OPTN Membership and Professional Standards Committee
Performance Monitoring Enhancement Subcommittee
Meeting Summary
May 7, 2021
Conference Call

Richard Formica, M.D., Chair

Introduction

The Performance Monitoring Enhancement Subcommittee of the Membership and Professionals Standards Committee (MPSC) met via Citrix GoToTraining teleconference on May 7, 2021, to discuss the following agenda items:

1. Welcome and Agenda
2. Setting boundaries for adult transplant review
3. Special Situations
    - Small volume/pediatric
    - Pancreas programs
4. Wrap Up

The following is a summary of the subcommittee's discussions.

1. Welcome and Agenda

A staff member reviewed the agenda and explained the meeting's objectives. The MPSC Chair updated the subcommittee on the stakeholder meetings that have been held with the American Society of Transplantation/American Society of Transplant Surgeons and the National Kidney Foundation. He reported that the stakeholders provided valuable feedback. The MPSC Chair explained that the subcommittee would evaluate boundaries for adult review and discuss special boundaries for small volume/pediatric and pancreas programs. A staff member reviewed the project timeline, and stated that the MPSC would approve the public comment proposal at the June MPSC meeting.

The Subcommittee Chair discussed the subcommittee's previous request for a new approach to identify optimal boundary criteria. He noted that the subcommittee was uncomfortable with the initial approach to establishing individual boundaries for each organ separately based on an interest in limiting the number of programs identified. The Subcommittee requested that the SRTR determine the optimal boundary criteria that would distribute the flags across all four metrics for all organs while keeping the number of identified programs roughly the same. He reminded the subcommittee that the data being reviewed is for one reporting cycle and that the boundaries could identify different numbers in each cycle and potentially fewer programs as the overall transplant community improves.

2. Setting Boundaries for Adult Transplant Review

A staff member explained that the subcommittee would review the results from the Scientific Registry of Transplant Recipients (SRTR) data analysis, and finalize the boundaries for adult transplant programs. The questions for the subcommittee include:

- Do the suggested boundaries capture programs that the MPSC should review for potential patient safety concerns?
- Are there any refinements based on review of the captured programs' data and additional information on reviews of those programs, if applicable?

Staff presented data on the number of programs identified under the current monitoring criteria for Spring 2019 through Fall 2020 Program Specific Reports (PSR) cycles. She then explained that the average number of programs flagged under the current criteria over the last four cycles was 68.5. She presented the results of the data analysis, and mentioned SRTR's suggested boundaries for adult transplant programs:

- Waitlist Mortality – 50% Probability with RR > 1.75
- Offer Acceptance – 50% Probability with RR <0.30
- 90-day Graft Survival – 50% Probability with HR >1.75
- 1-year Conditional Graft Survival – 50% Probability with HR > 1.75

Staff noted that the SRTR was able to suggest the same criteria for three of the metrics (waitlist mortality, 90-day graft survival, and conditional 1-year graft survival). Staff reported that six programs that were identified by multiple metrics. Staff explained that there were 56 unique programs flagged for review under the suggested boundaries (*corrected data*). Of these, 53 programs were active (*corrected data*). Staff also reviewed the MPSC's previous actions taken on programs identified for the 90-day and 1-year conditional graft survival. Staff and the Subcommittee Chair reminded the subcommittee that, as is currently the case, a fair number of programs will be identified in multiple reporting cycles so the number of newly identified programs will be much less than the total programs identified each reporting cycle. The subcommittee reviewed the SRTR tool, which provides aggregated data for all organ programs for each metric. Subcommittee members reviewed the data for programs identified by the suggested boundaries for the 90-day and 1-year conditional graft survival as well as the programs identified if the boundaries were moved slightly higher or slightly lower and offered feedback and questions for each these metrics. The Subcommittee also began discussion of the suggested boundaries for waitlist mortality and offer acceptance.

The Subcommittee Chair noted that the distribution of the flags by organ is consistent with the data the subcommittee previously reviewed on the program performance variability for each organ type for each metric. For example, no kidney programs are identified for waitlist mortality since there is not much variability between kidney programs on waitlist mortality and more kidney and liver programs are identified than heart or lung for offer acceptance reflecting more variability in performance of kidney and liver programs on the offer acceptance metric.

