

SRTR Visiting Committee Minutes

Teleconference

September 2, 2020, 9:00 AM- 3:30 PM CDT

Voting Members:

Ken Newell, MD (Co-Chair)
Jeffrey Orłowski, MS, CPTC (Co-Chair)
Jonathan Chen, MD
Richard Formica, MD
Richard Knight, MBA
Brent Logan, PhD
James Markmann, MD, PhD
Sumit Mohan, MD, MPH
James Pittman, RN, MSN

Ex-Officio Members:

Shannon Dunne, JD (HRSA)
Alexandra Glazier, JD, MPH (OPTN-POC)
Jonah Odim, MD, PhD, MBA (NIH)
Darren Stewart, MS (OPTN/UNOS)

HRSA:

Chris McLaughlin

Guests:

Bob Carrico, PhD (OPTN/UNOS)

SRTR Staff:

Ryutaro Hirose, MD
Larry Hunsicker, MD
Ajay Israni, MD, MS
Bertram Kasiske, MD, FACP
Donald Musgrove, PhD
Caitlyn Nystedt, MPH, PMP
Nicholas Salkowski, PhD
Jon Snyder, PhD, MS
Andrew Wey, PhD

Welcome and Opening Remarks

Dr. Ken Newell called the SRTR Visiting Committee (SVC) to order. Dr. Jon Snyder reminded members about conflict of interest management, and began with the first agenda item.

Adjusted Survival Rates versus Adjusted Hazard Ratios

Dr. Andrew Wey explained that some members of the transplant community considered an unadjusted survival benchmark to be better than an adjusted hazard ratio. However, SRTR was skeptical of the approach because it explicitly motivates risk aversion. Recently, a heart metrics taskforce member pointed out that the clinical implications of a hazard ratio are not clear, and an adjusted survival benchmark could provide a better clinical interpretation without motivating risk aversion. Rescaling metrics presented as hazard ratios into metrics presented on the survival scale could benefit the MPSC and program-specific reports (PSRs), and might help characterize the clinical implications of particular programs' relative outcomes. It could also frame the discussion on MPSC flagging rules, specifically what the flagging threshold of 1.2 means for actual survival. The committee would not vote on the issue, but discussed the feedback.

Dr. Wey used the Ohio State University Medical Center's current posttransplant PSR report to demonstrate adjusted survival percentage, saying that the adjusted hazard ratio would be replaced by the estimated probability of surviving with a functioning graft at 1 year had the program performed transplants in every recipient nationwide. As an approximation, the 1-year survival in the U.S. can be exponentiated by the program's hazard ratio. A more correct calculation in the PSR would require transforming the entire bell curve for the hazard ratio into a bell curve for the survival distribution. Because the calculation had no closed form solution, the distribution would have to be simulated.

Due to the simulation, the probability and credible intervals could change if the simulation was repeated due to Monte Carlo error. The Monte Carlo error may not be tolerable to the transplant

community because, for example, a program could be flagged for MPSC review in one simulation but not a different simulation. Errors could be reduced by running the simulation longer, but may not be practical given reporting time constraints.

A few members asked for clarification of the calculation process. Dr. Brent Logan considered that to transform every patient's prediction, patients had to be averaged to get the right target quantity. Dr. Nick Salkowski explained that individual patients couldn't be transformed since they're either 0 or 1 (deceased or living). Dr. Richard Formica said that it was important to make sure any measurements created were understandable to the average person. Dr. Newell suggested using the same metric for both established survival and hazard ratio to avoid confusion. The differences between the two came down to statistical significance and clinical relevance. He and Dr. Formica agreed that adding a threshold would be beneficial. Mr. Jeff Orłowski said the metrics should be clear and consistent.

Mr. James Pittman proposed implementing the unadjusted survival benchmark, focusing on the performance and organ offer acceptance rate in the practices of the programs. Dr. Ryutaro Hirose said that no adjustments might temper risk-taking behavior, which may be harmful. He cautioned against unadjusted survival as a metric because some programs understand risk adjustment and take on adjusted risk. Ms. Alexandra Glazier and Dr. Newell agreed about individualized metrics for accurate assessments.

