SRTR Visiting Committee Minutes

Minneapolis, MN
July 29, 2019, 1:00 PM – 4:00 PM CDT

The spring meeting of the SRTR Visiting Committee (SVC) commenced at 1:00 PM CDT. Following is a list of participants:

<table>
<thead>
<tr>
<th>SVC Voting Members:</th>
<th>Ex-Officio Members:</th>
<th>SRTR Staff:</th>
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</thead>
<tbody>
<tr>
<td>Susan Gunderson, MHA (Co-Chair)</td>
<td>Shannon Dunne, JD (HRSA),</td>
<td>Bertram Kasiske, MD, FACP</td>
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<td>Jonathan Chen, MD</td>
<td>Alexandra Glazier, JD (NEDS,</td>
<td>Ajay Israni, MD, MS</td>
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<td>Richard Formica, MD</td>
<td>OPTN Policy Oversight Committee</td>
<td>Jon Snyder, PhD, MS</td>
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<td>Richard Knight, MBA</td>
<td>Chair)</td>
<td>Larry Hunsicker, MD (via phone)</td>
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<td>Brent Logan, PhD</td>
<td>Jonah Odim, MD (NIH)</td>
<td>Caitlyn Nystedt, MPH, PMP</td>
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<td>James Markmann, MD, PhD</td>
<td>Darren Stewart, MS (UNOS)</td>
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<td>Luke Preczewski</td>
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<td>Sharon Shepherd, JD, MSN, RN (UNOS)</td>
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| SVC Voting Members Unable to Attend: | Guests: | |
|-------------------------------------|---------||
| Ken Newell, MD, PhD (Co-Chair) | Chris McLaughlin (HRSA) | |
| Rachel Patzer, PhD | Joyce Hager (HRSA) | |
| | Janet Kuramoto-Crawford (HRSA) | |
| | Bob Carrico, PhD (UNOS) | |
| | Sharon Shepherd, JD, MSN, RN (UNOS) | |

Ms. Gunderson welcomed people to the meeting and participants introduced themselves. Alexandra Glazier was welcomed as new member ex-officio member in her role as chair of the Organ Procurement and Transplantation Network’s (OPTN’s) Policy Oversight Committee. Following a brief review of the agenda, Dr. Kasiske reminded members about management and disclosure of relevant conflicts of interest. After this brief introduction, Ms. Gunderson commenced with the agenda.

Hospital Mergers and Implications for PSR Reporting

The discussion from the April 2019 meeting was reviewed regarding the OPTN Board of Directors-approved updates to the OPTN bylaws defining a transplant program (Appendices D.2, D.22.F, and M). The Committee discussed two options for how SRTR should treat a merge of two programs. Historically, SRTR has based program designation on OPTN four-letter member codes and three-character OPTN member type codes. Reports are generated for any member institution with active patients during a given time period covered by any table in the report.

Two options were discussed: 1) Program A would merge program B into it and program B would be shut down/absorbed upon merger. 2) Pretend program B never existed and program A begins reporting all present and former patient data. During the April meeting, it was felt that option #2 would lose the history of what happened at the merged program's prior to the merger and the committee preferred option #1.

The OPTN-MPSC had some concerns about the SRTR implementing option #1. Sharon Shepherd, Transplant Systems Performance Manager in the Member Quality Department at the United
Network for Organ Sharing (UNOS), spoke to the MPSC perspective, saying that the current bylaw does not give adequate guidance. Historically, all operating rooms where transplants were performed needed to be in attached buildings. In December 2016, new bylaws were approved, effective December 2017. These specified that all operating rooms had to be in a single DSA, and all facilities must be under common governance/oversight, geographically contiguous, and within 1 mile walking distance. The new geographical requirements may result in mergers of current OPTN transplant hospital members. The MPSC felt that it was important that continuity be established in historical program reporting in the event two previously separate member institutions merged. For example, if an institution with a thoracic program merges with an institution that did not historically have a thoracic program, it would appear the new member institution had a new thoracic program when in fact the thoracic program was preexisting. The MPSC therefore prefers SRTR follow option #2 which would treat the merged program as always having existed within the new merged institution.

