SRTR Review Committee Meeting Minutes

Teleconference

April 28, 2022, 10:00 AM – 1:00 PM CDT

Voting Members:	**Ex-Officio Members:**	**SRTR Staff:**
Roslyn Mannon, MD (Co-Chair, '23)	Shannon Dunne, JD (HRSA)	Allyson Hart, MD, MS, MD
Jeffrey Orlowski, MS, CPTC (Co-Chair, '22)	Nicole Turgeon, MD, FACS (OPTN-POC)	Ryutaro Hirose, MD
Richard Knight, MBA ('22)	Jonah Odim, MD (NIH)	Larry Hunsicker, MD
Sumit Mohan, MD, MPH ('22)	Darren Stewart, MS (OPTN/UNOS)	Ajay Israni, MD, MS
James Pittman, RN, MSN ('22)	Rachel Patzer, PhD (OPTN-DAC)	Bertram Kasiske, MD, FACP
Chris Zinner ('23)		Grace Lyden, PhD
David Vock, PhD ('24)	**HRSA:**	Jon Miller, PhD
Not in attendance:	**Not in attendance:**	Cory Schaffhausen, PhD
Kiran Khush, MD, MA, MAS ('23)	Adriana Martinez	Jon Snyder, PhD, MS
Ginny Bumgardner, MD, PhD ('24)	Chris McLaughlin	David Zaun, MS
	Shannon Tait	Nicholas Wood, PhD

Dr. Roslyn Mannon called the SRTR Review Committee (SRC) meeting to order. Voting members Drs. Kiran Khush and Ginny Bumgardner were not present. Dr. Mannon reviewed conflict of interest management and proceeded with the first agenda item.

Approval of the minutes

Dr. Mannon welcomed a motion to approve the minutes from January 11, 2022. The minutes were unanimously approved.

Reports from subcommittees

Dr. Allyson Hart, SRTR co-chair of the Patient and Family Affairs Subcommittee (PFAS), reported that at the PFAS meeting on March 9, 2022, patient education materials to be provided in advance of the Task 5 consensus conference were discussed. She also mentioned recruiting more members for the subcommittee, including a living liver donor, a family member of a lung recipient, and pediatric transplant family members through the Starzl Network. Dr. Mannon offered additional contacts as well.

Dr. Cory Schaffhausen, SRTR co-chair of the Human-Centered Design Subcommittee (HCDS), reported that Task 5 consensus conference attendee materials were reviewed at the meeting on March 10, 2022. These included templates to collect data from attendees: "Transplant Patient Journey" and "Transplant System" diagrams. These diagrams highlight the patients as key stakeholders. They are intended to inform patients on the different transplant stages and how various metrics may address information of interest at various stages of the transplant process.

Dr. Mannon asked if these tools could be translated into other languages, and Dr. Schaffhausen said pilot research had been done to translate a new organ offer tool. Mr. Richard Knight added that an

explanation of referral versus listing, as well as referring patients to other resources outside of SRTR, would be helpful. He also said the concepts of metrics need to include qualitative factors (eg, a high kidney donor profile index [KDPI] may dissuade a patient from accepting a kidney but informing the patient of how long that organ may last might elicit a different response). Dr. Ryutaro Hirose suggested adding asterisks to the list of patient questions that cannot currently be answered with SRTR data if there are resources available elsewhere. Dr. Hart said the documents were meant to have a narrow focus on data and not go outside the purview of Task 5, but Dr. Hirose noted that just because certain information is outside the scope of what SRTR does, does not mean it is information SRTR can't help patients get to.

Dr. Jon Snyder, SRTR co-chair of the Analytical Methods Subcommittee (AMS), reported that at the next meeting on April 29, 2022, the organ offer and discard mechanisms within the simulation models and how match run complexity can be considered as a quality to be summarized by the simulations would be discussed. Dr. David Vock, co-chair of the AMS, added that at the last meeting the COVID-19 carve-out was discussed and no changes to the current process were recommended.