Dr. Wey overviewed MPSC flagging rules with programs flagged if they had a 75% probability of a hazard ratio above 1.2. This helped frame discussion of absolute survival difference between overall survival and survival implied by the hazard ratio. Dr. Snyder added that the flagging meant there was 75% certainty the ratio was greater than 1.2. He noted that programs must have an estimated hazard ratio of 1.5 or higher to achieve the 75% probability threshold of being greater than 1.2.

Dr. Formica and Dr. Newell said the metrics highlighted the difference between clinical relevance and statistical significance. Dr. Wey suggested using a certain survival for a given organ to design the flagging system, giving a better idea of what the hazard ratio might be. Dr. Newell agreed. Dr. Formica said whatever metric was chosen should make it easier to explain that SRTR wasn't grading programs against each other, but on how well they treating their patients.

Mr. Logan asked what would be the easiest way to give an acceptable benchmark, suggesting that a program be flagged if it was less than 2% from an overall survival target. Dr. Newell and Dr. Formica proposed letting the community set an acceptable survival benchmark. Dr. Hirose said community input would be valuable, but divided. Mr. Orłowski said it may create complications.

After Dr. Salkowski clarified that the survival benchmark was adjusted, the conversation concluded and Mr. Orłowski transitioned to the next agenda item. SRTR will continue to explore the concept and report back to the committee.

Multiorgan Transplants: LDKI-DDLI

Dr. Salkowski introduced a program's question on whether a simultaneous combined living donor kidney and deceased donor liver transplant was a multi-organ transplant. The current multi-organ transplant definition is based on an organ transplant involving multiple organs from the same donor, with two special exceptions being a living donor liver and living donor kidney transplant on

the same day, or a living donor kidney and deceased donor pancreas transplant within 3 days. There was concern over the definition causing incentives for programs to schedule transplants to qualify as multi-organ for regulatory or public reporting purposes. Dr. Salkowski asked the committee if the definition should be left as is, changed to eliminating special cases, or expanded any time a recipient receives more than one organ type within a specified period of time.

Dr. Newell, Dr. Hirose, Dr. Formica, and Mr. Orlowski agreed that scheduling manipulation was possible, but not probable. Dr. Formica said that policy should not be built based on that behavior. Dr. Hirose asked the committee to consider expanding the special case of a multi-organ transplant into 2 or 3 days for living donor kidney transplants, maybe even 30 days. Dr. Formica suggested going out to 60 days.

Dr. Wey suggested coming back to the committee with additional data to help inform the discussion. Mr. Orlowski and Dr. Newell agreed. Dr. Salkowski thought that a discussion of 30 or 60 days was worthwhile, and the expansion would cover the liver-kidney example. Mr. Orlowski suggested collecting data to consider in the next meeting since making an interim policy wouldn't accomplish much. The committee agreed it wasn't wise to make up policy quickly. The committee decided to tell the program that the current multi-organ transplant definition was still current policy, though an updated one may follow once the committee has the opportunity to consider the matter more carefully.

Heart-Lung Candidates: Inclusion in Heart and Lung Waitlist Metric Cohorts

Dr. Wey outlined that for waiting list models, candidates were listed for the corresponding organ type. An exception to the rule was pancreas candidates who were listed for technical reasons. Under OPTN policy, heart-lung candidates have their own waiting list, and are also recommended to register on the heart and lung lists in addition to the heart-lung list. SRTR received a letter from a program concerned about the negative impact a waitlisted heart-lung candidate death had on waitlist mortality statistics for all three organ types. Because of this, they requested that SRTR remove the heart-lung candidate from the heart and lung PSR waitlist statistics.

SRTR was skeptical of the request, since waitlist models were viewed as intent-to-treat, and were a summary of what clinically becomes of patients who need a specific organ. The request to exclude these candidates from heart and lung models was for administrative reasons rather than clinical ones. Other reasons were kidney-pancreas candidates being in a similar situation and perhaps needing to be changed too, risk-adjustment models taking heart-lung candidates into consideration, and heart-lung reports perhaps requiring revision.

Committee members discussed how much heart-lung deaths affected waitlist statistics in relation to other organs. Dr. Salkowski clarified that these were program-specific reports about programs, not the hospitals. If a transplant hospital had a lung and heart, no death was going to count more than once for each program in the specific report.