Dr. Formica voiced a concern about whether merging programs would hide previous performance issues at one of the merged programs and whether mergers could potentially affect center-of-excellence status or public impressions of programs. Merging program data will present technical challenges for SRTR analyses. Dr. Snyder asked whether UNOS planned to overwrite program codes when implementing the merger, changing the program codes for patients currently listed to the new program code. One challenge will be handling patients who had been previously removed from the waiting list prior to the merger, as these patients will not have their program codes overwritten. SRTR will need adequate time to prepare for handling the code changes.

The committee expressed that doing the right thing for public reporting should be the guiding principle. As such, there was now support for preserving the history of merged programs rather than making it appear that a program shut down at a merged program and a new program began at the merged institution.

In December 2019, the OPTN Board of Directors will vote on any requested mergers, and, if approved, they will be made effective no sooner than early January 2020. SRTR would then attempt to implement any approved mergers in the July 2020 reports. OPTN is preparing a database table containing the information necessary to accurately identify approved mergers. SRTR will need this table to make the required reporting modifications.

Ms. Gunderson made a motion to endorse the process that would adopt option #2 (program A would absorb all of B's experience and B ceases to exist). The motion was seconded by Mr. Preczewski. The motion passed with 0 opposed and 0 abstentions.

The role of biopsy results in donor and recipient risk adjustment

During the April meeting, the SVC voted to include kidney and liver biopsy results in posttransplant outcomes models and organ yield models. The MPSC requested a few modifications to the SRTR's modeling of biopsy results and an analysis of how inclusion of biopsy affects which programs meet the current MPSC flagging rules and how SRTR tier evaluations may be affected. Drs. Salkowski and Wey presented the results of the updated analyses for the posttransplant modeling and organ yield modeling, respectively. MPSC flag status changes were minimal. Tier evaluations would have changed by 1 tier for a few kidney programs. For liver programs, no flag status changes resulted from including biopsy results. Four programs would have been assigned to a lower tier had biopsy results been included.
Dr. Hunsicker commented that whether including biopsy results is adopted or not, it won't change evaluation much, but he is interested in what it would do to program behavior. Dr. Kasiske noted that Dr. Krista Lentine, transplant nephrologist at Saint Louis University and Mid-America Transplant, the Organ Procurement Organization (OPO) in St. Louis, MO, were leading a pilot randomized controlled trial of the impact of procurement biopsies on kidney utilization and had requested the SRTR adjust for biopsy results in the evaluation of both organ yield and program outcomes.

Unintended consequences of including biopsy results in the risk models was also discussed. Dr. Salkowski noted that the model lumps together “no biopsy” with “good biopsy,” so the potential incentive to perform a biopsy is minimal unless there is concern that the results would show more substantial levels of glomerulosclerosis or macro vesicular fat.

Mr. Stewart noted that the definitions surrounding the biopsy collection on the deceased donor registration (DDR) form needed to be clarified, and it was agreed that now is a good time to discuss it, since the DAC is working with the OPO committee to update the DDR form.

The committee voted on whether biopsy results should be added to the posttransplant outcomes models for the fall 2019 PSR cycle for the reports to be released in January 2020? The committee supported the motion with 0 against and 0 abstentions.

The SVC voted for categorization of macro vesicular fat for liver yield. A concern was expressed that the “not available” category may identify both good and bad donor characteristics. A split of DCD/not available/DBD was requested. Not available DCDs have significantly lower yield than DBDs.

The committee supported implementing the new parameterization of liver biopsy results for the liver yield risk adjustment model with 0 against and 0 abstentions.

Biopsy results will be included in the risk adjustment models for posttransplant outcomes and organ yield for kidney and liver programs starting with the January 2020 program- and OPO-specific reporting cycles.

**Continued development of a Survival-From-Listing metric**

Continued development of a metric to assess the survival experience of candidates after listing at a program was discussed. At the April SVC meeting, discussion addressed how geographic location could influence estimated hazard ratios for survival after listing, e.g., low donor supply areas may have worse survival from listing from listing evaluations. Further investigations were requested for: C-statistics for the models, distribution of hazard ratio by OPTN region, geographic distribution of DSA-level hazard ratio, association of hazard ratio with donor supply and demand.

Dr. Wey presented the results of the updated analyses. C statistics ranged from 0.64-0.72. Dr. Wey presented variation in HRs by OPTN region and DSA, No significant correlation was observed between supply-demand or program size and evaluations of survival from listing in kidney, liver, heart, or lung evaluations.