Continued monitoring of COVID-19

Dr. Snyder noted that the COVID-19 agenda items were divided into three sections: updates to the COVID-19 application, a manuscript under review regarding COVID-19 carve-outs and an assessment of regional bias, and a response to the letter from the heart program at Medical City Dallas.

COVID-19 monitoring application updates

Dr. Snyder reported that the COVID-19 monitoring application was updated with data through August 21, 2021. Updates through December 2021 will be ready in the next day or so. The application will continue to be updated quarterly. Dr. Snyder reviewed current data from the tool: death referrals to the organ procurement organizations (OPOs) as reported by the OPOs; eligible death referrals; actual number of eligible deaths; deceased kidney donors by brain death or circulatory death (DBD/DCD) status; waitlist mortality rate for kidney, liver, heart, and lung; deceased donor transplant rate for kidney and liver; and transplant counts for all organs.

Dr. Snyder pointed out the expiration of the Organ Procurement and Transplantation Network (OPTN) Policy 1.4.F on April 11, 2022. This policy allowed transplant programs to carry forward laboratory values during the pandemic as to avoid patients coming into the clinic for the purpose of updating waitlist status.

Geographic bias paper under review

Dr. Snyder followed up on the presentation from last January, which focused on the effects of the carve-out period on the program-specific report (PSR) evaluations for posttransplant patient and graft survival. He showed figures included in the manuscript that compared the carve-out versus no carve-out, and the carve-out versus additional censoring at a reported COVID-19 death, overall and by region of the country.

Dr. Snyder asked if the committee wanted to see additional data, or if there were any reasons to change course with the COVID-19 carve out. Dr. Mannon commented that many people questioned

if a carve-out was needed, and thought the SRC implemented one because, at the time, it seemed like the best option. Mr. James Pittman said it was better to be transparent and present data objectively, and asked if the SRC should recommend eliminating the carve-out. Mr. Jeffrey Orlowski supported the initial implementation of the carve-out due to sizable interruption on normal transplant operations in the short term.

Dr. Mannon noted the recent viewpoint article published in the *American Journal of Transplantation* (*AJT*) speculating that the SRTR's carve-out would be biased against certain areas of the country. Dr. Sumit Mohan suggested responding to the two solutions proposed in the viewpoint, which were 1) censoring all data during COVID-19 waves and 2) collecting the data and halting all public reporting until the impact of COVID-19 is more fully understood. Dr. Mohan noted that the SRC likely has responses for each of those suggestions. Dr. Hirose agreed a response was necessary.

Dr. Mannon thought that censoring all data was not reasonable due to ongoing COVID-19 variants, etc. Dr. Vock added that rescinding the carve-out would cause issues. He thought it would be productive for creating specific guidelines for when future data censoring would be implemented (eg, natural disaster, pandemic). Dr. Hirose added that many in the community wanted to extend the carve-out. As discussed in previous SRC meetings, the carve-out is not regionally biased. Ms. Shannon Dunne thanked the committee for their deliberations and supported continuing the current carve-out.

Mr. Orlowski said the carve-out should be kept. He agreed that the SRC should respond to the viewpoint, highlighting that the carve-out will not be rescinded or extended. Mr. Pittman said data should be as objective as possible, reasoning against future potential carve-outs. Dr. Rachel Patzer and Dr. Jonah Odim agreed with Mr. Pittman. Dr. Patzer said the purpose of SRTR data is for patients to make decisions, and to have the most accurate and complete data as possible.

There was a motion to maintain the current carve-out and for an SRC-authored response to the viewpoint in the form of a letter to the editor. Voting members unanimously approved the motion. Mr. Pittman supported the concept that the SRC commit to not repeating these types of carve-outs going forward.

Letter responses

Dr. Snyder said SRTR had drafted a response to the heart transplant team at Medical City Dallas, which was provided to the members in advance of today's meeting. Regional figures showing no regional disparity are included. Voting members voiced no objections to the response to the Medical City Dallas letter, with the exception of Mr. Pittman who abstained.

