

**OPTN Membership and Professional Standards Committee
Performance Monitoring Enhancement Subcommittee
Meeting Summary
March 12, 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 March 12, 2021, to discuss the following agenda items:

1. Welcome and Agenda
2. Review of Project Timeline
3. Follow-up to MPSC Breakout Sessions
4. Wrap Up

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 and explained the meeting's objectives. The Subcommittee Chair stated that there were no action items on the agenda noting that the Subcommittee requested data from the Scientific Registry of Transplant Recipients (SRTR) showing what it thought to be reasonable thresholds of 3%, 5%, and 7% below the national average. When reviewing the resulting data, it became apparent that the magnitude of the differences from the national average may be less than the subcommittee originally identified because the range of program performance is much tighter.

Additionally, the Chair observed that there is a need for the MPSC members to really understand the metrics and how the probabilities and percentage thresholds interact in order to be able to explain it to the community. The SRTR staff have developed a tool to help the subcommittee and the MPSC understand the interaction between the probabilities and the percentage thresholds as well as providing data on the programs captured by various thresholds. The Chair encouraged the subcommittee to ask questions during the meeting in order to understand fully the metrics and the concepts of probability and percentage difference from the national average the subcommittee is discussing. He asked the subcommittee not to think in terms of flagging or not flagging but rather consider whether a particular program's performance would raise clinical concerns for members of the subcommittee.

2. Review of Project Timeline

Staff provided an overview of the meeting agenda and summarized the timeline for the MPSC Performance Monitoring Enhancement Project. Staff noted that the subcommittee would need to meet more frequently during the next few months to meet the deadlines for summer public comment. The Subcommittee reviewed a summary of cut-off recommendations made during the MPSC Breakout Groups at the February MPSC meeting, which included:

- Abdominal Group
 - Post-transplant 90-day and 1-year conditional: 50% probability that programs are 3% lower than the national average for the red zone.
 - Pre-transplant waitlist mortality and offer acceptance: Request data using Bayesian modeling for the 2.5, 2.0, and 1.5 SD from the national average

- Thoracic Group
 - Pre-transplant (Heart):
 - 90 Day - 75% probability that programs are 5% lower for red and 3% lower for yellow
 - 1-year conditional- 50% probability that programs are 3% lower for red and 2% lower for yellow
 - Pre-transplant 90-day and 1-year conditional (Lung): 75% probability that programs are 5% lower than the national average for red zone and 3% for yellow.
 - Post-transplant (Heart & Lung):
 - Waitlist mortality – 3.0 SD red and 2.5 SD yellow
 - Offer Acceptance – 2.5 SD red and 1.5 SD yellow

3. Follow-up to MPSC Breakout Sessions

- **SRTR Presentation**

As an introduction, the Subcommittee Chair noted that the SRTR Director is going to provide more explanation of the probability curves and how the probability interacts with proposed cutoff points. The SRTR Director gave a presentation reviewing the decision points involved in determining a flagging boundary. He then explained that the first decision was to determine the appropriate cutoff value, followed by a second decision to determine the degree of certainty or probability. The director explained that a 50% certainty that a program is higher than a particular cutoff means that there is a 50% or higher probability that a particular program's performance is to the right of a given cutoff, not whether there is 50% certainty that the program's performance is higher than the national average. Another SRTR staff person noted that the 50% certainty is also not 50% certainty that the program is above or below expected, it is 50% certainty that the program's observed performance is higher than the difference from expected incorporated in the proposed cutoff.

The Director demonstrated the Post-Transplant Algorithm Explorer (SRTR tool). The SRTR has completed work on the post-transplant outcome tool and is working on the pre-transplant tool that will be made available to the subcommittee prior to its next meeting on March 26. 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 survival difference or hazard ratio, and level of certainty. The director used the February 24 MPSC thoracic breakout group's suggested thresholds for heart as an example of how to use the tool. The director demonstrated and explained the tool and noted that the thoracic group's current recommendations would not identify any programs in the red MPSC intervention zone or the yellow cautionary zone. The tool provides

- A plot that shows the zone in purple shading
- A second plot based on a simulation of the chosen criterion that provides the false positive rate and the power of the chosen criterion to capture true positives
- A table is included that notes the false positive rate (the probability that a program would be identified that was not underperforming) and the power to identify programs that have a hazard ratio greater than 2 for small, medium and large programs. The power of a criterion

illustrates that if you assume all programs have double the national average failure rate, the probability that the chosen criterion would capture programs.