The committed felt that it would be necessary to educate the community and the public that an intent-to-treat analysis like survival from listing captures both elements of transplant program quality and elements beyond the control of the transplant program, e.g., organ supply and allocation policy.
The committee supported the idea of providing programs with tools like the expected survival workbooks currently provided for pre- and posttransplant evaluations. Dr. Wey noted that we can develop workbooks to allow programs to more closely evaluate the survival from listing metrics.

Mr. Knight suggested analyzing variation in candidate acceptance criteria across programs, noting consistent listing standards would be helpful. Discussion focused on whether a patient-facing metric would be useful to patients listed at a particular program, how it would be expressed, and whether a tiered evaluation should be created.

Integration steps were listed as:

1. Release an FAQ on the survival-from-listing metric by winter 2019
2. Release a preview for the risk-adjustment models
3. Release a preview for the evaluation on the secure website during the January 2020 PSR release
4. Offer to give presentations to OPTN organ specific committees on upcoming releases and to solicit feedback on the risk adjustment models
   a. Simultaneously release “expected workbooks” to help programs understand the patient-level calculation of, and contribution to, expected events.

Mr. Knight asked whether focus groups should be conducted to gauge patient understanding of the metrics. Dr. Israni noted that he conducted both local and national focus groups when the SRTR was developing the initial tier evaluations through an AHRQ-funded project. Dr. Israni supported the concept of continued patient engagement as new metrics are developed and implemented.

Ms. Gunderson asked if voting members had any additional feedback, and there was none. A consensus was reached to move forward with the proposed plan to integrate survival from listing into the PSRs. The rollout will follow the steps detailed above.

Data Advisory Committee (DAC)

As of July 1, 2019, Dr. Patzer became the chair of the DAC. The OPO/DAC workgroup is working to revise and update the DDR form. Proposed changes in OPTN policy would address data submission deadlines and “data locks,” and those policy proposals will be out for public comment beginning August 2, 2019. The proposal involves an increased time frame for data submission along with a stricter data lock. Changes to submitted data would require approval of the member organization's official OPTN representative or his or her designee. The reason for any data change must be reported in the data collection system prior to changing the data.

Ms. Gunderson noted that extending the deadline is good as long as it is linked to a stricter data lock and clear expectations for data definitions and quality. Mr. Knight noted the opportunity to educate regarding changes and communicate upcoming changes to/get feedback from the public.

Organ Procurement Organization Performance Metrics

Recently, the President of the United States issued and Executive Order that included a request to develop new OPO performance metrics to support the goal of increasing utilization of available organs. Dr. Snyder reviewed administrative data sources for donor potential, including:

1. CDC-NCHS Mortality Multiple Cause:
   i. Contains ICD10-coded cause of death, plus up to 20 contributing causes. Excludes ventilator status.

2. HCUP National Inpatient Sample:
      i. Contains ventilator status, procedure, and diagnosis codes, but does not cover all of the United States.

SRTR is currently working on a DUA with the CDC to obtain the CDC Mortality Multiple Cause data with the goal of calculating the metric for each of the 58 OPOs and comparing results with data currently being captured in the Region 8 Donor Potential Pilot project.

Dr. Snyder gave an update on the Region 8 project. Data collection continues. Cause-of-death classifications are being refined to 23 categories. We are working with donor hospitals and/or state hospital associations to extract inpatient death list meeting inclusions, ICD-10 diagnosis codes for cause of death and comorbid conditions, and procedure codes for mechanical ventilation. Finally, the Region 8 team is working on developing a standardized reporting process for accounting for potential donor drop-out from the time of death through to the time of eventual donation.

Mr. Stewart asked whether they would list all causes of death that apply. We are currently asking the programs to classify the deaths into one primary cause, but multiple causes or comorbidities could be captured. We often see secondary causes of death to a primary (underlying cause). We would be advising the OPOs to classify based on the primary cause leading to the death.

**Brief Updates**

The Living Donor Collective Registry is moving along. The one thousandth donor candidate has been added. Tomorrow there will be a steering committee meeting here in Minneapolis.

**Closing business**

The next meeting will be an in-person meeting in Minneapolis on October 29, 2019, between 9:00 and 3:30 CDT. Hearing no other business, Ms. Gunderson adjourned the meeting at 4:01 CDT.