SRTR/OPTN death ascertainment

Dr. Snyder explained that SRTR's access to death information using the National Technical Information Service's Limited Access Death Master File (LADMF) changed in 2011, with many state restricted deaths removed from the file. This change removed about 4 million records from the death master file (DMF), with an additional estimated 1 million fewer deaths annually.

At that time, the Health Resources and Services Administration (HRSA) worked with the US Department of Health and Human Services (HHS) to establish a process whereby the state restricted deaths could be available to OPTN in partnership with the Centers for Medicare & Medicaid Services (CMS). OPTN began to use data through this process, whereby state restricted deaths are put through an additional verification process, in July 2013. The OPTN death verification process initially focused on deaths that impacted the performance metrics reported in the SRTR PSRs. Most of the cohorts reported in the PSRs are recent cohorts, within the previous 6 years of waitlisting and/or transplanted patients. Over time, as patients become farther out from those PSR reporting cohorts, any deaths received through this process would not be put through the verification process. These accumulated as unverified deaths within the SRTR and OPTN data systems.

In the fall of 2021, SRTR was instructed by HRSA to no longer include unverified state restricted deaths in the publicly available SRTR standard analytic file (SAF) limited dataset made available under a data use agreement (DUA). In response, the United Network for Organ Sharing (UNOS) implemented a new process to put all unverified deaths through the verification process, rather than just the deaths impacting the PSR evaluations. This resulted in 35,000 newly verified deaths within the OPTN data system beginning in March 2022. UNOS put out a press release on April 27, 2022, announcing the addition of deaths to their public files.

SRTR performed data analyses last fall to study the impact of removing the unverified deaths from the publicly available files. In 2021, approximately 29% of the waitlist deaths had a restricted source. About 30% of the posttransplant deaths identified in 2021 fell into this restricted category. Kidney and pancreas were the most affected organs. Deaths are more likely to be in the restricted category if they are beyond the initial PSR evaluation windows, as expected. In addition, the data suggested that restricted deaths are more common in minority populations, particularly the Hispanic population, and more likely in older patients. Finally, the frequency of restricted deaths is differential by state given that the state restricted deaths are differential by state.

Dr. Snyder said this impacted the SRTR SAF releases in September and December of 2021 and was corrected beginning with the March 2022 SAF. Beginning in March 2022, SRTR received updated death verification data from OPTN, resulting in approximately 35,000 additional verified deaths available for inclusion in OPTN standard transplant analysis research (STAR) files (as stated above). There were 28,076 additional deaths added to the SRTR March public SAF. With this new process, restricted deaths have been reduced by 80% among waitlisted candidates, from 50,000 to 11,000. Restricting the analysis to transplant recipients, restricted deaths drop from 25,500 to 4700, also an 80% reduction. SRTR is currently working with OPTN on a joint announcement about the potential effects of these changes.

Dr. Patzer expressed concern over the implication of these changes, and how they affected retrospective analyses research conducted with these data. Dr. Mohan agreed, questioning how reliable the data were if no one knows how the data are coming in or the extent of the missingness. He stressed the need for transparency when communicating this to the public. Mr. Knight also wondered if disparities are greater than currently stated since the missing data are skewed toward minority populations. Mr. Darren Stewart added that for the entire OPTN database of recipients and candidates, there have been 342,000 deaths and only 6.6% (ie, 22,500 or so) were unable to be verified. Dr. Snyder said SRTR is working with OPTN to have a publication that identifies these issues out to the transplant community as soon as possible. Dr. Odim agreed on releasing a detailed

publication with a root cause analysis of the problem and potential solutions. Dr. Vock suggested having documentation on the SRTR website and/or SAFs that go through each of these different sources of death dates and what the assumptions are underlying them in terms of who is reporting, availability, summary measures, etc.

