

SRTR Visiting Committee Minutes

Teleconference

April 14, 2020, 9:00 AM- 3:00 PM EDT

Voting Members:

Ken Newell, MD (Co-Chair)
Jeffrey Orlowski, 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 Odum, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)

HRSA:

Chris McLaughlin

Guests:

Bob Carrico, PhD (OPTN/UNOS)
Cory Schaffhausen, PhD (HHRI)

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

The SRTR Visiting Committee (SVC) meeting was called to order by Co-Chair Jeffrey Orlowski. Mr. Orlowski welcomed members and guests and conducted a roll call for voting and ex-officio members. Dr. Jon Snyder reminded members about conflicts of interest management and gave an overview of the agenda. Mr. Orlowski and Dr. Kenneth Newell commenced with the agenda.

Implementation Plan of Period Prevalent/Long-Term Posttransplant Outcome Evaluations

The first item discussed was the implementation plan for period prevalent cohorts. Dr. Andrew Wey overviewed the proposal from the October 2019 meeting, which suggested replacing incident cohorts with period prevalent cohorts for the primary posttransplant outcomes evaluations. Dr. Wey demonstrated that period prevalent cohorts enable estimation of long-term outcomes by including patients who underwent transplant prior to the evaluation window but had follow-up time during the evaluation window. Dr. Wey assessed the impact of different widths of the period prevalent evaluation window (6, 12, ... ,30 months) and different lengths of posttransplant follow-up (1, 3, and 5 years). Results suggested that evaluations with longer follow-up, i.e., 5 years vs. 1 year, and wider evaluation windows, e.g., 30 months vs. 6 months, had stronger associations with subsequent transplant recipient outcomes.

Dr. Wey sought committee feedback on whether recipient follow-up should be censored at the last available posttransplant follow-up form. To investigate the possibility of surveillance bias for graft and patient survival, using what would be the period prevalent cohort for the summer 2019 PSR cycle, Dr. Wey assessed how often deaths or graft failures were delayed and reported after the anniversary of the next follow-up form. The analyses for individual organs showed that most programs report the number of events in their cohorts on time, with the exception of kidney recipients. Events were missed because programs were unaware of graft status changes until the next follow-up form was due. Dr. Wey proposed that the period prevalent posttransplant evaluations censor at the date the last transplant follow up form was due to ensure better data quality.

Some members asked for clarification of the effects of implementing censoring at the follow-up anniversary date and SRTR's current process. Dr. Wey clarified that the alternative to the proposed censoring methodology was to continue follow-up after the last transplant follow-up form was due. He confirmed that if a status change was discovered after the due date, it could not be corrected for that cycle, but would be reflected in future

PSRs. Dr. Nicholas Salkowski added that SRTR currently applies administrative censoring only at the end-of-follow-up with exception for lung recipients. Currently, lungs are the only organs censored at the last available patient follow-up form or graft/patient status report.

Dr. Brent Logan concurred that censoring was necessary to avoid bias if there was variation in timely reporting across programs. Mr. Orłowski agreed that censoring at the last follow-up form created consistency. Dr. Newell made a motion to censor at the time of the last follow-up. The motion was seconded. The motion passed unanimously.

Dr. Wey then sought the committee's guidance on whether the period prevalent assessments of patient survival should exclude re-transplants, similar to how re-transplants are excluded from current posttransplant patient survival evaluations. Dr. Wey proposed a compromise of including the re-transplant event in the period prevalent evaluation once follow-up for the original transplant within the period-prevalent window ended. Dr. Newell said the compromise was reasonable. There was brief discussion followed by a motion for the compromise, seconded by Dr. Newell. The motion to include re-transplants once the primary transplant was no longer within the period-prevalent window passed unanimously.

Next, Dr. Wey outlined the plan to incorporate period prevalent outcome evaluations in the PSRs. He proposed replacing calculations of the 3-year evaluation with a 5-year evaluation. Most committee members had a favorable opinion of the 5-year evaluation though there were a few concerns. Dr. Snyder said that changing metrics in the PSRs can often cause complaints, e.g., insurance providers that currently review the 3-year outcomes. Dr. Mohan questioned whether data quality would deteriorate with the longer-term evaluations and whether transplant centers would lose patients to follow-up. Dr. Salkowski noted that SRTR does search other sources for deaths. Members agreed that the benefits of focusing on long-term survival outcomes outweighed foreseen drawbacks. Dr. Newell made the motion to replace the 3-year evaluation with the 5-year evaluation, seconded by Mr. James Pittman. The motion passed unanimously.

