Minutes

SRTR Visiting Committee

Date: October 4, 2017
Time: 1:00 PM-4:00 PM CTD
Second of Two Required Annual Teleconferences

Voting Members:
John Gill, MD, MS (Co-Chair)
Susan Gunderson, MHA (Co-Chair)
Scott Biggins, MD, MAS
Walter Kremers, PhD
David J. Lederer, MD, MS
Dan Meyer, MD
Rachel Patzer, PhD
Luke Preczewski
Bethany Foster, MD, MSCE

Ex-Officio Members:
Monica Lin, PhD (HRSA)
Jennifer Milton, MBA (OPTN-POC)
Jonah Odim, MD (NIH)
Darren Stewart, MS (OPTN/UNOS)
Eric Engels, MD (NCI)
Joseph Kim, MD, PhD (OPTN-DAC)

Guests:
Joyce Hager (HRSA)
Corey Schaffhausen, PhD (MMRF)

SRTR:
Bertram Kasiske, MD
Jon Snyder, PhD, MS
Ajay Israni, MD, MS
Laura Klein, MPH
Nicholas Salkowski, PhD
Andrew Wey, PhD
Larry Hunsiker, MD
Mona Shater, MA
Ryan Follmer
Bryn Thompson, MPH
Alyssa Herreid, MPH
Amy Ketterer

Welcome & Introductions

Co-Chair Dr. John Gill called the meeting to order at 1:05 PM CDT.

Dr. Bert Kasiske noted that three members were rotating off the committee and thanked them for their service. Departing members are Dr. David Lederer, Dr. Dan Meyer, and Dr. Gill. Dr. Kasiske also informed the committee that new members have been selected to replace the departing members. Incoming members are:

- Dr. Richard Formica, Professor of Medicine and Professor of Surgery at Yale-New Haven Transplantation Center.
- Dr. Jonathan Chen, Chief, Congenital Cardiac Surgery; Co-Director of the Heart Center; Samuel and Althea Stroum Endowed Chair in Pediatric Cardiovascular Surgery at Seattle Children's Hospital.
- Dr. Kenneth Newell, Professor of Surgery, Division of Transplantation, Department of Surgery, Emory University School of Medicine

Dr. Newell will serve as Co-Chair, replacing Dr. Gill.

Susan Gunderson thanked the three departing members for their participation. Dr. Gill thanked SRTR for its work and said that he appreciated being involved.

Dr. Gill then roll-called the members. All voting members were present.

Regarding conflicts of Interest (COIs), Dr. Kasiske reminded committee members that SRTR must ensure that they manage any potential COIs, and asked them to bring forward any potential COIs during committee deliberations and possibly recuse themselves from related discussions. Dr. Kasiske reminded the members to contact SRTR with any changes to their COI disclosures.

Dr. Gill disclosed his affiliation with an ASTS/AST workgroup on metrics.
Dr. Rachel Patzer disclosed her affiliation with an ASTS/AST workgroup on metrics .
Jennifer Milton disclosed a potential conflict as a result of her connection to XynManagement.

Update on the Recommended Changes to the SRTR Website (Slides 7-11 with AHRQ slides inserted.)

Dr. Jon Snyder began the presentation by noting that the meeting would focus primarily on changes being made to the SRTR public website (www.srtr.org) based on previous recommendations. He restated the two primary topics discussed during the last SVC meeting that are driving the current changes:

1. Develop new models to support a tier system for transplant rate and waitlist mortality rate.
2. Gather information relating to whether waitlist mortality should be displayed for kidney programs on the primary search results page.

Dr. Snyder previewed a screenshot of the summary listing page of the website currently in development as it would look based on the SVC recommendations. The list of programs and their assessments would be displayed on this page in a general search. Dr. Snyder pointed out the elements that had been altered:

1. The “Assessment” column was renamed “Survival Following Transplant.”
2. The “Transplant Rate“ column was renamed “Getting a Transplant Quickly.”
3. A “Waitlist Survival” column was added.
4. “Volume” was split into deceased and living donor transplants.
5. Assessment tiers were added for transplant rate ratios and waitlist mortality rate ratios.
6. Assessment bar positioning was changed from horizontal to vertical.

Dr. Ajay Israni began the presentation on the AHRQ-funded study results, speaking about the most recent results of surveys and patient focus groups. He started by briefly summarizing the key milestones that the study has completed to date.