<u>Subcommittee Feedback:</u>

The Subcommittee and other MPSC members attending provided the following feedback.

- **90-Day Graft Survival and 1-year Conditional Graft Survival**

The SRTR representative explained that under the proposed criteria for these two metrics, programs that have a hazard ratio above 1.75 would be identified. A member asked why the current 1-year post-transplant survival was divided into two separate metrics. The Subcommittee Chair stated that during previous discussions, the subcommittee noted that the new post-transplant metrics allow the MPSC and programs to evaluate different phases of the post-transplant experience, the 90-day measures the donor-recipient matching and early management of the recipient, and the 1-year conditional measures the care received by the recipient following release for longer-term care. He noted further that, as discussed previously, the 1-year post-transplant survival could be replaced in the future with the longer-term 5-year period prevalent metric but that metric is not yet available. The SRTR representative also noted that there is very little overlap between the programs flagged for 90-day and the programs flagged for 1-year conditional, which supports that the two metrics are measuring two different aspects of recipient care.

While reviewing the data for the heart programs identified, the SRTR representative responded to member questions regarding the methodology for determining the hazard ratio and the confidence level for the hazard ratios for smaller volume programs. A staff member noted that the heart programs that are identified for 90-day graft survival are currently under review and the subcommittee reviewers have identified significant opportunities for improvement at those programs. In response to a question about the lower number of liver programs, the SRTR representative agreed that one reason would be that there was less variability in the performance of liver programs, and therefore, fewer outliers. No significant concerns were raised about the application of the suggested boundaries to each organ. The data for the programs identified would raise concerns for potential patient safety issues and therefore, it would be appropriate for the MPSC to inquire.

- **Waitlist Mortality**

A member stated that since programs do not have as much control of the care of patients on the waiting list and there is not yet a well-developed plan for improvement, it is appropriate that fewer programs are identified under the suggested boundary for the waitlist mortality metric than for the other three metrics. A number of questions were fielded on the program data presented and the waitlist mortality methodology. The SRTR representative noted that there is no simple way to present the waiting list for each program because it is fluid over the measurement period – candidates are constantly be added and removed from each program's waiting list. A couple of committee members expressed that, in the context of heart, the waitlist mortality ratio is not adequately risk-adjusted. The SRTR Director stated that SRTR would look at any data to further evaluate and modify the risk adjustment model. However, adjusting the risk model is beyond the scope of this project. The Subcommittee Chair acknowledged some members' concerns about the community's understanding of the metric. The OPTN and the SRTR will make available resources on the metrics during public comment and reference those resources in the public comment document. He also stated that there is an opportunity to collect more data to make the expected survival a more useful number. A staff member also added that the MPSC could include a question about additional data variables for risk-adjustment in the public comment document, and based on the results, the MPSC could

make recommendations for additional data collection to the OPTN Data Advisory Committee. A member asked if additional information could be distributed on the proposed metric and the mathematical bases of it before the next meeting.

- **Offer acceptance**

The SRTR representation and Subcommittee Chair addressed member questions about the risk adjustment for the offer acceptance metric. The SRTR representative addressed concerns raised about offers received from longer distances stating that distance is factored into the risk adjustment. In response to concerns about not risk adjusting for predictive heart mass or a donor risk index for heart offers, the Subcommittee Chair noted that only one heart program was identified out of the 15 programs flagged for this metric. This is indicative that heart programs are using the same approach to offers resulting in only one program being identified as an outlier. The SRTR representative explained the metric noting that turning down many good offers results in a higher number of expected acceptances. In evaluating the data, one cannot equate the number of expected acceptances to the number of transplants the program would have performed. A program could be declining multiple offers for one patient. The SRTR explained that the model takes into account the sequence number when risk adjusting. For example, if the organ has been turned down for a hundred patients before yours, the model would expect that you would turn down that offer too. If you turn down that offer, it will not make a huge difference in your offer acceptance ratio. The SRTR website provides information on all the variables that are included in the model and how the weight given to those variables fluctuates in determining the expected offer acceptance.

