SRTR Visiting Committee Minutes

Crystal City, VA
April 9, 2019, 9:00 AM- 3:30 PM EST

The spring meeting of the SRTR Visiting Committee (SVC) commenced at 9:00 AM EDT. Following is a list of participants:

<table>
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<tr>
<th>SVC Voting Members:</th>
<th>Ex-Officio Members:</th>
<th>SRTR Staff:</th>
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<tbody>
<tr>
<td>Susan Gunderson, MHA (Co-Chair, via phone)</td>
<td>Shannon Dunne, JD (HRSA)</td>
<td>Bertram Kasiske, MD, FACP</td>
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<td>Ken Newell, MD (Co-Chair)</td>
<td>Jennifer Milton, MBA (OPTN-POC, via phone)</td>
<td>Ajay Israni, MD, MS</td>
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<td>Jonathan Chen, MD (via phone)</td>
<td>Jonah Odim, MD (NIH)</td>
<td>Jon Snyder, PhD, MS</td>
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<td>Richard Formica, MD</td>
<td>Richard Knight, MBA</td>
<td>Larry Hunsicker, MD (via phone)</td>
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<td>Brent Logan, PhD</td>
<td>Rachel Patzer, PhD</td>
<td>Darren Stewart, MS (OPTN/UNOS)</td>
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<td>James Markmann, MD, PhD</td>
<td>Luke Preczewski</td>
<td>Caitlyn Nystedt, MPH, PMP</td>
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<td>Rachel Patzer, PhD</td>
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<td>Nicholas Salkowski, PhD</td>
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<td>Luke Preczewski</td>
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<td>Andrew Wey, PhD</td>
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Dr. Newell welcomed people to the meeting and participants introduced themselves. Following a brief review of the meeting’s agenda, Dr. Kasiske reminded the members about management and disclosure of relevant conflicts of interest. Following this brief introduction, Dr. Newell commenced with the agenda.

The role of biopsies and biopsy results in donor and recipient risk adjustment.

The first item discussed was the potential role of biopsies and biopsy results in risk adjustment models for posttransplant outcomes and donor yield. Dr. Salkowski and Dr. Wey reviewed work they performed in response to a request at the previous meeting of the SVC. In an effort to investigate whether the presence of a biopsy and the biopsy findings meaningfully contribute to both posttransplant outcomes models for kidneys and livers, Dr. Salkowski presented results of analyses attempting to incorporate these factors into the models. Discussion followed on the findings, and clarifications were provided about how dual kidneys were handled in the modeling. A primary finding was, when biopsies were performed on both kidneys in a dual or en bloc kidney transplant, using the minimum reported percent glomerulosclerosis (%GS) yielded the best results.

The committee discussed the categorization of the %GS for kidneys, which is collected in categories rather than the raw percentage. The committee questioned if SRTR could obtain the raw %GS from DonorNet®, if it is not provided on the Deceased Donor Registration (DDR) form. Mr. Stewart indicated it may be possible to find the raw %GS in DonorNet, but SRTR would need to look into it further.

For livers, the actual percentage of macrovesicular fat is recorded and not categorized on the DDR. After some discussion about the best way to handle the parameterization of both %GS for kidneys
and % macrovesicular fat for livers, the committee recommended combining no value with low results, i.e., combining no biopsy with the 0-15% GS range for kidneys, and combining no biopsy with 0-10% macrovesicular fat for livers. Mr. Knight made a motion to adopt the recommendation that the SRTR include biopsies and biopsy results in future posttransplant risk adjustment models pending programming and that the SRTR investigate these new parameterizations and report back to the committee at their next meeting. Dr. Markmann seconded the motion and the committee voted unanimously to support the motion.

Next, Dr. Wey presented additional data on how these same biopsies impact donor yield assessments for OPO performance. Dr. Formica made a motion to review additional data when stratifying by DCD/DBD and combining the “not done” category with 0-10%. Dr. Markmann seconded the motion and the motion passed by unanimous vote.

