

**OPTN Membership and Professional Standards Committee
Performance Monitoring Enhancement Subcommittee
Meeting Summary
March 26, 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 03/26/2021 to discuss the following agenda items:

1. Welcome and Agenda
2. Performance Review Data
3. Discussion of Boundaries for Kidney Metrics – SRTR Presentation

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

1. Welcome and Agenda

The Chair of the MPSC Performance Monitoring Enhancement Subcommittee welcomed the subcommittee and other MPSC members to the call. Staff provided an overview of the agenda and explained the meeting's objective was to discuss potential boundaries for kidney performance metrics.

2. Performance Review Data

Per the Subcommittee's request, staff gave a presentation reviewing historical performance review data. The presentation contained graphs that showed a breakdown of components of the Spring 2020 program-specific reports (PSRs) for each organ type (heart, kidney, liver, lung, and pancreas). Staff explained each component and how many programs were newly identified or were under review by the MPSC. Staff also presented data through a bar graph that showed the length of program performance reviews for all programs that were under review during the 2020 calendar year. Additionally, staff presented a chart that showed the number of components identified and the number of programs that received an inquiry for both cycles in 2019 and the Fall 2020 PSR cycle. Staff explained the relevant questions for developing boundaries overall and for each organ. Finally, staff provided information on the number of kidney programs flagged and the number of inquiries sent to kidney programs for all reporting cycles in 2019 and 2020 to support the discussion of appropriate kidney metric boundaries. Staff welcomed any feedback or suggestions from the MPSC.

Feedback:

Members discussed the historical performance review data and the potential enhanced performance review process. One member stated concern about the yellow zone as an additional level of oversight, as well as additional new metrics, because it could incentivize programs to decrease the number of transplants. He stated that programs could show more risk-averse behavior because of the MPSC's oversight. The Subcommittee Chair clarified that for those who might be concerned that the MPSC would not be fulfilling its responsibility as an oversight body, notifying a program that the OPTN is aware that the program is trending in the wrong direction is a level of oversight. However, in the yellow zone,

programs would not be required to participate in interventions with the MPSC but could voluntarily request process improvement assistance if they choose. It is part of a system of staged oversight.

One member mentioned that the yellow zone would be helpful and would become widely adopted by programs. Another committee member noted that it had not been his experience at his program that oversight resulted in risk-averse behavior or decreased transplants. He supported the yellow zone concept stating that the yellow zone was analogous to programs reviewing its CUSUM data, which all programs should be doing. The CUSUM data allows programs to understand which direction they are trending and all programs should use CUSUM data in their improvement efforts. He also mentioned that, contrary to some perceptions in the transplant community, doing more transplants helps programs with CUSUM data metrics and with the program's survival metrics so the inclusion of a yellow zone should not discourage programs from doing more transplants. The Subcommittee Chair noted that the yellow zone is a process improvement zone and provides an opportunity for programs to get assistance in improving processes if the program is interested.

Many subcommittee members stated that they were in support of the yellow (cautionary) zone.

3. Discussion of Boundaries for Kidney Metrics – SRTR Presentation

As an introduction, staff noted that the Scientific Registry of Transplant Recipients (SRTR) Director would demonstrate the SRTR Algorithm Explorer Tool. The first decision would be to determine the boundary of the red zone.

The tool allows the subcommittee to choose organ type, graft or patient survival, adult or pediatric, and 90-day or conditional 1-year survival, and then use sliders to set various survival differences or hazard ratios, and level of certainty. Using the tool, the Director explored several different criteria for 90-day graft survival and included the current MPSC boundary on the plot in addition to the chosen criteria for comparison purposes. The Director displayed the boundary suggested by the MPSC breakout group of 50% probability that a program is 3% below the national average, which identified two programs, and for comparison, displayed the results of 50% probability that a program is 2.5% below the national average, which identified three programs. The Director also displayed 50% probability that the program is 2.0% below the national average, which identified seven programs, and 50% probability that the program is 1.5% below the national average, which identified 12 programs. The subcommittee reviewed the data on the programs identified for each of these boundaries, evaluating whether the observed versus expected for the volume of transplants performed for each program raised clinical concerns.

Feedback:

During the demonstration, the members offered feedback and questions:

The subcommittee agreed that the 50% probability was appropriate.