One member noted that the question the subcommittee needs to decide is if the data for the programs identified by the suggested boundary raises concerns for potential patient safety issues at the program. Would a patient find it concerning that a program was expected to accept 180 offers and only accepted 29. The MPSC would then ask some questions to determine if there are reasonable explanations or possibly the program may need to put in more organ offer filters. Another member noted that the MPSC cannot ignore the number of offers that programs turn down all the time. The data indicates it is an obvious area for improvement for the transplant community.

In response to a member question about what transplant program behavior the MPSC wants to encourage with this metric, the Subcommittee Chair noted two behaviors previously discussed by the subcommittee:

- The MPSC wants to discourage programs from setting filters so broadly that they are receiving offers that the program would never accept because that results in inefficiency in the system.
- The MPSC wants to encourage programs to be more likely to accept offers that the program indicates they would accept.

The Subcommittee Chair stated that it is important to educate the community on how the offer acceptance metric works. A staff member reported that the bylaws could be written so that the pre-transplant metric criteria have a delayed effective date to provide the community time to adjust to the new pre-transplant metrics through education and self-evaluation of

performance. The staff member also stated that UNOS professional education staff are assisting in the creation and distribution of resources during public comment to help the community understand the proposed metrics.

3. Special Situations

The Subcommittee agreed to continue the discussion on small volume/pediatric and pancreas programs during the next meeting.

4. Wrap Up

The Subcommittee Chair summarized the progress during this meeting including that the MPSC members are:

- Satisfied with the overall distribution of flags across pre- and post-transplant metrics
- Comfortable with the types of programs that the two post-transplant metrics are identifying under the suggested boundary

Finally, the Committee would like to have a better understanding of the offer acceptance rate and the denominator for the waitlist mortality metric. Staff committed to sending out a link to the relevant pages on the SRTR website that provide information on the variables included in the two metrics and the relative weight provided to those variables.

The Subcommittee Chair stated that the subcommittee would continue the discussion on waitlist mortality and offer acceptance during the next meeting. Staff also will consider sending out a survey to get initial thoughts of the members prior to the next meeting.

Upcoming meetings

May 21: Performance Monitoring Enhancement Subcommittee Meeting, 4:00 – 6:00 pm EDT
May 25: MPSC Meeting, 2:00 – 4:00 pm EDT
June 1: Performance Monitoring Enhancement Subcommittee meeting, 11:00 am – 1:00 pm EDT
June 11: Performance Monitoring Enhancement Subcommittee meeting, 2:00 – 4:00 pm EDT
June 24: MPSC Meeting, 1:00 – 3:00 pm EDT

Attendance

- **Committee Members**
    - Richard N. Formica Jr (Subcommittee Chair)
    - Sanjeev K. Akkina
    - Nicole Berry
    - Matthew Cooper
    - Adam M. Frank
    - Catherine T. Frenette
    - Michael D. Gautreaux
    - Alice L. Gray
    - John R. Gutowski
    - Ian R. Jamieson
    - Christy M. Keahey
    - Mary T. Killackey
    - Heung Bae Kim
    - Jon A. Kobashigawa
    - Jules Lin
    - Didier A. Mandelbrot
    - Virginia(Ginny) T. McBride
    - Willscott E. Naugler
    - Matthew J. O'Connor
    - Jennifer K. Prinz
    - Lisa M. Stocks
- **Other MPSC Members**
    - Theresa Daly
    - Maryjane Farr
    - Anne Krueger
    - Clifford Miles
    - Nicole Pilch
    - Zoe Stewart-Lewis
    - Gebhard Wagener
    - Parsia Vagefi
- **HRSA Representatives**
    - Marilyn Levi
- **SRTR Staff**
    - Ryo Hirose
    - Nicholas Salkowski
    - Jon J. Snyder
    - Bryn Thompson
- **UNOS Staff**

- Nicole Benjamin
- Tameka Bland
- Robyn DiSalvo
- Nadine Drumn
- Amanda Gurin
- Danielle Hawkins
- Ann-Marie Leary
- Amy Minkler
- Jacqui O'Keefe
- Liz Robbins-Callahan
- Sharon Shepherd
- Leah Slife
- Stephon Thelwell
- Gabe Vece
- Betsy Warnick

- **Other Attendees**

  None