**Hospital Mergers and Implications for PSR Reporting**

The next agenda item was a discussion on how the SRTR should handle possible future mergers of transplant programs if the OPTN Board of Directors passes modified OPTN membership bylaws at the December 2019 Board Meeting. SRTR could handle mergers in the SRTR Program-Specific Reports (PSRs) in two different ways:

1) Treat a merger of program A into program B as a closure of program B at the time of the merger.
2) Treat a merger of program A into program B as a historic elimination of program A, treating all historic patients as if they have always been at program B.

In option 1, program A’s PSR would remain in future PSR cycles until all patients have passed through all reporting periods. This would retain the historical record that these patients were cared for under program A while it was a valid OPTN member. Under option 2, program A’s PSR would cease to exist and would be effectively absorbed into Program B’s PSR.

The committee questioned whether programs could be given options for how to handle the merger in the public reports, but SRTR prefers a standard way to handle these cases. The committee expressed concern that historic record of patient care at two different programs would be lost under option 2. The committee also had concern that programs could potentially obfuscate historically bad outcomes at a program by absorbing their data into the other program’s data. SRTR noted that currently, if a program’s OPTN member code changes, the PSR for the old code continues to be produced until all patients roll out of the report’s cohorts. This is effectively option 1.

Dr. Newell expressed his support for option 1 as it preserves the status quo of the public reports and preserves the history of actual OPTN member institutions. Mr. Prescewski expressed support for option 2 given that it would be a more accurate representation to patients about the breadth of experience at the program and is truer to the spirit of the potential change in the OPTN bylaws. The committee took an informal poll of which option is preferred, and the vote was 7 in favor of option 1 and 2 in favor of option 2. SRTR will revisit this with HRSA and UNOS leadership and may come back to the committee with more information.

**Potential removal of a case from a PSR evaluation**
The next agenda item was whether or not there is ever a case that would warrant removal from SRTR evaluations and public reporting. The discussion was spurred by a case of a program's claim that a particular outcome was the result of the failure of the broader transplant system outside of the direct control of the program itself. The program felt that they were not at fault for the poor outcome and wished to have the case removed from their evaluation cohort.

The committee felt that special exemptions should not be granted and the public reports should remain a complete accounting of the transplants that took place. The members noted that this case was a rare event and will be dealt with through the standard member quality and policy monitoring framework of the Membership and Professional Standards Committee (MPSC) of the OPTN. Dr. Newell motioned that the SRTR not establish a precedent of removing cases from the public reporting. The motion was seconded by Dr. Logan and the vote was unanimous in favor of the motion.

**Continued Development of a Survival-from-Listing Metric**

Dr. Wey presented progress on his development of a metric to assess survival from the time of listing along with how the metric will be incorporated into future PSRs. The metric's goal is to describe patient experience at a program once listed. The committee noted a concern that such a metric will also be used by insurance providers to further judge program performance. The committee remarked that this metric will require targeted educational efforts similar to, or perhaps more than, traditional SRTR training on metrics, both for patients and for transplant providers. Dr. Wey stated that this metric is targeted to describe patient experience at a program, to recognize factors such as organ availability and show how the allocation system impacts at each program are largely out of the control of the program. Therefore, Dr. Wey emphasized that a survival from listing metric is not an ideal choice for performance monitoring or compliance metrics, but it is a good metric for describing patient experience at a program.

The current goal is to publish the models in preview form on the SRTR website so that programs can familiarize themselves with the metric. SRTR is proposing to develop the preview and educational material to accompany the preview. The committee suggested that programs will want to see a version of what the metrics will look like when eventually published in the PSRs. The committee inquired about the performance of the models and Dr. Wey reviewed the model building process. He referred to his recent paper describing how c statistics should not be used to assess the predictive ability of the models (Wey A, Salkowski N, Kasiske BL, Skeans MA, Gustafson SK, Israni AK, Snyder JJ. The relationship between the C-statistic and the accuracy of program-specific evaluations. Am J Transplant. 2019;19:407-413).