Next, Dr. Wey sought the committee's guidance on whether a 5-tier assessment based on 5-year outcomes should potentially replace the current 5-tier assessment based on first-year outcomes. Dr. Mohan opposed posting a 5-tier assessment for 5-year outcomes on the website as he felt it discouraged performing higher-risk transplants, and he feared confidence intervals would be wider than those for first-year evaluations. Dr. Salkowski and Dr. Wey explained that the confidence intervals would become narrower and that 5-year evaluations predict future outcomes better than 1-year evaluations. Dr. Mohan feared the data would encourage centers to deprioritize the oldest patients and reiterated his opposition to replacing the current 5-tier evaluation based on 1-year outcomes with a 5-tier evaluation based on 5-year outcomes. Dr. Formica agreed.

Dr. Snyder suggested tabling the discussion as it was perhaps premature given that the committee will also be asked to consider replacing all tier evaluations with a tier based on overall survival from listing. Both Dr. Newell and Mr. Richard Knight felt that a 5-year tier was more effective and helpful to patients. Mr. Knight said that patients are more interested in longer-term data. Members agreed that information was insufficient for a decision, and they would table the discussion for now.

Dr. Wey noted that CUSUMs would continue to be based on 1-year posttransplant patient and graft survival.

Because of the proposal to transition to a 2-year cohort to align with current OPTN bylaws enforced by the Membership and Professional Standards Committee (MPSC), SRTR will reach out to MPSC leadership about these changes. A tentative timeline for changes includes: SVC/HRSA approval in April 2020, and discussion with MPSC about changes in April/May 2020. A public announcement of the transition to period prevalent cohorts and longer posttransplant evaluations would follow HRSA approval. Model building to support the period prevalent evaluations is expected to be completed in summer 2021. Integration into the PSRs will take place fall/winter 2021. Members agreed the timeline seemed reasonable, but anticipated future adjustments because

OPTN may need to modify the bylaws. The SVC supported transitioning the posttransplant models into a period prevalent cohort.

COVID-19: Impact on the System and the PSRs/OSRs

Committee members shared their COVID-19 experiences and insights. Mr. Orlowksi said that OPO challenges included a decrease in viable referrals, referral types of disproportionately patients with underlying health problems, and varying ability to pursue donors due to strained hospital resources. The placement rate decreased with fewer DCD donors than normal. Yield was off by 10%-15% of organs for transplant, mainly thoracic.

Ms. Alexandra Glazier reported that her group was able to continue clinical activity for organ donation at normal rates through early March. An extreme drop in late March was brought on by COVID-19+ referrals, which constituted approximately 40% of referrals in the New England region. Organ donation potential dropped 50% in the 3 weeks that followed, with zero DCDs since mid-March. Organ transplants were still occurring, with numerous organs going to the New York area. Ms. Glazier was concerned that data and analysis from the COVID period would not be accurately reported, particularly on death certificates. She was interested in how the pandemic would influence discussions of evaluating OPO performance. She was also concerned that post-COVID-19, an even greater supply-demand problem would occur, as transplant candidates may be forced to wait out the pandemic, while donors missed during the pandemic cannot be deferred to the post-COVID era.

Dr. Formica remarked that Yale was currently using operating rooms for ICUs. The hospital mandated that only urgent transplants be performed, and staff had become more selective with donors and recipients. The nursing staff had been stretched. Their acceptance and transplant rates had decreased significantly, and there may not be a return to operations until June.

Ms. Glazier commented on the importance of encouraging programs not overly affected by COVID-19 to continue exporting organs and performing surgeries. However, other participants disagreed, reasoning it was better to not overwhelm the system and to prioritize minimizing patients' exposure to COVID-19. Members agreed that it is imperative for SRTR to evaluate the impact of the pandemic on the nation's transplant system to evaluate what changes may need to be made to future program- and OPO-specific reports.

Dr. Wey presented SRTR's evaluation plan for COVID-19, which focuses on quantifying the effect COVID-19 has on performance metrics in the PSRs and OSRs. Initial analyses will focus on metric differences before and after COVID-19, followed by analyzing whether regional variability occurred at the OPO and program levels. Dr. Snyder added that if too much geographical variability was present in the data, the "COVID-19 era" could be excluded from future performance metrics.

Dr. Ajay Israni felt it would be beneficial to consider how COVID-19 affected minorities. Dr. Ryutaro Hirose added potential comparisons of insurance status, and public versus private payers. He felt that adding these would help sort out the effects of transplant rates, waitlist mortality, and other outcomes.