However, Dr. Chen pointed out the complexities of a heart-lung transplant, and the likelihood of patients with a high propensity to die on the waiting list counting as a death in three different programs. Dr. Newell agreed. The members briefly compared heart-lung candidates to kidney-liver, and Dr. Newell suggested they should be counted separately.

Dr. Wey transitioned to updating heart-lung reports. SRTR had updated the waitlist and posttransplant models over the past 5 years, but not heart-lung models. Potential solutions were keeping the current cohorts, removing heart-lung candidates from the heart and lung models, revising the heart-lung reports, and/or updating the reports' modeling framework if kept.

Members agreed to remove heart-lung recipients from heart and lung lists, and supported consideration of revising the definition of all multi-organ candidates. Mr. Orłowski reasoned this made the most sense since these transplants ranged from 15-45 a year. Dr. Newell began the vote to remove combined heart and lung recipients from the program statistics for heart and lung independently. There was unanimous support. Dr. Snyder said that the decision would be communicated to the program, and SRTR would begin planning for the change.

Period Prevalent Posttransplant Cohorts: Handling Transferred Patients

Dr. Wey said that in meetings with the MPSC and a heart transplant task force, members asked SRTR how patients would be transferred to a different program after transplant. He gave the example of a patient who underwent transplant at program A moving from New York to California, and posttransplant follow-up transferring to program B in California. SRTR was skeptical of transferring responsibility across programs, because PSRs are intent-to-treat-analyses, meaning outcomes after a transfer would reflect back on the transplanting program. Unintended consequences could include a program being hesitant to accept a patient with a potentially bad outcome. SRTR wanted to avoid incentivizing programs to reject potential transfers. Lastly, current PSRs don't integrate transfer information.

Dr. Wey asked the committee members if they agreed it was not appropriate to integrate posttransplant transfers into the period prevalent cohorts. Dr. Formica opposed the idea of transferring care, since there was already a negative disincentive attributed to responsibility and cost, with taking a patient who already underwent transplant elsewhere. Dr. Sumit Mohan said doing so would hurt patients since the program that performs the transplant has a standing relationship with the patient. Ms. Glazier agreed. Dr. Wey made a motion to vote, seconded by Mr. Pittman. There was universal support for agreeing it wasn't appropriate.

Handling OPO Merges in OPO-specific Reports (OSRs)

Mr. Orłowski asked members to refrain from voting on the following topic if they were conflicted or affected by it. Dr. Snyder introduced Ms. Glazier's organization, New England Donation Services, which has requested approval by CMS to merge the two OPOs MAOB and CTOP into one OPO under the MAOB OPTN code. The DSA served by MAOB would expand to include the CTOP DSA. The discussion's purpose was to consider SRTR's role in evaluating cohorts of donor conversion and donor yield that crossed over the date of the merger.

Ms. Glazier gave an overview of the OPOs and the merger process. The two OPOs came together under an affiliated structure in 2017, New England Donor Services, but remained separately designated OPOs. They achieved their affiliation goals of increasing organ donation and deriving financial efficiencies. The OPOs also saved Medicare about \$4 million in reduced kidney costs in the first 3 years. Ms. Glazier said they were taking the necessary steps to ensure a smooth transition, effective January 1, 2021, if approved by CMS. There could be a 1-year delay if CMS didn't give timely

approval. Seeing that the merger would affect OPO performance data, Ms. Glazier suggested combining the CTOP and MAOB data since they were operating under the affiliation as one organization prior to the merger and the merger is voluntary.

Dr. Snyder added that most of the metrics SRTR reported in the OPO cover a 1- or 2-year period, specifically eligible death conversion rate and donor yield. Donor yield uses a 2-year cohort and would have three consecutive reporting periods where data would overlap with the merger date. SRTR could either transfer all the pre-merger OPO donor data to the post-merger surviving OPO, or consider donor data only after the merger, publishing separate reports of older cohorts until they rolled out of the reports.

Dr. Formica was concerned that rolling pre-merger data of the OPO that is being merged into the post-merger surviving OPO might be a disincentive for an OPO to decide to merge with another lower performing OPO. Dr. Snyder asked if there should be separate policies for voluntary and involuntary mergers.