- A table that provides details on the characteristics of programs that fall within the boundary, including the number of transplants over the 2.5 year cohort, the observed survival, the expected survival, the hazard ratio, the national survival rate, and the standardized survival rate for the program. The standardized survival rate takes into account the risk adjustment and the shrinkage used to determine the hazard ratio.

The user can also check a box to show the current MPSC boundary on the plot in addition to the chosen criteria for comparison purposes. A separate check box will show the curved event lines on the plot identifying the programs that had a certain number of events.

The Subcommittee Chair asked the subcommittee to review the data regarding the programs identified under various criteria and think about at what point they would have clinical concerns about a program. SRTR also demonstrated the results for the recommended thresholds for other organs and how the tool could be used to review results for pediatric programs.

- **Subcommittee Discussion**

The Subcommittee used the SRTR tool to demonstrate different cut-off values for each organ type (heart, kidney, liver, and lung). During the demonstration, the Subcommittee offered feedback and questions:

A subcommittee member emphasized the importance of recognizing "survival benefit." He stated that the cutoff-values recommended by the thoracic breakout group during the February MPSC meeting are clinically acceptable considering the critical state of most heart transplant patients. He also added that lowering the threshold would allow more "extended criteria donors" to be used and could increase the number of transplants. Based on these goals, he is not concerned clinically with the performance of any of the programs at the higher end of the plot. He then emphasized that the yellow zone is where the MPSC should focus their efforts. The Subcommittee Chair reminded the subcommittee that first, the MPSC is focused on setting the boundary for the red intervention zone where the program will provide the MPSC formal documentation in response to an inquiry. The yellow cautionary zone remains to be determined. The yellow cautionary zone would identify programs that will receive notice of concerning trends that includes a request that the program self-evaluate and an offer of performance improvement assistance if the program chooses to use them. The Chair acknowledged that one of the goals of the project is to increase transplants. The Chair also encouraged the subcommittee to consider the harm associated with a program that chooses to perform transplants on very high risk patients who have a low probability of doing well and the graft fails or the patient dies. In that situation, the program has performed more transplants but has also essentially denied a transplant to someone else who could have a higher probability of doing well.

SRTR staff mentioned that there should not be an assumption that a program is taking on a large amount of risk that is not already a part of risk-adjustment. SRTR staff provided an example of a heart program that has the highest hazard ratio explaining that the program, in terms of the adjusted risk, appears to be performing lower risk transplants than the average program so unless the transplants are low-risk using the adjusted factors and somehow extremely high risk on the unadjusted risk factors, the program is underperforming on lower risk transplants. In order to explain a hazard ratio of 2.0 as due to a program performing transplants with risk factors that are not risk adjusted, all of the patients the program transplanted would need to have those unadjusted risks and no other program in the country was taking on those same unadjusted risks. The SRTR Director also mentioned various factors included in the risk adjustment used to calculate the

number of expected patient deaths. SRTR staff encouraged feedback on how to improve the current risk adjustment process and model.

The Subcommittee Chair requested that the subcommittee ask themselves how much of a false positive rate the subcommittee is willing to accept and how little power is the subcommittee willing to accept. The false positive rate identifies the likelihood that a program that is truly not underperforming would be identified resulting in a request for information. Power, in this context, represents the likelihood that programs would be identified that need performance improvement intervention. Low power percentages would mean that there is a high likelihood that programs that need performance improvement intervention will not be identified. Then evaluate clinically the data for programs that are identified at varying probabilities and cut-off levels using the sliders in the tool.

One subcommittee member suggested that the goal is to develop a flagging system that is more permissive to innovation and acceptance of high-risk organs and transplantation of patients with historically poor access to transplant. He asked the subcommittee to consider the economic and opportunity costs of flagging, which could take away from the mission of increasing the number of transplants. Following a demonstration of the kidney results by the SRTR Director, the Subcommittee Chair noted that his opinion has migrated somewhat as the subcommittee moves through this process, in that he agrees that the goal to encourage programs to feel more comfortable accepting higher risk organs in order to increase the number of transplants is important. However, the MPSC also needs to make sure that it is intervening where necessary. He stated he has come to recognize that if a program is accepting more organs in an effort to perform more transplants and then underperforms when transplanting those organs, it results in the denial of access to a candidate who did not receive that organ. Both of these factors need to be considered in developing a threshold for review.

