

SRTR Review Committee Meeting Minutes

Teleconference

January 11, 2022, 10:00 AM – 1:00 PM CST

Voting Members:

Roslyn Mannon, MD (Co-Chair, '23)
Jeffrey Orlowski, MS, CPTC (Co-Chair, '22)
Richard Knight, MBA ('22)
Sumit Mohan, MD, MPH ('22)
James Pittman, RN, MSN ('22)
Kiran Khush, MD, MA, MAS ('23)
Chris Zinner ('23)
Ginny Bumgardner, MD, PhD ('24)
David Vock, PhD ('24)

Ex-Officio Members:

Shannon Dunne, JD (HRSA)
Nicole Turgeon, MD, FACS (OPTN-POC)
Jonah Odum, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)
Rachel Patzer, PhD (OPTN-DAC)

HRSA:

Adriana Martinez

Not in attendance:

Chris McLaughlin
Shannon Tait

SRTR Staff:

Allyson Hart, MD, MS
Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, MD, MS
Bertram Kasiske, MD, FACP
Grace Lyden, PhD
Jon Miller, PhD
Cory Schaffhausen, PhD
Jon Snyder, PhD, MS
David Zaun, MS
Not in attendance:
Peter Stock, MD, PhD
Nicholas Wood, PhD

Mr. Jeffrey Orlowski called the SRTR Review Committee (SRC) meeting to order. All voting members were present. Dr. Jon Snyder reviewed the agenda and welcomed two new voting members:

- David Vock, PhD, Associate Professor of Biostatistics, School of Public Health, University of Minnesota
- Ginny Bumgardner, MD, PhD, Professor of Transplant Surgery, The Ohio State University

Dr. Snyder reviewed conflict of interest management and proceeded with the first agenda item.

Approval of the minutes

Mr. Orlowski welcomed a motion to approve the minutes from November 2, 2021. The minutes were unanimously approved.

Reports from subcommittees

Dr. Allyson Hart, SRTR co-chair of the Patient and Family Affairs Subcommittee (PFAS), reported that the PFAS last met on December 1, 2021, and discussion focused on Task 5 updates, including getting patient feedback about the consensus conference agenda. Mr. Richard Knight, PFAS co-chair, added that there was a productive update on focus group progress, along with discussions on COVID-19's effect on program-specific reports (PSRs). Dr. Hart noted that the PFAS members thought it was important to continue public reporting of transplant and organ procurement organization (OPO) performance during the COVID-19 era, that the carve-out of the first 3 months of the pandemic was understandable given the initial disruption to the transplant and health care system, and that the

current notices on the SRTR website making users aware that the pandemic has affected the nation's transplant system during this reported period were sufficient.

Mr. Chris Zinner, co-chair of the Human-Centered Design Subcommittee (HCDS), said the latest meeting on December 8, 2021, focused on the SRTR Donation and Transplantation Analytics (DATA) tool (a data query system), which will launch on January 12, 2022. The subcommittee also discussed assessing national transplant metrics for the consensus conference and the timeline for making the SRTR website more patient friendly. Mr. Zinner also mentioned the possibility of having a joint meeting with the PFAS in the future. Dr. Cory Schaffhausen, SRTR co-chair of the HCDS, agreed that SRTR needs to help patients navigate SRTR data, and said he hoped for the HCDS to focus on more design concepts for development of a patient-focused SRTR website in the next 6 months to 1 year.

Dr. Jon Snyder, SRTR co-chair of the Analytical Methods Subcommittee (AMS), noted that the subcommittee has not met since the prior SRC meeting. The next meeting of the AMS is scheduled for January 21, 2022. Dr. David Vock replaced Dr. Brent Logan as the new AMS co-chair, and Dr. Logan agreed to remain on the subcommittee. Dr. Snyder noted that the AMS will be resuming discussion of the period-prevalent analytic approach at future meetings, but the upcoming meeting will be devoted to review of recent COVID-19 data and SRTR's development of decision aids, with Dr. Grace Lyden presenting her recent work on patient decision aids at the next AMS meeting.

Review of COVID-19 changes to PSRs/OSRs

Dr. Snyder reviewed previous decisions about how the SRTR's PSRs and OPO-specific reports (OSRs) were modified in response to the COVID-19 pandemic. Updated reports were released on January 6, 2022, which implemented a carve-out of the first 3 months of the pandemic. Transplants prior to March 13, 2020, are not followed beyond March 12, 2020; transplants from March 13 to June 12, 2020, are not assessed for outcomes; and transplants after June 12, 2020, are followed per standard processes. The SRC and its subcommittees had previously approved these modifications since the initial major disruption to the nation's transplant system had largely resolved. These changes were announced on July 6, 2021. Since then, the AMS received two letters opposing the decision, to which the AMS responded as previously approved by the SRC at the November 2021 meeting. Four additional letters, originally sent to the Secretary of Health and Human Services and the Health Resources and Services Administration (HRSA) Division of Transplantation, have since been received for SRC consideration at this meeting.

