is nearly complete. Each subcommittee will be led by an external co-chair who will also be a voting member of the main SRC, along with an SRTR staff co-chair.

Dr. Andrew Wey, staff co-chair of the Analytic Methods subcommittee, gave an overview of the subcommittee's goals to take an in-depth look at the statistical methodology used to estimate performance metrics included in the program- and OPO-specific reports (PSRs and OSRs). The subcommittee will also have expertise in operations research and simulation modeling and will review the methods used in the SRTR's simulated allocation models. Dr. Brent Logan, external co-chair, made a few comments in support of the new subcommittee's direction.

Dr. Cory Schaffhausen, staff co-chair of the Human-Centered Design subcommittee, gave an overview of the subcommittee's goals to provide human-centered design expertise to the SRTR, including data visualization and user interface design. The subcommittee also hoped to broaden SRTR's knowledge of design methods. Mr. Chris Zinner, external staff co-chair, concurred with Dr. Schaffhausen's introduction of the committee and noted his enthusiasm to begin.

Dr. Allyson Hart, staff co-chair of the Patient & Family Affairs subcommittee, gave an overview of how the subcommittee will bring the patient voice directly to the work of the SRTR. Membership currently includes representation from kidney, pancreas, heart, lung, and liver transplant recipients, with recruitment underway for a living donor and deceased donor family member. Mr. Richard Knight, external co-chair of the subcommittee, noted his approval of the direction of the subcommittee and looked forward to creating a comfort level in which patients felt welcome to participate.

Dr. Snyder envisioned that future SRC meetings would include updates from the subcommittees and that the main SRC committee would hear recommendations and provide oversight of the subcommittee activities.

Dr. Snyder then turned to the updated SRC Charter for review and approval. Hearing no recommended changes from members, Mr. Orlowski called for a vote. The SRC Charter was unanimously approved.

SRTR Task 5: Identify Metrics

Dr. Snyder updated the committee about a new task in the SRTR contract. Task 5 requires the SRTR to identify key stakeholders in the information produced by the SRTR, identify metrics of interest to the stakeholders, develop plans to implement those metrics most effectively, and develop a system of continuous review and improvement of the metrics. The contract requires the SRTR to host a consensus conference during the second year of the 5-year contract cycle, with preparatory work taking place during the first year. The consensus conference will bring key stakeholders together to

debate metrics and make recommendations to the SRTR. SRTR will take the feedback to the SRC and its subcommittees to guide changes to the information provided by the SRTR. A follow-up consensus conference would be held every 3 years to ensure continued review and improvement. SRTR is establishing a steering committee for the effort made up of representatives from currently identified key stakeholder groups. Dr. Mannon noted that the consensus conference was an opportunity to engage the public in a positive way. Mr. Knight and Dr. Hart agreed on the importance of preparing patients before the conference so they could maximize their contributions.

COVID-19 and PSRs and OSRs

Dr. Snyder gave a brief introduction to the next topic of deciding how to handle performance metrics in the July 2021 release of the PSRs and OSRs in response to the COVID-19 pandemic. He stressed the importance of the committee's decisions at this meeting because the SRTR will begin production of the July reports in March. Shannon Dunne stated that HSRA supported resuming production of the metrics, possibly with some statistical adjustments or continued carve-outs due to the impact of COVID-19. HRSA was looking forward to receiving the committee's recommendations. Mr. Orlowski also offered some introductory remarks encouraging a decision at this meeting. The co-chairs turned the presentation to Dr. Andrew Wey, who reviewed each performance metric individually.

Posttransplant Outcomes

Dr. Wey first reviewed proceedings from the June 2020 meeting, in which the committee decided to censor follow-up of all risk-adjusted metrics on March 12, 2020 for the January 2021 reports. This gave SRTR time to evaluate the impact of COVID-19 and identify the best response.

The July 2021 reports need to have a more nuanced approach. For many metrics, a large portion of the evaluation cohort would be removed under the censoring approach. For transplant rate ratios, waitlist mortality rate ratios, and patient mortality after listing rate ratios, 40% of the evaluation cohorts would be removed, and 12% would be removed for posttransplant outcomes evaluations. The offer acceptance metric would have 80% of the cohort removed. For organ procurement performance metrics, 40% of the evaluation cohort for donor yield would be removed, and 80% of the evaluation cohort for the eligible death donation rate would be removed. Truncation of the cohorts results in less-precise evaluations. In addition, all metrics would continue to rely on data from before the national emergency declaration, preventing programs from demonstrating improvement, a concern the SRTR has heard from the community.

Dr. Wey recommended the option, regardless of recommendations on specific metrics, to enhance the disclaimers on the SRTR website, acknowledging that COVID-19 impacted the system during this timeframe. In addition to enhanced disclaimers, Dr. Wey noted that options for each metric range from continued censoring on March 12, 2020, to carve-outs for specific periods of time, to full resumption of normal reporting cohorts.