Mr. Orlowski said the problem was no one knew when the new CMS regulations for OPOs were going happen. He thought that in a voluntary merger, data should be combined as of the merger date but still be available separately from prior to the merger. For a forced merger, data should be kept separate for public reporting for a period of time. Dr. Newell agreed with the latter comment.

Ms. Glazier said that was one possibility to consider. She pointed out that it was important to incentivize voluntary mergers between a lower-performing and higher-performing OPO. A concern was raised that if data were immediately combined, that would be a disincentive to voluntary merger. Any merger generally would take about 3 to 4 years to turn around performance. Dr. Newell reiterated the idea of keeping data separate for involuntary mergers.

Because of the uncertainty of CMS's final rule on OPO performances certification, Mr. Orlowski suggested that for a voluntary merger, historical data should be kept separate, and, moving forward post-merger, the data should be combined. For involuntary mergers, the two DSAs should be kept separate in public reporting indefinitely. Dr. Formica considered merging OPOs to have a window of time to declare that they are ready for a data merge. Mr. Orlowski agreed, and changed his suggestion to giving OPOs a voluntary choice of when to start merging the data, up to a reasonable sunset period.

Dr. Snyder added that the MAOB and CTOP merger wouldn't start affecting the reports until summer 2021. He suggested a future discussion of how to handle involuntary mergers. There was a motion to vote, seconded by Dr. Newell. Mr. Orlowski called the motion of merging the CTOP and MAOB reports going forward for the public reporting purposes as of the date of the merger. If the merger occurred January 1, 2021, as planned, the first cycle that affected reports would be summer 2021. All present voting members were supportive.

Updated SRTR Website

Dr. Snyder gave a live demo of the new interactive format for PSRs and OSRs. The new website was planned for launch in a few weeks. The OPO statistics are displayed as an interactive map with hovering features displaying the organization name of the OPO serving the area. OPO statistics

could be compared in the boxes below that section. Users could click on individual states for detailed information such as counties in the OPO's DSA, density and death rates, donor characteristics and trends, eligible death donation rate by organ, and organ yield with MPSC metrics. All data have improved graphic display and interactivity. Users have the options of printing and downloading data.

Mr. Orlowski approved of the changes. Dr. Jonah Odim suggested implementing conversion rates at different OPOs, discard rates, and infectious disease organ characteristics. Dr. Snyder replied that SRTR planned to add data in the future. Members discussed the importance of discard rates, particularly where and how discards occur relative to allocation changes. Dr. Hirose added that it was important to factor in system metrics instead of regulatory ones for quality purposes.

Dr. Snyder then reviewed transplant center data. Users could view a transplant center's adult and pediatric data by organ type. Data include transplant summaries and four tabs that follow the flow of the transplant process. The waitlist overview tab contains candidate numbers on the waiting list from the past year, reasons for removal, time to transplant percentiles, candidate characteristics, and four pretransplant metrics. The offer acceptance practices tab has an offer acceptance rate ratio comparing a center to the national distribution. For transplant procedures, users could see the donor type, demographics, and medical and transplant characteristics. Under the posttransplant outcomes tab, recipient, time frame, donor type, and survival results are interactive variables for viewing different outcomes.

The committee was happy with these improvements. Dr. Odim suggested factoring cost into the reports, which was an avenue SRTR would explore further. SRTR plans to track activity on the pages to understand what information patients want. The target launch data is September 16, 2020.

Update on COVID-19 and SRTR

Dr. Wey told the committee that SRTR has received questions about implementation of the censoring in response to the COVID pandemic, and concerns about the impact removing follow-up would have on small programs. At this time, SRTR will implement the censoring on March 12, 2020, for the January 2021 PSR cycle, but does not currently have a longer-term solution. The COVID-19 evaluation application reviewed at the last SVC meeting was approved by HRSA, and SRTR planned to post it to the website next week. SRTR is investigating the feasibility of adjusting for county-level incidence to see if it mitigates the effect of geographic variability of the pandemic on SRTR performance metrics.