Resumption of the COVID-19 monitoring application updates

Dr. Snyder noted that both the AMS and the SRC had previously recommended that SRTR resume updates to the COVID-19 monitoring application on the SRTR website, which was also requested in the two prior letters received by the AMS. The tool was initially designed to present 1 year of data prepandemic and 1 year of data postpandemic, with monthly updates. In response to the recommendation to resume updating the tool, Dr. Jon Miller said everything has been updated except for kidney offer acceptance and kidney posttransplant models due to technical complications stemming from the size of the data. Dr. Miller continues to resolve these issues, and any gaps will be noted within the tool. Members agreed with Dr. Miller that it was reasonable to launch an ongoing update to the tool quarterly. Mr. James Pittman and Dr. Sumit Mohan said that many centers may not be aware of the tool. Dr. Mohan suggested having more data on the donation service area (DSA)

level because many centers that end up using the tool may struggle figuring out which data apply to them. On a broader note, Dr. Ryutaro Hirose said it was important for SRTR to be open minded about the data it can and does collect, and which data OPOs and transplant centers are collecting relative to COVID-19 in donors and recipients. There were no objections to relaunching the application with quarterly updates.

COVID-19 deaths in SRTR's PSRs

Dr. Miller presented analyses of two additional scenarios regarding COVID-19 deaths in the PSRs. One was censoring the PSRs at COVID-19–reported deaths: if a patient died of COVID-19, follow-up would stop and the death would not be counted against a center's observed deaths. The second scenario was the effects on PSRs when removing the initial 3-month carve-out. Dr. Miller explained that early in the pandemic, the Organ Procurement and Transplantation Network (OPTN) started adding COVID-19 as a cause of death to their data collection instruments. For each organ, COVID-19 can be noted as a primary or contributing cause of death. Kidney and liver sets also have a code for "Infection Viral- Other Specify" with a text field. Any patient with COVID-19 as their primary or secondary cause of death, or with it noted in the text field, was considered a COVID-19 death.

SRTR data show that as of October 31, 2021, the number of deaths caused by COVID-19 for heart, kidney, liver, and lung recipients is 4318. Most fall under primary cause of death at 4047, with secondary cause of death at 256, and text field at 15. In the Fall 2021 PSR cohort (2.5 years of transplants plus an additional half-year of follow-up), COVID-19 deaths followed the initial COVID-19 surge timeline, starting in March 2020 to the end of the cohort in June 2021. The cohort was also affected by the winter wave in 2020-2021. Dr. Snyder clarified that the death counts presented by Dr. Miller do not implement the carve-out. Dr. Miller reviewed the proportion of COVID-19 deaths by center and noted that these deaths accounted for a relatively small proportion of deaths per center, with none being higher than 21%. Although Dr. Miller mentioned that SRTR compared the sum of the internal analyses to predicted excess deaths from prior work (which were close in number), Dr. Mohan cautioned against using excess deaths since non-COVID-19 mortality dropped in the general population. Dr. Ginny Bumgardner agreed with Dr. Mohan about being cautious in reporting and accuracy of COVID-19 attributable deaths.

Dr. Miller compared the results from an analysis of censoring COVID-19 deaths to the current carve-out. He explained a series of scatter plots representing the hazard ratios (HRs) that are the basis of the Membership and Professional Standards Committee (MPSC) flagging and 5-tier system. The HR for each center was plotted according to the January 2022 PSR, and compared to the censored methodology. Dr. Snyder added that in addition to the censoring, the risk adjustment models were rebuilt for this evaluation. Dr. Miller evaluated the effect on all adult and pediatric kidney, liver, heart, and lung graft failure and patient survival outcomes. Correlation between the two methods was high, with an R^2 of 0.96 and a slope of 1.0. A similar analysis compared the results of the carve-out to what results would have looked like had SRTR not implemented the carve-out. The effect on the HRs was larger, with an R^2 of 0.82 and a slope of 0.89. In addition, to assess whether the current carve-out resulted in bias geographically, SRTR assessed what the PSR would look like without the current carve-out by OPTN region. No biases were evident by OPTN region. Dr. Bumgardner said that making assumptions in terms of causation or solutions from the data was premature based on current knowledge about the virus.