Dr. James Markmann was concerned that viewers would over-interpret the tier ratings without noticing the disclaimer. Dr. Sumit Mohan mentioned that the disclaimer would not inform readers of differential geographic effects of the pandemic. Many may not know how to interpret the disclaimer or the data. Dr. Wey replied that most would realize that COVID-19 affected different parts of the

country differently, to which Dr. Mohan agreed, to a point. Dr. Mohan suggested changing the color of the tier icons to highlight uncertainty due to the pandemic. Dr. Schaffhausen noted that the human-centered design subcommittee will make recommendations and could have the resources to evaluate visual component options before the posting of the reports in July. Mr. Zinner asked why SRTR couldn't provide censored and uncensored data views with a toggle for the user to choose the view. Dr. Wey noted that this was infeasible given that it would require recoding the entire process, along with retooling the website within the next quarter.

Dr. Ryutaro Hirose noted two primary questions for the committee to consider: 1) What statistical adjustments should the SRTR make to the performance metrics, if any? and 2) How should the data be presented publicly? Data may be regionally consistent, but responses and resources may vary significantly from program to program. Even regionally, there may be pushback from stakeholders to publish data without the caveat of COVID-19's local effects. Dr. Mohan agreed, adding that transplant programs may not have had control over hospital-level decisions about resource availability during the pandemic. Mr. James Pittman concurred. Dr. Logan suggested storing archived prepandemic performance reports for particular centers and incorporating postpandemic data for comparison.

Dr. Snyder suggested that Dr. Wey talk through the statistical alternatives. Dr. Wey explained that SRTR modified January 2021 public reports because of potential confounding by geography early in the pandemic, particularly for waitlist mortality rates, transplant rates, and posttransplant outcomes. The New York donation service area (DSA) had a hazard ratio for kidney graft survival of 2.83 early after the emergence of COVID-19 (March 13 through April 30, 2020), indicating a 183% higher than expected rate of kidney graft failure. Liver graft failure in the New York DSA had a slightly smaller but elevated hazard ratio of 1.69. Lung transplant outcomes had less geographic variability, and no variability was observed early on in heart transplant outcomes.

Dr. Wey went through the state and potential confounding by geography for the different performance metrics with updated data through present day. He also offered suggestions for potential modifications for each metric. He began with posttransplant graft survival, showing the differences before and after COVID-19 for posttransplant kidney graft failure. Breaking down geographic variabilities across the country, Dr. Wey offered examples by highlighting the New York/New Jersey areas, Texas, and the upper Midwest. While the New York City area had elevated rates of graft failure early in the pandemic, Texas had a peak in the summer, elevating graft failure rates. Mr. Pittman said it was important to note that the difference in overall hazard ratios might be less significant. Dr. Hirose pointed out the caveats in looking at this type of data with case-fatality rates and surges for COVID-19 fluctuating over time.

In terms of liver posttransplant graft failure, New York—but not the Texas DSA—was impacted disproportionately. Though COVID-19 had an initial system-level effect on posttransplant liver graft failure, it significantly attenuated after June 12. Mr. Darren Stewart asked how the OPTN's amnesty policy was handled in terms of graft survival. Dr. Wey replied that SRTR assumed graft function unless otherwise reported and that amnesty does not apply to reporting graft failures and deaths. There were no overall differences in outcomes for heart transplant after COVID-19.

Dr. Wey proposed assigning each organ to one of three different options for posttransplant follow-up. For kidney, given continued evidence of geographic variability and its associated potential to confound the evaluations, Dr. Wey suggested continuing to censor on March 12, 2020. For liver, confounding by geography seems to have dissipated after the first quarter of the pandemic, so he suggested carving out the first quarter from March 13 to June 12, 2020. For other organs, Dr. Wey suggested resumption of normal reporting cohorts.

The committee debated if they should censor differently by organ type. Dr. Mohan cautioned against implementing complicated policies that would be hard to explain. Dr. Mannon felt it was important to recognize the different effects on different organs rather than having a blanket policy. Dr. Markmann agreed and suggested suspending the 5-tier summaries for this reporting cycle. Dr. Mohan agreed. Mr. Pittman said that due to the unpredictability of COVID-19, he didn't see a benefit in not censoring other extrarenal organs. Dr. Nicholas Salkowski said that censorship decisions could be changed in the future. He also expressed concern about suppression of the tiered simple summaries of the data while continuing to display the more complex granular assessments. Dr. Wey asked to focus on statistical issues today and reserve the Web presentation and tier discussion for the April meeting.

The committee expressed support for different solutions for different organs, recommending also censoring liver outcomes on March 13 rather than carving out the first quarter of the pandemic. Dr. Salkowski noted that this was reasonable since the carve-out would only include two additional weeks of liver transplants, from June 13 to June 30, 2020. Dr. Wey offered the caveat that restarting on June 13 would allow for additional follow-up through December 31, 2020. Dr. Jonah Odim and Ms. Alexandra Glazier were concerned about returning to regular reporting for thoracic organs since that community might disagree, and the thoracic representative on the SRC, Dr. Khush, was unable to attend today's meeting. Dr. Odim expressed favor for returning to normal cohorts of all organs.