Dr. Wey said that SRTR planned to develop a web-based application that could be updated regularly. The committee was supportive of SRTR's plans to evaluate the impact of the pandemic on the nation's transplant system.

Patient Mortality after Listing: Feedback and Long-Term Plan

Dr. Wey overviewed the patient mortality after listing metric. The evaluations are currently being previewed on the SRTR secure site. SRTR had received a few clarifying questions about the methodology during the preview, but has yet to receive any feedback. Participants discussed why this was, despite announcements on the secure site, announcements through the SRTR social media channels, and direct notifications to all users of the secure

site. Dr. Markman and Dr. Mohan said that contacting program directors directly may yield better results. Dr. Snyder was surprised at the lack of feedback, and said the plan was to bring feedback to the committee though not much was received.

Dr. Wey explained that patient mortality following listing combines both pretransplant and posttransplant outcomes. The long-term plan for patient mortality after listing is inclusion in the PSRs and supplementing or replacing the current tiers on the SRTR website with a 5-tier system of the overall patient mortality after listing metric. Dr. Wey proposed three analyses for understanding the 5-tier system for patient mortality after listing: the distribution of programs in a 5-tier system, the stability and volatility of program-specific 5-tier assessments over time, and the association of 5-tier assessments at listing with subsequent outcomes after listing.

Various members voiced concern that the metric may unintentionally be interpreted as measuring program quality. Others questioned how patients would use this information. Mr. Knight said the information was helpful for patients to decide where they wanted to receive treatment. Dr. Wey added that Dr. Cory Schaffhausen offered to collect patient feedback through web-based usability testing.

A concern of the committee was whether geography or transplant center behavior would influence the metric. Dr. Mohan opposed the metric as it would be influenced by geography. He proposed a modification looking at patient mortality from the time of the first declined organ offer. Dr. Mohan also suggested separating geographical and behavioral aspects of system performance. Dr. Wey and Dr. Salkowski disagreed, noting that the metric was meant to help patients make informed decisions about transplant centers, regardless of whether it was due to geographic location or program performance. They emphasized that the metric did not create geographic disparities, but reflected them. The metric was not meant to solely measure a transplant center's performance, but to measure the outcomes of patients on the program's transplant waiting list.

Other members cautioned that Dr. Mohan may be looking at the matter from his own perspective, rather than from a patient's viewpoint. A suggestion was made to adjust for regional factors, i.e., geography, in order to remove the effect of geographic disparities and organ supply, but other members thought this would only reduce the utility of the metric for patients. Dr. Snyder said that the purpose of the metric was to combine numerous aspects of system performance into one metric of importance to patients in an effort to make the data more accessible to patients.

The survival-from-listing metrics will be in the public report starting with the July 2020 reporting cycle. SRTR will continue development of the tier system based on this metric for future consideration by the visiting committee. The committee agreed with this plan and will review additional data at the next meeting.

Evaluation Plan for the Acuity Circles Liver Policy

Acuity circles for liver allocation were implemented on February 4, 2020. Though evaluations are arguably premature, SRTR aims to outline metrics for evaluation, develop an updateable report on the effect of the policy, and post the report on the SRTR website. SRTR is evaluating how to correctly factor in the effects of COVID-19 on evaluation. For the primary adjusted analyses, SRTR plans to stop the evaluation on March 12, the day prior to the declaration of the national emergency. SRTR will continue to report descriptive statistics after that point. Acuity circle evaluation consists of three sections: waitlist metrics, liver utilization, and transplant characteristics. Analyses will include both descriptive statistics and inferential difference-in-differences analyses. An interactive draft report is active and Dr. Wey walked the committee through the initial results. Dr. Snyder commented that the goal is to have data readily available while the community debates the effectiveness of the policy. Mr. Orłowski approved of the start, though the data are preliminary due to COVID-19. He approved of the presentation approach, finding it interesting and informative from an OPTN perspective.