The Subcommittee Chair mentioned that it would be of great value to set boundaries that could be easily understandable and explained to the transplant community. Using the fixed difference from the national average is more easily understood than the current use of the hazard ratio.

The subcommittee and other participating MPSC members were divided in their support for the various displayed cut-off values. Subcommittee members who supported a 3% critical survival difference cut-off stated that anything below 3% would flag more programs, reduce the number of transplants, and increase organ discards. Subcommittee members who supported a 2% critical survival difference cut-off stated that it was important to be more cautious in the beginning of the process. One subcommittee member noted that kidney transplants are more elective and kidney waitlist mortality rates are normally lower than other organs so when evaluating risk, it may be appropriate for a program to favor keeping the patient on the waiting list rather than performing a transplant that is likely to fail. He suggested a 2% critical survival difference cut-off for 90-day outcomes and 1% critical survival difference cut-off for 1-

year conditional. Other subcommittee members suggested that anything below a 2% critical survival difference cut-off could be too aggressive and could increase the MPSC's workload.

Another member asked if the policy would have to go back through the policy development process if the chosen metrics do not flag enough programs. Staff responded that the boundaries for the red zone would need to be included in the bylaws since programs that fell within that boundary would be required to interact with the MPSC. Any changes to that red boundary would need to go through an additional public comment period. Staff also added that there will be an evaluation plan included in the public comment document that would describe how often the MPSC would evaluate the boundaries and what data would be used to perform the evaluation to determine if the project goals were met.

Members stated concerns that adding additional metrics to the performance review process will result in an increase in the number of programs under review overall. The Subcommittee Chair explained that even though there are additional metrics, the MPSC would still flag fewer programs than are currently being flagged for post-transplant one-year survival. Subcommittee members noted that it would be important to emphasize that the MPSC would be flagging fewer programs and some noted that it is difficult to see when evaluating one metric at a time. One member expressed concern that the subcommittee may not be able to develop a sufficient rationale for the boundaries using the current process for determining boundaries since it is based on a quick review of the data of the programs identified. If we use this process, we may want to develop a process by which we can change the boundaries later using principles developed now. The Subcommittee Chair suggested a rationale that is based on the MPSC experience reviewing programs, the subcommittee's evaluation of the program's number of events observed and expected in the context of volume is appropriate to determine whether an intervention should be required or self-evaluation and improvement would be sufficient. The Subcommittee Chair noted that the subcommittee is evaluating whether the program data suggests a clinical risk to patients.

An MPSC member noted a concern that the community could view the metrics for 90-day outcomes as a surgeon issue, and outcomes for 1-year conditional as a nephrology issue. The Subcommittee Chair noted that we need to be clear that the 90-day outcome metric would measure several factors including waitlist management, patient selection, organ selection, peri-transplant clinical pathways, and immunosuppression algorithms, so it measures the multi-disciplinary approach to the early post-transplant phase not just the outcome of the surgery.

Subcommittee members discussed concerns with the current risk-adjustment model and emphasized the community's concern that some risk factors are not risk-adjusted. One member provided an example of a high-risk candidate on ECMO that has a high chance of poor outcomes. He stated that ECMO is not a risk-adjusted factor, and he would be reluctant to list a patient who has higher chances of poor outcomes because it affects the program. The MPSC needs to decide if we want to encourage programs to transplant patients with a high chance of poor outcomes and if so, those high risk factors need to be reflected in the models. The Subcommittee Chair noted that we are identifying those programs that the MPSC believes should be required to submit information to determine if there is an issue. The subcommittee is weighing its responsibility to inquire with programs that need help with performance improvement and its interest in not creating a disincentive to transplant higher risk patients. A subcommittee member asked whether there would be an opportunity to thoroughly review the risk models and identify risk factors that are not included in the models. The Subcommittee Chair noted that improving risk adjustment and altering the flagging boundaries are two different conversations. Risk adjustment could be improved but that is a different conversation and project than the current MPSC project. The SRTR Director noted that the SRTR welcomes MPSC feedback to improve the risk adjustment models. In addition, the SRTR adjusts the models every 6 months. He also referred

to the subcommittee member's suggestion that there may be factors that should not be adjusted for if the community agrees that a patient with that characteristic is not a good candidate for transplant.