Dr. Cory Schaffhausen gave an overview of the feedback from participants in the current phase of the study, which is patient focus groups. In this phase, he presented the website elements to focus group participants and looked at the headings and graphics as currently presented, and he discussed with participants what they understood about waitlist mortality.

Regarding headings, suggestions were (summarized):

1. Add the phrase “in a year…” to clarify the transplant volume metrics.
2. Clarify the meaning of “survival” in different areas. Is it organ or patient survival?
3. Add a “key” that explains the tier range.
4. Risk-adjusted metrics should state “compared to national” rates or somehow clarify what “quickly” means, perhaps with a key.
5. Remove the “small print” under a header and instead provide a link to a pop-up explanation.

Regarding graphics, focus group members generally favored the horizontal tier icon. There was no strong opinion regarding colors changing from lighter to darker, but the group felt strongly that if one color was used, the darkest color should not be used.

Dr. Schaffhausen discussed the feedback regarding a new idea presented to the focus group, the option of creating a "custom search." Users would be presented with several criteria they could select to determine whether a program performed transplants in patients like them, and/or provided "special services" they might need or want. The focus group was receptive to this idea.

The Committee discussed this point. Two topics were emphasized. Dr. Gill was curious about how well the focus group was able to grasp what was presented or whether it needed guidance, and about how representative it was. Dr. Patzer also expressed concern about how representative the group was, and she asked about the organ mix.

Dr. Israni said that the local group was made up of kidney transplant candidates at Hennepin County Medical Center and the University of Minnesota. Participants waiting for liver transplant were listed only at the University of Minnesota. The national focus group comprised transplant *recipients*, rather than waitlisted candidates.

Concerns were raised specific to the custom search option. Overall, the Committee liked the idea, but cautioned forethought regarding what to include. Patients may find a program based on their preferences instead of on the metrics they really should consider; patients might avoid a program if the search results suggest that it is unlikely to list them, which could be self-fulfilling. Or, this type of tool may give false hope if it implies that a particular program would list candidates who it actually would not.

The suggestion was made to consider clinicians' input on this decision tool, since they may ultimately be faced with questions from patients who use it. The tool could possibly be used as a shared decision aid, which clinicians and patients could consider together.

Dr. Israni noted the option to print the results page, allowing patients to bring it to their providers. Dr. Snyder added that the beta website could again be used to present the idea to providers and get their feedback. Dr. Israni said that there were many good questions for him to think through, which would help him develop the website further.

Dr. Schaffhausen continued his presentation with the final issue presented to the focus groups, how the search page appears with the changes Dr. Snyder previously described.

The group was receptive to splitting living and deceased donor transplants. Feedback was positive regarding a key to indicate the meaning of the different bars in the tier ratings, particularly because of the proposal to remove the words below the current icons, e.g., "Good (as expected)." Due to the space constraints and the danger of the page becoming busy and confusing, the focus group was presented with two concepts: include or omit the waitlist mortality assessment tiers. Reaction from focus group participants was mixed. Overall feedback indicated that including the waitlist mortality metric should not crowd out the patient-specific information, and more research is required to determine if the waitlist metric affects patient decision making.

Dr. Schaffhausen mentioned some additional concepts SRTR was working on developing, which were simply noted to the focus group; the reception was positive, and some group members made additional comments.

Dr. Israni presented a series of slides showing the evolution of the patient search page based on the feedback from the focus group. One idea was to add a legend that explained the tier range in the tier graphic. Another idea was to provide the option to hide the waitlist mortality metric if a patient didn't want so see it. A third idea was to hide the small print under the headers and instead provide links or pop-ups for the explanations.

In conclusion, there was support to incorporate patient-specific information. No conclusion was reached regarding whether to include the waitlist metric on the primary search results page. Minor revisions to the headings and graphics were supported. And, overall, patients supported a "one-stop" resource for both metrics and program-reported data.

Dr. Israni briefly explained the plan going forward, including preparing abstracts. He gave credit to the others involved in the study.

Dr. Snyder followed up Dr. Schaffhausen's presentation by summarizing the goal to post the revised design to a beta website by the time of the January public release, and he outlined some additional decisions to be made, including those relating to the headers, the waitlist mortality metric, and the reference ranges.

Dr. Dan Meyer suggested that adding the reference ranges made the page look cluttered, and suggested putting more thought into a cleaner way of presenting the key and reference range information.

Dr. Gill asked whether patients will look at this information to decide between various transplant programs, or to determine whether their current program has good outcomes. Dr. Schaffhausen said that, overall, the answer is both. But, primarily, the purpose of the focus group was to get feedback on the website and on how the data are presented. The patients said that this search page does not give them everything they need to make a decision, but it does educate them.