Dr. Wey presented the updated options for posttransplant outcomes, including 1) continue censoring on March 13, 2020, 2) censor kidney and liver on March 13 and return to normal for other organs, or 3) resume normal cohorts for all organs. Mr. Orlowski called a vote. The committee unanimously supported option 1, to continue censoring outcomes evaluations on March 13, 2020 for all organs.

Deceased Donor Transplant Rates

Dr. Wey turned next to deceased donor transplant rates. While COVID-19 had affected kidney transplant rates, it didn't appear to have had a nationwide COVID-19 impact on deceased donor transplantation after June 12. In terms of lung, it was difficult to differentiate changes in DSA-level transplant rates before and after COVID-19, as they didn't seem to respond to the pandemic. Dr. Wey presented option A, return to normal cohorts, or option B, carve out the first quarter of the pandemic from March 13, 2020, to June 12, 2020. Under option B, the evaluation cohort would include January 1 to March 12, 2020, and June 13 to December 31, 2020.

Mr. Orlowski called a vote. Mr. Zinner, Mr. Pittman, Dr. Markmann, and Mr. Knight voted for option A. Dr. Mohan, Mr. Logan, Dr. Mannon, and Mr. Orlowski voted for option B. Subsequent discussion ensued to address the tied vote, and Mr. Zinner changed his vote to option B. The final vote was 5-3

in favor of option B, to carve out the first quarter of the pandemic when calculating deceased donor transplant rates.

Waitlist Mortality

Dr. Wey next addressed waitlist mortality rates. COVID-19 continued to affect kidney waitlist mortality rates nationally and geographically. Results were less conclusive for lung, with no national trends observed but evidence of geographic variability remaining. For liver, there were few system- or national-level COVID-19 effects. Dr. Wey proposed an organ-specific solution as follows:

- Kidney: Continue to censor the waitlist mortality cohorts at March 12, 2020. The cohort would include January 1, 2019, to March 12, 2020.
- Liver, lung, heart, pancreas, and intestine: Return to normal cohorts.

Alternative options were to continue censoring for all organs or return to normal cohorts for all organs.

Mr. Orlowski asked those comfortable with the organ specific option to say 'aye.' With no opposition, the committee did not discuss option C or D. Dr. Mannon raised the question of grouping lung with kidney in option A, given continued uncertainty. Dr. Mohan and Mr. Orlowksi agreed that lung should be moved to option A. No one opposed this motion, so lung was combined with kidney. The committee unanimously supported the option to continue censoring kidney and lung cohorts on March 12, 2020, while resuming normal reporting cohorts for liver, heart, pancreas, and intestine.

Offer Acceptance

Dr. Wey moved on to offer acceptance. COVID-19 had affected kidney offer acceptance rates early in the pandemic, but this effect attenuated over time. Heart offer acceptance rates were slightly lower after the emergence of COVID-19, with no obvious trends. The acceptance rates had less-obvious geographic variability. Dr. Wey proposed option A, to return to regular offer acceptance cohorts for each organ, January 1 to December 31, 2020. Option B was to return to regular offer acceptance cohorts for non-kidney organs and carve out the first quarter of the pandemic for kidney transplant, giving an evaluation cohort of January 1 to March 12, 2020, and June 13 to December 31, 2020.

Mr. Orlowski and Dr. Mannon favored option B. Mr. Pittman felt comfortable with an uncensored cohort, because many programs acted in the same way regardless of where the pandemic was currently affecting the system. Ms. Glazier disagreed, noting that not all programs were in the same condition. Mr. Orlowski said that while there were varying impacts, they didn't seem to be regionally attributable, rendering a censoring approach less convincing. Dr. Mohan cautioned against using the supposed absence of geographic variation to make an informed decision. He suggested not making the reports public but rather viewable to individual centers.

Mr. Orlowski asked for a roll call vote. Mr. Orlowski, Dr. Mannon, Mr. Knight, Mr. Pittman, and Mr. Zinner voted for option A. Dr. Logan, Dr. Mohan, and Dr. Markmann voted for option B. Option A passed 5-3 to resume normal reporting cohorts for offer acceptance evaluations.

Closing Business

Dr. Snyder noted that the committee will still need to make a recommendation on the donation metrics before the April meeting of the SRC. SRTR will circle back with HRSA and co-chairs about options to address these items before the April meeting. Dr. Snyder suggested convening the committee for a special meeting before April to conclude this discussion. Hearing no other business, Mr. Orlowski and Dr. Mannon adjourned the meeting at 1:15 PM CST. Pending scheduling an interim special meeting of the committee, the next meeting is scheduled for April 27, 2021.