Following discussion, the subcommittee participated in three polls to determine support for various boundary criteria:

- Red-zone boundary for 90-day outcome at 50% probability – The votes were split, with 43% support for a 2.0 critical survival difference cutoff, 36% for a 2.5 critical survival difference cutoff, and 23% for a 3.0 critical survival difference cut off.
- Red-zone for 1-year conditional outcome at 50% probability – The votes were split, with majority support of 62% for a 2.0 critical survival difference cut-off and 38% for a 3.0 critical survival difference cut-off.
- Should the yellow zone be from the current MPSC boundaries to the new implemented threshold? The majority of the subcommittee supported the yellow zone starting at the current MPSC boundary (91%).

Since the results of the 90 day survival poll were essentially even between the 2.5 and 3.0 critical survival difference, the subcommittee participated in a new-poll for the red-zone boundary with these two options.

- The majority of the subcommittee (67%) supported a 2.5 critical survival difference cut off.

A staff member stated concerns about the length and outcome of the discussion and suggested changing the approach in order to meet public comment deadlines. She also stated that the total number of programs flagged seemed to be of importance to the subcommittee and recommended working with the SRTR to apply specific flagging criteria to all metrics to provide the subcommittee with a holistic view of the boundaries for each organ type. The subcommittee could then review and discuss the results and adjust the boundaries, as appropriate. The subcommittee supported the approach suggested by staff. However, one subcommittee member emphasized the importance of choosing metric boundaries carefully and understanding the rationale for why the boundaries were chosen.

The Subcommittee Chair then requested feedback from the subcommittee on the pre-transplant metrics. He suggested that the subcommittee might want to set less strict boundaries initially, identifying true outlier programs, since the MPSC has not previously evaluated programs on these metrics. The MPSC could then tighten the boundaries over time. A subcommittee member noted concern that reviewing offer acceptance will reduce transplants since programs will change offer filter parameters, and suggested that there are factors other than the program's actions that affect a program's offer acceptance rate. Another subcommittee member acknowledged that, in order to increase transplantation and reduce organ discard, monitoring offer acceptance is a good idea.

Upcoming meetings

- April 13, 2021 -Performance Monitoring Enhancement Subcommittee meeting, 3 – 5:00 pm EST
- April 22, 2021 - MPSC meeting, 1 – 3:00 pm EST
- April 27, 2021 - Performance Monitoring Enhancement Subcommittee meeting, 3 – 5:00 pm EST
- May 7, 2021 - Performance Monitoring Enhancement Subcommittee meeting, 2 – 4:00 pm EST
- May 21, 2021 - Performance Monitoring Enhancement Subcommittee meeting, 4 – 6:00 pm EST
- May 25,2021 - MPSC meeting 2 – 4:00 pm EST
- June 11, 2021 - Performance Monitoring Enhancement Subcommittee meeting, 2-4:00 pm EST

Attendance

- **Subcommittee Members**
 - Richard N. Formica Jr (Subcommittee Chair)
 - Sanjeev K. Akkina
 - Errol L. Bush
 - Adam M. Frank
 - Mary T. Killackey
 - Jon A. Kobashigawa
 - Jules Lin
 - Didier A. Mandelbrot
 - Virginia(Ginny) T. McBride
 - Willscott E. Naugler
 - Lisa M. Stocks
- **Other MPSC Members**
 - Christy Keahey
 - Maryjane Farr
 - Alice Gray
 - John Gutowski
 - Edward Hollinger
 - Clifford Miles
 - Steven Potter
 - Scott Silvestry
 - Parsia Vagefi
- **HRSA Representatives**
 - Marilyn Levi
 - Arjun U. Naik
 - Raelene Skerda
- **SRTR Staff**
 - Nicholas Salkowski
 - Jon J. Snyder
 - Bryn Thompson
 - Andrew Wey
- **UNOS Staff**
 - Sally Aungier
 - Tameka Bland
 - Robyn DiSalvo
 - Nadine Drumn
 - Amanda Gurin
 - Ann-Marie Leary
 - Amy Minkler
 - Jacqui O'Keefe
 - Sharon Shepherd
 - Leah Slife
 - Stephon Thelwell
 - Gabe Vece
 - Betsy Warnick
- **Other Attendees**

- None