Dr. Snyder asked for the Committee's support in moving forward with the changes to the assessment results, incorporating some of the focus group results. Overall, the committee supported this move. There were no objections. Dr. Snyder summarized that SRTR staff will work on the suggested changes and bring a version back to the SVC for consideration at the January 2018 meeting. The committee will then decide whether to make the revised site available on SRTR's beta website.

Overall Survival Following Listing (Slides 13-33)

Dr. Snyder started this topic with an overview of the SRTR contract and the multiple metrics we are contractually obligated to report on. Although it is required by the contract, SRTR does not currently

report "overall survival following listing." SRTR has recently devoted resources to development of this metric.

Dr. Andrew Wey took over the presentation at this point, as he's been working on the methodologies that could be employed to develop a metric of overall survival following listing. He first described two ways to define the patient cohorts to be used in the metric, incident vs. period prevalent. He explained both approaches and the pros and cons of each. He then showed the committee a table comparing the variability in program effects for the Incident and period prevalent cohorts, and scatter plots comparing these cohorts for liver, kidney, lung, and heart programs.

Dr. Wey asked committee members for their opinions as to which cohort definition is better. Some members thought the incident cohort was preferable. Drs. Walter Kremers and Joe Kim preferred the period prevalent cohort definition because the data are more timely.

Dr. Wey delayed discussing the evaluation period SRTR could use for each cohort based on the discussion points raised by Drs. Kremers and Kim, and said that he would give their comments further consideration.

Dr. Wey discussed other technical details, such as the censoring events. Should retransplants and relistings be censoring events? Dr. Kremers said that censoring for relisting or retransplant may be inappropriate from an intent-to-treat perspective. Dr. Nicholas Salkowski suggested viewing the censoring procedure from the point of view of "program responsibility," which could suggest censoring for retransplant at a different program. Generally the committee thought that the data in the waitlist outcomes should mirror the data in the posttransplant outcomes. SRTR considers a relist a failure, so relistings should also be considered failures in waitlist outcomes. SRTR does not consider retransplants in patient survival but does in graft survival. Re-transplants should be factored in similarly. These issues will be considered further.

After discussing the points raised by the committee, Dr. Wey agreed to consider some of the input to further develop the concept. He will run both period prevalent and incident models and submit findings to the SVC at the next meeting.

PSR/OSR Reporting Period (Slides 35-40)

Dr. Snyder informed the committee of the idea of limiting or discontinuing the formal data review period that is currently part of each semi-annual cycle of the program- and OPO-specific reports. Currently, SRTR allows programs a semi-annual review period during which they can review the data that will be used in the upcoming reports. SRTR is proposing to provide monthly data reports as part of the CUSUM reporting that could be used for the purpose of data quality review. Currently, SRTR provides a 3-year cohort of patients monthly for programs to review as part of the CUSUM reports. SRTR could modify these reports to ensure that they would be adequate for the semi-annual review of data that will go into the reports, and the current data review period could be eliminated. Dr. Snyder noted that this change would hopefully instill a culture of continuous data quality review by programs, with less focus on the semi-annual reports. Dr. Snyder noted that the Expected Survival Worksheets will still be available to programs and only the Data Integrity Reports and the data review periods of October 1-31 and April 1-30 would be eliminated.

Committee members raised some concerns. Dr. Kremers thought that the CUSUMs may not be as intuitive as the Data Integrity Reports, and program quality professionals might find it difficult to piece together the data in the CUSUMs that are included in the models. Dr. Snyder noted that the data are provided in tables along with the CUSUM charts, and the data elements included in the risk adjustment models are provided. Dr. Kremers suggested that SRTR ensure that all patients who would be included in the evaluation cohorts are included in the CUSUM data review tables.

Ms. Gunderson asked if there would also be something like a monthly reports for OPOs. Dr. Snyder said that a similar monthly report could be provided on the secure site.

Dr. Snyder recognized that the committee thought that programs and OPOs should have an easy-to-access report of the data that will be used in their key metrics for regulatory oversight. SRTR will continue to develop the idea and bring a more concrete example to the committee at the January meeting.

PSR/OSR Changes (Slide 42)

Dr. Snyder gave a quick overview of changes made to the PSRs/OSRs that will be incorporated into the January 2018 release. There were no questions or comments about the changes.

Closing business

There was a call for additional business. There was none and the meeting was adjourned at 3:55PM