Update: Patient-Centered Research Projects

Dr. Israni gave an update on AHRQ work for creating a patient-centered search and decision aid. The website is complete with usability tests done. The liver transplant decision aid is now live online. The aid was also featured in *Liver Transplantation* as the cover article. Another article is pending acceptance. Dr. Israni gave an overview of navigation tools for the decision aid website, and the type of information it provides. It shows transplant metrics similar to the SRTR website, tailored to the candidate's profile. The next step is to conduct a trial to test the decision aid in summer 2020. It will randomize patients at Hennepin Healthcare and the University of Minnesota-Fairview. Subjects will be screened by testing their knowledge about a hypothetical scenario (age and BMI). Those that answer the questions correctly will be randomized. There will be 288 transplant candidates, with a focus on kidney and liver candidates first, then heart and lung. The randomization scheme will consist of 36 subjects per organ type randomized to see the AHRQ website first or the SRTR site first. The two groups of 18 will be asked a question regarding BMI or age, with 30 minutes to view the website. Age may vary, depending on the organ type. A five-point Likert scale will gauge how useful subjects perceived the information to be, and the Ottawa Decisional Conflict Scale will assess their decision-making process.

Dr. Schaffhausen reviewed his work aimed at preparing liver candidates for an organ offer decision. His objective is to create a tool where patients can experience the donor offer process. Dr. Schaffhausen is currently putting together a manuscript that summarizes AASLD focus group results from November 2019. Results involve the need for continuing patient education of the transplant process. Between January and April 2020, a graphic designer created PDF mockups of the tool. University of Minnesota clinicians and coordinators gave feedback. Dr. Schaffhausen overviewed the tool. From April to December 2020, they will recruit liver transplant patients for remote feedback, and begin the working prototype website. He then showed three mockup PDFs.

Mr. Orłowski commented that the tool seemed intuitive and easy to understand. He asked how the tool would address changing offer types. Dr. Schaffhausen responded that the tool overviewed how a patient's priority changes based on MELD score, and how the change in priority determines how a patient gets a match. Dr. Snyder said that the project was a result of SRTR wanting to understand how and what information patients looked for when researching transplant programs.

SRTR Living Donor Collective Update

Dr. Bert Kasiske gave an update on the Living Donor Collective pilot project. He overviewed the project's timeline from 2015 when HRSA asked SRTR to conduct a feasibility study, up until September 2019 when all 10 pilot LDC sites were operational. The LDC Data Collection included candidates who came to transplant centers to determine organ donation eligibility. The number of suitable candidates varied by center. SRTR will use survey and data linkages to follow candidates and donors. Of the 10 LDC pilot sites, six were kidney and liver programs, four were kidney-only. The LDC is currently updating its database with March 13 as the cutoff date.

As of September 2019, 1,553 donor candidates had been registered. Almost all registered donor candidates had completed registration. About half went on to the decision to donate, and half of those were approved to donate. Four hundred donor candidates did not donate, citing various medical reasons. The average time from registration to decision was 132 days. Donation was approved, but ultimately unnecessary for 6% of donor candidates, a group that could be used as an ideal control group for future analyses.

Dr. Kasiske said they would finalize data analyses and provide a final report to HRSA in June. HRSA will decide whether to continue the Living Donor Collective into the next contract period. Dr. Kasiske felt the pilot was a success. Ideally, he would like all living donor programs to participate in the LDC. Incentives that may increase participation include providing more information on risks and outcomes to candidates, and providing process

comparisons across programs. Providing follow-up information on donors may be helpful. Dr. Kasiske also suggested that the LDC assisting programs with data collection may reduce the burden on the transplant programs. Mr. Pittman suggested the potential for partnership with Quest and/or LabCorp if the LDC was to attempt collection of laboratory data. Committee members remarked how the LDC was good for the field of living organ donation.

Brief Updates

Dr. Snyder had two items to update the committee on in follow-up to the previous meeting. The committee previously discussed specific adjustments for patients with hilar cholangiocarcinoma (CCA) in risk adjustment models for liver. It was the committee's recommendation not to modify the risk adjustment models at this time. SRTR analyses demonstrated that specific adjustment for CCA patients did not affect risk adjustment models for living donor liver transplant. There was a risk in the deceased donor transplant model. The committee recommended not to call those patients out separately at this time. Though the program did request reconsideration, the co-chairs reviewed the issue with Drs. Markmann, Hirose, Lake, and Kim and recommended not bringing the issue back to the full committee for review. In the future, liver models will be rebuilt, at which time this issue will be reconsidered.

At the last meeting, the committee supported a website change in response to a complaint from the lung program at NYU Langone Health. SRTR made the change to the website the day after the last meeting. The change is still in effect. The facility expressed disappointment that more action wasn't taken.

Dr. Snyder appreciated the debate and participation in today's virtual meeting. He wanted the committee to understand SRTR aims to continually improve the metrics. He approved of where the recommendations were heading.

Closing Business

Hearing no other business, the meeting concluded at 3:00 PM. The next meeting is scheduled via teleconference for July 7, 2020, from 9am-12pm CDT.