Dr. Miller said that on average, the carve-out was beneficial because the HR tends to increase without it. Dr. Miller then presented an assessment of the effects of censoring at COVID-19 deaths on MPSC flagging and the SRTR 5-tier rankings. For MPSC flagging, 1608 outcomes were looked at for adult and pediatric graft survival for kidney, heart, lung, and liver. The average censoring for COVID-19 would be a net detriment, with four additional centers flagged. If censored, eight flags would be removed with 13 added. The net detriment increased without the carve-out. Dr. Miller presented data on how the COVID-19 incidence by region will roll through the PSR cohorts over time, comparing PSR cohort windows to daily COVID-19 case counts. Dr. Miller noted that given the width of the PSR evaluation window, all areas of the country had experienced waves after the initial carve-out. The carve-out stops follow-up for all patients who underwent transplant prior to the pandemic on March 12, 2020.

Mr. Orlowski observed that most of the regional variation occurred during the carve-out period with variation more significant in some regions. Dr. Roslyn Mannon noted censoring COVID-19 deaths had limited impact in the model provided, and likewise, the carve-out seemed to have limited effect. Dr. Mohan suggested SRTR publish the data so centers are aware of the analysis, and thought censoring deaths was the right way to go. He emphasized that analyses like this are meant to be tools to help centers improve clinical practice, and there needs to be a conversation with centers about what can be improved and what that improvement means.

Dr. Kiran Khush suggested focusing on the transplant enterprise at large (eg, hosting a webinar) instead of addressing centers individually. Dr. Bumgardner repeated what other members had said: COVID-19 data completeness and meaning were two important factors. Dr. David Vock suggested figuring out the goal of the carve-out or any method to handle the impact of COVID-19 on the evaluations, because when outcomes of people who underwent transplant prior to the carve-out are censored, data are reduced and information is lost. Mr. Knight put into question how getting flagged affects a center's number of transplants and discard rates. In addition, he suggested looking at the impact on facilities that primarily do transplants for people of color. Mr. Pittman and Dr. Hirose were cautious on censoring for COVID-19 deaths, citing concern over centers requesting censorship for additional types of death, and the accuracy in adjusting for these. Dr. Jonah Odum said SRTR should present unvarnished data to the public. Dr. Rachel Patzer added that actual data are also important for patients.

Consideration of additional letters

Dr. Snyder highlighted the main ideas presented in the letters from the following facilities and noted that the letters were previously provided to SRC members. The first letter was from Medical City Dallas (heart program). They thought the peak of the carve-out did not affect where they were and, perhaps mistakenly, interpreted the carve-out by worrying that deaths would be counted for patients who survived through the carve-out period. They asked for SRTR to present non-carved-out data for all programs in addition to the carved-out analyses.

The second letter, from UT Health San Antonio, requested that analyses address COVID-19 geographical variation, a possible carve-out extension due to the Delta variant surge, the number of PSR cycles that will affect Centers of Excellence (COE) designations, and what data can be collected to measure the broader impact of COE designation losses.

The third letter, signed by 12 programs in the Southeast United States, requested suspension of reporting until a better assessment is created and shared with the community and consideration of how COVID-19 affected communities of color and the socioeconomically disadvantaged, among other groups. The programs also asked for an assessment of COVID-19 variants, COVID-19 surges varying by geographic location, and fluctuating access to medical services.

The fourth letter, from Dr. Alan Langnas, University of Nebraska Medical Center, reiterated the requests made in previous letters.

Ms. Shannon Dunne mentioned that HRSA did not think the current carve-out period should be extended, and concurred with the 3-month carve-out period. Dr. Bumgardner questioned if data had to be attached to a rating, as opposed to raw data that did not hold centers to MPSC or COE action. Dr. Snyder said that MPSC was aware of SRTR's carve-out method and some members of the MPSC expressed interest in also reviewing the non-carved-out evaluations; MPSC also noted that they will be considering the pandemic in their evaluations. Dr. Allyson Hart added that patients are interested in these data and would like to have the data available as reiterated by the PFAS at their December meeting.

Members discussed courses of action to take. Dr. Mannon suggested a drastic action may be necessary, such as MPSC, COEs, and insurance companies taking a step back from transplant centers for a period. She listed actionable items already mentioned: webinar, data improvement, additional education, and responding to centers. Dr. Hirose suggested finding a balance between public disclosure, transparency, and data being used for internal quality and quality improvement issues.

The members did not recommend altering any previous decision thus far regarding the carve-out. SRTR will continue to evaluate this topic, as well as relaunch the COVID-19 web application. Dr. Snyder noted that SRTR will move to publish the data presented today, stratifying the analyses by organ type, and possibly presenting the scenario where SRTR removes the carve-out and applies the censoring at a COVID-19 death (an analysis that Dr. Miller has completed but did not include in the SRC discussion today due to time constraints and similarity with other findings). HRSA is responding to the two letters addressed to them, and SRTR will respond to the others. The committee agreed on the importance of targeted communication, and Mr. Orłowski suggested staff convening to divide communication tasks so materials could be distributed to the public in the future.

Closing business

With no other business being heard, the meeting concluded. The next meeting is scheduled for April 28, 2022, 10:00 AM – 3:30 PM, CDT.