

Minutes

SRTR Visiting Committee

Date: April 18, 2018

Time: 9:00 AM-3:00 EDT

First of Two Required Annual In-person Meetings

Voting Members:

Susan Gunderson, MHA (Co-Chair)
Ken Newell, MD, PhD (Co-Chair)
Scott Biggins, MD, MAS
Jonathan Chen, MD (via phone)
Richard Formica, MD
Bethany Foster, MD, MSCE
Walter Kremers, PhD
Rachel Patzer, PhD
Luke Preczewski

Ex-Officio Members:

Monica Lin, PhD (HRSA)
Jennifer Milton, MBA (OPTN-POC)
Jonah Odum, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)

Guests:

Janet Kuramoto-Crawford (HRSA)
Cory Schaffhausen, PhD (MMRF)
Sara Taranto (OPTN/UNOS)

SRTR:

Katie Audette, MS (via phone)
Allyson Hart, MD, MS (via phone)
Alyssa Herreid, MPH (via phone)
Larry Hunsiker, MD (via phone)
Bertram Kasiske, MD
Ajay Israni, MD, MS
Jon Snyder, PhD, MS
Laura Klein, MPH
Andrew Wey, PhD
Nicholas Salkowski, PhD
Mona Shater, MA (via phone)
Bryn Thompson, MPH (via phone)
David Zaun, MS (via phone)

Welcome & Introductions

Co-Chair Susan Gunderson called the meeting to order at 9:05 AM EDT.

Ms. Gunderson roll-called the participants. All voting members of the committee were present. Jennifer Milton disclosed a potential conflict, her connection to XynManagement. Non-voting members and guests also introduced themselves.

Dr. Bert Kasiske informed the committee regarding conflicts of interest (COIs). Dr. Kasiske emphasized that SRTR must ensure management of any potential conflicts, and asked committee members to bring forward any potential COIs during deliberations and recuse themselves from related discussions.

SRTR Website Search Results (Slides 9-102)

Dr. Jon Snyder noted that this portion of the meeting would be focused on reviewing the history of the 5-tier system and the current rendition of the website search results that were shown to the committee at the January meeting. This would be followed by discussion of recommended changes from Drs. Ajay Israni and Cory Schaffhausen's Agency for Healthcare Research and Quality (AHRQ) work and the plan to make the changes to the beta site to gather feedback from the public.

Dr. Snyder started the presentation by discussing SRTR's contractual obligation to provide public evaluations of transplant program performance. He then outlined the 5-tier system development timeline, the limitations of the 3-tier system, and the reasons for moving from the 3-tier system to

the 5-tier system. SRTR used AHRQ's best practices in public reporting to develop the 5 tiers. Program differences between the 3-tier and 5-tier systems were highlighted.

Dr. Snyder outlined common themes in the feedback SRTR received regarding the 5-tier system, and described resulting revisions and responses. Committee members discussed whether 1-year outcomes are the best metric to inform patients, whether absolute differences should be presented instead of hazard ratios, whether emphasis should be placed on posttransplant outcomes when transplant rate is more important, and whether outcomes should be ordered based on importance. A question was raised regarding whether adult programs that serve few pediatric patients, and pediatric programs that serve few adults, should be excluded, as well as programs that have closed but have survival cohorts. Ms. Milton recommended that these programs should be excluded if this tool is meant to inform patients. There was also a comment about reliability, wondering whether we can reliability detect quality differences between programs that frequently move between tiers.

Dr. Andrew Wey presented on the predictive ability of the 5-tier system. Much of this work was completed in response to a paper by Jesse Schold et al. that was critical of the 5-tier system due to variability in tier assignment over time compared with the 3-tier system. Dr. Walter Kremers expressed the belief that the Schold paper failed to critically evaluate the 5-tier system.

Dr. Wey discussed the association of posttransplant evaluations at listing with posttransplant outcomes. The effect of a 1-tier difference on eventual 1-year posttransplant graft survival was a 4% reduction in risk for kidney, 7% for liver, 10% for lung, and no difference for heart, regardless of the length of waiting time. Dr. Wey concluded that while the association with eventual posttransplant outcomes is interesting, it may not be relevant to many candidates because they may never undergo transplant. Discussion included recognition that timeframes after listing used in the analysis might not be appropriate for kidney transplant since waiting times are much longer than for other organs. There was a recommendation that kidney candidates be educated to recheck the tiers.