Dr. Formica asked how SRTR planned to factor in major regional virus fluctuations in the evaluations. Dr. Wey explained that county incidence changed weekly, so SRTR was considering whether the effect changed over time. Ms. Glazier asked how this would affect OPOs, and Dr. Wey didn't have a clear answer at this time as investigations are ongoing. Dr. Newell questioned the accuracy of measuring county-level data of the county of the transplant program due to the geographic variation across even nearby counties. Dr. Formica said that from a clinical context, patients moved between counties and became infected in different places. Dr. Mohan added that COVID-19 testing was another difficult variable. Dr. Hirose said that measuring by county was too limited a geographic option to consider, and it was important to define adjusting for geographical

differences in COVID-19 death rates or incidences. Dr. Newell said the adjustment might be impossible to do since many hospitals decided there would be no transplants, regardless of what COVID-19 was doing, affecting OPOs and organ donors.

Mr. Orłowski thought that the incidence of COVID-19 by county only scratched the surface of understanding the complexities. It would be difficult to model. By trying to create accurate and ineffective adjustment, SRTR could unintentionally create a false impression of the pandemic's impact. Dr. Newell, Dr. Odum, and Dr. Formica agreed. Dr. Snyder suggested continuing the analysis to see what the data will show, but Dr. Newell said it was not worth the effort if it will result in inaccurate results. Ms. Glazier and Dr. Mohan agreed. Dr. Hirose's suggestion of using unadjusted data was dismissed, as was Dr. Wey's proposal to do an empirical investigation. Dr. Newell and Ms. Glazier agreed it was beneficial to decide what criteria were needed to resume normal reporting.

The final recommendation of the committee was that performance metrics should not be reported now or in the future for the COVID-19 pandemic era, beginning March 12, 2020, going forward until normal reporting could resume. Raw trend data such as transplants and organ donations would be reported. The recommendation by the committee was unanimous.

Update on AHRQ grant

Dr. Ajay Israni gave an update on the current AHRQ clinical trial, which focused on comparing the SRTR website with the AHRQ website that allowed patients to find transplant centers for their needs. COVID-19 hampered the trial, changing it from in-person to virtual. iPads were purchased for patients who didn't have an electronic device to access report cards.

Dr. Warren McKinney presented on his learning health systems project. He started postdoctoral training in the nephrology division, transitioning to investigator and faculty member in January. Dr. McKinney is a sociologist by training with research interest in race and ethnic studies in healthcare disparities.

His project focused on educating African American kidney patients on hepatitis C virus (HCV)+ kidney transplants. Goals included improving patient education and consultation on HCV+ donor options locally, and increasing kidney transplant opportunities for African Americans. His research aims were to determine which program characteristics related to HCV+ donors and patient willingness to accept this kind of transplant, and to develop a web decision tool to reduce aversion to HCV+ donor kidneys. Dr. Warren presented data on kidney transplants by race, and HCV+ kidney donor trends.

The committee approved of the project and gave feedback. Dr. Formica said it was important to distinguish between antibody positivity alone and antibody positive and NAT+. Dr. Mohan advised to check with providers on kidney acceptance policy since many centers were still unwilling to use HCV+ kidneys. Mr. Richard Knight said the research could help explore how involved patients were in the rejection and acceptance process.

Living donor collective update

Dr. Bertram Kasiske updated the committee on the LDC project, which was going forward regardless of who HRSA chose as the new SRTR contractor. The two manuscripts in preparation contained data

through March 12, 2020, and would be submitted before the end of September. Dr. Kasiske said the project was a success, and they were seeking the participation of all living donor programs and would be working with the OPTN living donor committee.

Closing Business

SRTR Contract and SVC

Dr. Snyder noted that this was the last SVC meeting, with the new SRTR contract period starting on September 21, 2020. HRSA changed the SVC title to the SRTR Review Committee (SRC). If HHRI was chosen as the new contractor, current membership would remain. The three outgoing members (Dr. Newell, Dr. Formica, Dr. Jonathan Chen) would be replaced at the start of 2021. If HHRI was not chosen, the new contractor could keep or change the current membership. The ex-officio positions would remain, with an added ex-officio position of Chair of the OPTN Data Advisory Committee. The new contract stipulated that the two in-person meetings would take place in the D.C. area. Members would also have to sign a conflict of interest document annually.

Next Meeting

The next teleconference meeting was not yet scheduled pending HRSA's contracting decision, but would likely take place in January-February 2021. With no further business, the meeting concluded.