The committee recommended finding ways to pilot the metric with patients as well as providing programs with examples of the reports (not necessarily with their actual metrics). Some committee members felt that programs should see their actual data prior to public roll out of the metric. A suggestion was made to create blinded versions of the reports as candidates may look for small, medium, and large programs, and programs in “organ-rich” vs. “organ-poor” areas of the country.

A motion was made by Dr. Patzer for the SRTR to come back to the committee at the next meeting with more detailed educational materials and some blinded reports. The motion was seconded by
Dr. Markmann. During the discussion the members reiterated their desire to see example reports from different areas of the country. The committee voted unanimously to support the motion.

**Data Advisory Committee**

Dr. Kasiske then presented a review of the history of the OPTN's Data Advisory Committee (DAC). At the conclusion of the history, Dr. Kasiske presented the SRTR's recommendation for the DAC to form organ-specific workgroups to review the current data collection forms and make recommendations for future revisions to the forms. This should ideally be done on a rotating schedule such that each of the forms are reviewed regularly. Dr. Kasiske also noted the DAC's current efforts to put in place a data lock period following which member institutions would not be allowed to modify the data. This portion of the meeting was informational and no formal voting item was put forward.

**CUSUMs for OPO Yield**

Dr. Wey presented work on development of CUSUM reports to be rolled out to the OPO community to aid in monitoring donor yield metrics in near-real-time. Donor yield is used in both MPSC monitoring as well as CMS monitoring of OPOs, so CUSUMs may provide valuable time trend analyses to OPOs. SRTR noted that it sought feedback from a number of OPOs about whether a calendar timescale or a donor-based timescale would be more meaningful to the OPOs. The OPOs unanimously favored a calendar timescale.

Following Dr. Wey's review of the CUSUMs, Ms. Gunderson made a motion for the SVC to endorse this work and advance it for roll out to the OPO community. The motion was seconded by Dr. Formica and the committee voted unanimously in favor of the motion.

**Measuring OPO Performance**

Dr. Snyder then reviewed with the committee a presentation he had given to the OPTN's Ad Hoc Systems Performance Committee at their meeting in Chicago in March 2019. Dr. Snyder covered current OPO metrics and controversies surrounding transparency and accuracy of OPO metrics. Dr. Snyder concluded his remarks by sharing the results of ongoing work in conjunction with AOPO called the Region 8 Donor Potential Pilot Study. In this study, Region 8's 5 OPOs are collecting data on all ventilated deaths under the age of 71 that may serve as the basis for a future metric on OPO performance. This presentation was informational only and no formal voting item was brought forward.

**SRTR Websites**

Dr. Snyder mentioned the SRTR launched a new secure website in early 2019 and the site has been well-received by the transplant community. Dr. Israni then provided a review of his ongoing work to enhance and create patient-friendly websites to disseminate information to patients about transplant programs. Dr. Israni is currently working on developing a patient-specific search tool that will allow patients to tailor program searches to their specific preferences. This item was informational and no formal vote was brought forward.
Brief Updates

The meeting concluded with a few brief updates. First, Dr. Salkowski informed the committee that SRTR will be removing PA pressures from pediatric heart transplant models following a recommendation that these data are not meaningful and can be dangerous to obtain in certain pediatric populations.

Dr. Kasiske provided a brief update on the progress to date of the SRTR’s Living Donor Collective (LDC) pilot project. All 10 pilot sites are now successfully entering data into the LDC’s system.

Finally, there was a brief discussion about ongoing efforts to forge a relationship between HHS and the National Death Index to allow for easier, cheaper access to the National Death Index. SRTR is continuing to work with Dr. Odim who has been instrumental in moving these efforts forward.

Closing Business
The next meeting of the SVC is scheduled to take place by teleconference on July 29, 2019, 1:00-4:00 PM CDT. SRTR is working to schedule the remaining meetings of 2019.

With no other business brought forward, the meeting adjourned at 3:30 EDT.