Dr. Wey then presented on the associations of waitlist mortality, transplant rate, and posttransplant outcomes with candidate mortality after listing. For kidney, liver, and heart, transplant rate had the strongest association with candidate mortality after listing. For lung, posttransplant graft survival had the strongest association with candidate mortality after listing.

Dr. Wey went on to discuss use of this information for public reporting. He noted that the associations with candidate mortality after listing are more important than eventual posttransplant survival, so candidates should be guided to these metrics as they have the strongest associations, i.e., transplant rate evaluation for kidney, liver, and heart transplantation and posttransplant graft survival for lung transplantation.

Dr. Snyder presented the effect of the tiers on prospective risk of death following listing (slide 85). The committee believed that this was a better way of presenting information to the public. Dr. Snyder noted that on the beta site for public comment, SRTR wants to include tiers for transplant rate, waitlist mortality, and 1-year graft survival, and to be able to tell patients what is most relevant to their overall survival if they list at a program. A recommendation was made to consider development of a weighted composite metric that takes into account multiple metrics.

Dr. Schaffhausen gave an overview of the results of his most recent AHRQ-funded randomized survey that tested the following three concepts:

- 1) National data table: typical results for each tier

- 2) Indicating which metric most impacts survival
- 3) Uncertainty disclaimer

In the survey, Drs. Schaffhausen and Israni used a factorial design in which they added one or more of the concepts to the mock-up presented to survey participants, who then answered five questions. They found that when the “impact note” was included in the mock-up to indicate that transplant rate has the highest impact on survival, more participants chose the program with the highest transplant rate. Dr. Schaffhausen noted that Dr. Israni had presented the impact note to OPTN’s Patient Advisory Committee (PAC), which voted unanimously to move it forward.

Dr. Schaffhausen then described the proposed changes to the beta site, which include moving the description of the column heading to the top to decrease the distance between the heading and the results. The disclaimer statement was present at the bottom of the program results. The site also includes the impact note icon, which depends on the organ and will be viewable at all times. The national table would also be accessible by clicking on a button at the top. During discussion, a recommendation was made to consider providing a “summary” composite score in the future, and to continue revising the language in the national data table to be understandable by the public.

Dr. Snyder asked for the committee’s support in implementing these website changes on the beta site and opening a 60-day public comment period to obtain feedback. He outlined the communications plan and timeline for implementing the changes and soliciting feedback (slides 99-101). The feedback would be reviewed at the next SVC meeting, July 16, 2018. During discussions, the following recommendations were made:

- 1) Exclude closed programs from the analyses before launch (SRTR staff indicated that this may be difficult to define given current OPTN data collection, but will investigate options);
- 2) Present to the councils of the AST and ASTS to inform them of the changes;
- 3) Provide a document detailing the changes for program administrators at the time of the announcement; and
- 4) Include documentation on the website that outlines SRTR responses (e.g., data, publications, etc.) to the feedback previously received on the 5 tiers.

The committee also made recommendations for future exploration by SRTR: Dr. Ken Newell recommended developing a summary metric, exploring new metrics, and also presenting the same data for 3-year outcomes. Dr. Bethany Foster recommended revisiting the hazard-ratio scale vs. absolute scale, as absolute risk is more meaningful to patients. Dr. Scott Biggins recommended exploring a patient questionnaire that considers their preferences.

Dr. Newell made a motion to support proceeding with the plan to implement changes to the beta site with the communications plan as outlined, and consider the other feedback for future iterations. The committee voted unanimously in support.

Update from Dr. Schaffhausen and Dr. Israni’s AHRQ-funded project (AHRQ slides)

Dr. Israni presented on his and Dr. Schaffhausen’s AHRQ-funded work to develop a patient-centered report card to help patients identify transplant programs that serve patients like them. To date, they have two manuscripts to submit, and have completed interviews and focus groups with transplant recipients and candidates to better understand what is important to them to develop a patient-specific search. Dr. Israni previewed the patient-specific search that allows patients to answer a

series of questions that will return search results for transplant programs that serve patients like them. This concept was presented to the OPTN PAC, which unanimously supported moving forward. The PAC also supported indicating which metric most impacts survival (presented earlier), and the integrated waitlist outcomes calculator (to be presented later). Dr. Israni outlined the next steps in the project, which include developing a working prototype, conducting usability testing, and refining the prototype based on feedback.