Dr. Mannon added there needs to be a working group within each transplant society working with Data Advisory Committee (DAC) and SRTR contacts to figure this out. All members agreed communication and transparency are vital. Dr. Hirose added there needs to be more transparency about the verification process. Dr. Mannon suggested members take the time to gather their thoughts, then send thoughts on the next steps to her, Mr. Orlowski, and Dr. Snyder.

NASEM report highlights

Dr. Snyder reviewed recommendations from the recent report on improving the nation's organ donation and transplantation system by the National Academies of Sciences, Engineering, and Medicine (NASEM) and potential SRTR actions in response to the report. The first recommendation was that HHS should extend regulatory oversight of organ transplantation starting when a patient reaches end-stage organ failure and extending beyond 1-year posttransplant. Dr. Snyder said there was potential to partner with the United States Renal Data System (USRDS) to study end-stage kidney disease.

The second recommendation was increased transparency for waitlisted candidates, specifically communicating routinely with 1) potential transplant recipients about their status and remaining steps in the process of the transplant evaluation; 2) waitlisted candidates about organs offered to them, including information on the risks and benefits of accepting different organ types; and 3) waitlisted candidates about the number of organs offered and declined. SRTR is currently developing organ offer decision aids under Dr. Schaffhausen.

Reducing kidney discards was the third recommendation, with having a goal for all transplant centers to reduce donated kidney nonuse to 5% or less. SRTR currently reports deceased donor kidney yield and rates of nonuse, as well as organ offer acceptance rate ratios, monitored by the Membership and Professional Standards Committee (MPSC) starting July 2023. The fourth recommendation was increasing minority donation and transplantation rates, in which SRTR can increase reporting of these existing disparities by providing subgroup analyses.

The fifth recommendation was to increase medically complex and DCD donors to at least 45% of all deceased donors. SRTR currently reports the fraction of DCD donors. The next recommendations were increasing offer acceptance and increasing transparency in organ offers. Increasing transparency included requiring transplant centers to share with a patient and their family the number and context of organ offer declines, having more reliable data on reasons organ offers were declined through improving refusal codes, monitoring transplant center performance metrics (SRTR has these new metrics going online this year), creating nudges using reports that show a transplant center's decisions about offered organs, and providing comparisons to other centers.

The next recommendation was creating a dashboard of standardized metrics to track performance and evaluate results in the US organ transplantation system. SRTR has PSRs and OPO-specific reports (OSRs) containing many metrics. The dashboard called for specific metrics such as working

with the National Quality Forum (NQF) to develop consensus measures, and the dashboard should be built on existing OPTN and SRTR measures. The next recommendations included nudging high- and low-performing programs and creating metrics of rating centers based on saving lives, not 1-year graft survival. A potential action of this could involve developing a ranking based on overall survival from the time of listing. The last recommendations were allocating kidneys based on survival benefit and having metrics that go beyond 1-year patient and graft survival, and recommendations for novel and existing measurements (referring organizations and transplant centers, donor hospitals, and OPOs).

Dr. Snyder said he would like to have SRC help strategize and prioritize where SRTR should be focusing its efforts. Dr. Mohan asked if an NQF representative would be at the consensus conference, or if at least there could be a conversation on what it would take to meet NQF criteria as new metrics are discussed. Dr. Hirose agreed this would be beneficial.

Consensus conference planning

Dr. Snyder reviewed current registration targets (professionals, patients, professionals and patients) and registration numbers. As of April 28, 2022, 130 were registered (in person and virtual). SRTR is working with companies interested in supporting patient travel.

Brief updates

Dr. Snyder said that changes were implemented in this PSR cycle to censor heart-alone and lung-alone candidates at the time of heart-lung transplant. Mortality follow-up stops at the time of the heart-lung transplant. In addition, there is debate within the OPTN's OPO Committee about removing the eligible death definition from data collection. Lastly, SRTR is exploring a race-free kidney donor risk index equation (also a NASEM recommendation).

Closing business

With no other business being heard, the meeting concluded. The next meeting is scheduled for August 17, 2022, 12:00 PM – 3:30 PM, CDT.