During further discussion, subcommittee members agreed that one of the important goals of the project is to encourage programs to perform more transplants through removing disincentives to use of higher risk donor organs and to perform higher risk recipient transplants. Subcommittee members also recognize that program performance improvement is a role of the MPSC noting that the MPSC should identify programs in order to encourage self-evaluation and analysis through their internal quality systems. The subcommittee agreed that the MPSC should establish lower thresholds that identify fewer programs than the current criteria and that there should not be an expectation that the MPSC identify programs every reporting cycle. The SRTR Medical Director suggested that in the context of kidney transplant, the clinical question is how much excess graft loss or death would the MPSC find acceptable and at what level is the concept that a program is doing better than dialysis no longer supported. Kidney transplant patients who lose a graft are either back on dialysis or have died and therefore, have not benefitted from transplant. Additionally, we now know that getting a kidney transplant and losing the graft is worse for the patient than staying on dialysis. The MPSC needs to decide how many excess graft losses at a program is acceptable without any level of performance improvement intervention.

Subcommittee members suggested that an important part of this project is an effort to destigmatize the MPSC review process emphasizing that the MPSC review is a peer support process. In support of those efforts, subcommittee members suggested that the MPSC transparently communicate how programs are identified and what happens when a program is identified.

The Subcommittee reviewed examples for 90-day and one-year conditional criteria for all organs and concluded that there is not a one-size fits all threshold for all organs so the subcommittee will be reviewing individual organs and establishing boundaries for each one in upcoming meetings.

Pediatric Outcomes Metrics:

The Subcommittee Chair stated that it would be difficult to set appropriate boundaries for metrics for pediatric programs because the volume of pediatric transplants is lower and there are relatively small numbers of pediatric graft losses and deaths. He asked the subcommittee members to think through the question of whether the MPSC should consider a process of clinical review of each pediatric graft loss and death. One subcommittee member noted that pediatric lung transplant outcomes greatly differ from other organs because pediatric lung recipients are incredibly high-risk. Additionally, not all pediatric lung risk factors are risk-adjusted. She also mentioned a large number of pediatric lung programs are currently identified and supported looking at alternatives to the current process.

4. Wrap Up

The Subcommittee Chair expressed appreciation for the Subcommittee's feedback and encouraged the Subcommittee to review the SRTR tool for post-transplant metrics. The SRTR Director stated that they are still working on the offer acceptance and waitlist mortality tool and would provide information on the tool when available.

Staff concluded the discussion, and the Subcommittee members had no further questions or comments.

Upcoming meeting (s)

- March 25, 2021, 1:00 pm – 3:00 pm (ET), MPSC Meeting
- March 26, 2021, 3:00 pm – 5:00 pm (ET), MPSC Performance Monitoring SC Meeting

Attendance

- **Subcommittee Members**
 - Richard N. Formica Jr (Subcommittee Chair)
 - Sanjeev K. Akkina
 - Errol L. Bush
 - Matthew Cooper
 - Adam M. Frank
 - Michael D. Gautreaux
 - Ian R. Jamieson
 - Mary T. Killackey
 - 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**
 - Maryjane Farr
 - PJ Geraghty
 - Alice Gray
 - John Gutowski
 - Edward Hollinger
 - Anne Krueger
 - Steven Potter
 - Scott Silvestry
 - Wagener Gebhard

- **HRSA Representatives**
 - Marilyn Levi
 - Arjun U. Naik
 - Raelene Skerda

- **SRTR Staff**
 - Ryo Hirose
 - Nicholas Salkowski
 - Jon J. Snyder
 - Bryn Thompson
 - Andrew Wey

- **UNOS Staff**
 - Sally Aungier
 - Tameka Bland
 - Matt Belton
 - Robyn DiSalvo
 - Nadine Drumn

- Amanda Gurin
- Ann-Marie Leary
- Amy Minkler
- Jacqui O'Keefe
- Sharon Shepherd
- Stephon Thelwell
- Gabe Vece
- Betsy Warnick
- **Other Attendees**
 - None