The SVC supported moving forward with the tool. A recommendation was made to use this decision tool as a conversation starter to educate patients with regard to accepting certain types of organs (e.g., Public Health Service high risk, donation after circulatory death, high kidney donor profile index) and the effect of their decisions on waitlist survival and posttransplant outcomes. Another recommendation was to include 5-10 questions asking patients to identify the metric most important to them.

Update on Survival From Listing Metric (Slides 104-120)

Dr. Wey presented an update on a metric SRTR is developing of overall survival from listing. This metric is most similar to intent-to-treat analysis; if a program lists a patient, what is the patient's overall survival? Dr. Wey highlighted the October 2017 SVC meeting discussion regarding defining the cohort (i.e., incident vs. period prevalent) and the censoring procedures. He then presented a simplified methodology for the metric. The cohort would be a 2-year period prevalent cohort and the event would be patient deaths within years of listing. SRTR would administratively censor anyone in this cohort at the end of the 2-year period or 5 years after listing. SRTR would not censor for transfer or relisting, but would censor for relisting at the same program. Dr. Wey presented graphical illustrations of the cohort using July 2017 program-specific report (PSR) data.

Committee members had several comments and questions about the metric. Specifically for kidney, there were concerns about death and inactivity on the waiting list, and about how this might affect program behavior, i.e., will programs change how they waitlist patients? There was also a question about whether the 2-year period would generate enough data for statistical significance. Does the previous 2 years reflect program performance?

Dr. Wey asked for SVC feedback regarding whether this cohort definition is reasonable enough to allow model building to begin. The SVC wanted to see more data to determine whether the window defines the relevant timeframe (i.e., enough patients undergo transplant or die) before beginning model building. Members also thought that the cohort may need to be different for kidney. Finally, they want to see event rates, and numbers of events per program, for the cohort as currently defined.

Coordination with OPTN for data quality review tools (Slides 150-151)

Dr. Snyder informed the SVC about the goal of coordinating and consolidating the data quality tools currently provided by OPTN and SRTR. SRTR proposes to eventually stop providing the data integrity report during the PSR cycle, since the tool would be provided more frequently by OPTN. He described the tools currently provided by SRTR, the data integrity reports, and the CUSUM data table. The data integrity report is provided semi-annually to programs, and is tied to the PSR cycle. The report includes only the variables used in the risk models. The CUSUM report is generated monthly, with essentially the same data as in the data integrity report. It covers all patients in the 3-year CUSUM window.

Ms. Sarah Taranto, from UNOS, described the OPTN Data Quality Report for the committee. OPTN started creating these reports because of many data requests from transplant programs that wanted to keep up with data quality in preparation for the PSRs. These reports are generated monthly, and they highlight fields that are missing or have unusual values. The reports currently include only PSR elements, but the intent is to grow over time to highlight other data elements. The reports are available for all major organs.

Dr. Snyder asked the committee for feedback regarding consolidating the data quality tools to provide them from one single source. The SVC supported proceeding with this consolidation, as long as there was careful coordination between OPTN and SRTR. Programs should still receive the data that go into the PSRs.

The committee also raised concerns about data definitions and data quality issues for all data elements, not just the risk adjusted variables. Ms. Taranto and Darren Stewart said that OPTN is working on both of these issues.

Kidney Waitlist Outcomes Tool (Slides 121-135)

Dr. Israni presented the background and methods for the kidney waitlist calculator, then described the current iteration of the decision tool. He reported that the decision tool was endorsed by OPTN's PAC, and Dr. Allyson Hart will be presenting it at American Transplant Congress (ATC) in June. He noted that the goal is to publish the decision tool on the SRTR website before the ATC presentation, if the committee supports that.

The committee liked the tool and supported posting it on the SRTR public site labeled as a beta version. A recommendation was to be careful about language in the tool, e.g., "who pays for the donor." Another recommendation was to allow public comment on the tool, which would be discussed at a later SVC meeting.

Closing Business

Dr. Snyder noted that the next SVC meeting will be a teleconference held on July 16, 2018. More information will be supplied regarding meeting logistics. The meeting was adjourned at 3:00 p.m. EDT.