

Meeting Summary

OPTN Membership and Professional Standards Committee Performance Monitoring Enhancement Subcommittee Meeting Summary June 11, 2021 Conference Call

Richard Formica, M.D., Subcommittee Chair

Introduction

The Performance Monitoring Enhancement Subcommittee of the Membership and Professionals Standards Committee (MPSC) met via Citrix GoToTraining on June 11, 2021 to discuss the following agenda items:

- 1. Welcome and Agenda
- 2. Draft Proposal Language
- 3. Implementation Plan
- 4. Evaluation Plan
- 5. Review of Topic from National Webinar
- 6. Wrap Up

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

1. Welcome and Agenda

A staff member welcomed the subcommittee, reviewed the agenda, and explained the meetings objectives. She explained that the purpose of the meeting would be for the subcommittee to review the draft language for the bylaw proposal, and to review the project's implementation and evaluation plans. She also reviewed the project timeline and the project goals.

2. Draft Proposal Language

The staff member reviewed a summary of the bylaw proposal and mentioned that the proposed bylaw language includes only those aspects of the project that would require programs to interact with the MPSC. These include the adult and pediatric criteria for the MPSC intervention or "red" zone, a high-level overview of the performance review process and the goal of these reviews. In addition, the bylaw proposal includes the addition of a section that notes when and how a peer visit is performed, and member expectations in Appendix M: *Review and Actions*. Additional sections in that appendix have proposed small revisions related to the new peer visit section. Finally, several administrative changes are proposed to Appendix N: *Definitions* to remove definitions of two defunct MPSC standing subcommittees and update the SRTR definition.

The staff member described operational aspects not included in the bylaw proposal that the MPSC had discussed and that will be included in the public comment document. She provided examples of some of the operational aspects discussed by the MPSC including:

- The establishment of a performance improvement or "yellow" zone
- Periodic review of small volume program data and collection of information to provide data for discussion of optimal ways to interact with small volume programs

• MPSC evaluation and identification of elements of risk that have not previously been incorporated into the risk-adjustment models while performing performance reviews to identify potential new data elements for risk adjustment.

The staff member displayed the draft proposal language. The subcommittee reviewed the draft proposal language and offered feedback.

Subcommittee Feedback:

The subcommittee chair stated that because the yellow zone is not in bylaw language, it could be modified if needed in the future without going through the public comment process.

Another subcommittee member asked if the proposal would include charts and examples of what the performance review process would look like. He recommended the proposal include charts that show how the proposed metrics would flag less programs. The staff member responded that the full public comment document would include a detailed explanation of how the committee chose the metrics, boundaries, and review process.

The subcommittee participated in a poll to measure support for recommending that the MPSC release the bylaw proposal for summer 2021 public comment. The majority of the subcommittee voted to move forward with the recommendation (95%), while one subcommittee member voted to Abstain (5%). There were no other questions or concerns expressed about the draft language proposal.

The subcommittee also discussed and compiled a list of questions they would want to ask the transplant community about the proposal:

- Do you feel comfortable with risk adjustment or do you have educational needs on risk adjustment?
- Questions to gather feedback on possible future addition of longer-term post-transplant outcomes (5-year period prevalent).
- Does the emphasis on pre-transplant outcomes decrease emphasis on longer-term posttransplant outcomes?
- What type of resources do you anticipate needing to respond to these new metrics?
- What educational resources would you need so you can describe these metrics to your patients?
- Do you think the proposed is better than the current system?0

3. Implementation Plan

A staff member summarized the project's implementation plan. She reported that the post-transplant implementation would occur approximately 6 months after board approval since transplant programs have experience post-transplant graft survival metrics. The pre-transplant metrics would be implemented based on the first available SRTR reports that will include a full cohort following board approval. The staff member mentioned that the OPTN would provide educational offerings prior to implementation. In addition, after implementation, the OPTN may ask programs that would be identified using the pre-transplant metric criteria to provide information voluntarily to support development of resources and the inquiry process. The subcommittee asked questions about the implementation plan and provided feedback.

Subcommittee Feedback:

Subcommittee members asked about the accountability of programs before the implementation date. A staff member responded that programs would not be identified for pre-transplant metrics prior to implementation, but would be held accountable for data that accumulates from board passage to the implementation date.

Another subcommittee member stated that the MPSC should have a communication strategy during the implementation phase to prepare programs for what is coming.

A HRSA representative asked about delaying implementation for individual programs that express concerns about being identified with the new metrics. The subcommittee chair and staff stated that it would not be wise to offer a delay in implementation to individual programs, but rather have an educational period for the entire community.

The subcommittee supported recommending the implementation plan for full review by the MPSC and had no other questions or concerns about the implementation plan.

4. Evaluation Plan

A staff member discussed the proposed evaluation plan to monitor the effect of the proposal post-implementation. The staff member explained that there are many potential outcomes to monitor in order to determine if the project is meeting the project goals. The staff member also summarized the proposed monitoring plan and discussed seven outcomes of interest.

- 1. Utilization Rates (Transplant per Donor) National Mean Utilization Rate, by Organ
- 2. Waitlist Addition Rates (Additions per day) National Mean Listing Rate, by Organ; Variability in Listing Rates Across Programs, by Organ
- 3. Offer Acceptance Rates (Acceptances per Offer) National Mean Acceptance Rate, by Organ; Variability in Acceptance Rates Across Programs, by Organ
- 4. Waitlist Mortality Rates (Deaths per Person- Year) National Mean Mortality Rate, by Organ; Variability in Mortality Rates Across Programs, by Organ
- 5. Post-transplant Graft Failure Rates (Survival with a Functioning Graft) National Mean Survival Rate, by Organ; Variability in Survival Rates Across Programs, by Organ
- 6. Number of New/Unique Programs Identified for Review Number of programs identified, by metric; Number of New programs identified, by metric
- 7. Qualitative insights from individual program interactions

The staff member explained the scope of monitoring and stated that monitoring would take place over an extended period of time and would involve separate organ specific analyses. He also stated that certain outcomes may not be measurable immediately after implementation, but others can and should be. The staff member also explained timing considerations and reported that the pre-transplant metrics would not be evaluated until they have been fully implemented. He concluded the discussion and requested feedback from the subcommittee.

Subcommittee Feedback:

A member of SRTR asked staff about incorporating benchmark reports as part of the monitoring of waitlist mortality to examine trends and waiting list composition with respect to different demographics (race/ethnicity; age) and risk groups. He stated this would help identify any unintended consequences of the waitlist mortality metric.

Another subcommittee member suggested that there could be possible confounders that may change how programs accept or decline patients. He provided the example of DCD and perfusion technology.

The subcommittee chair stated that the proposal should include language that the MPSC would also monitor for equity and inclusion.

In response to a subcommittee request to perform independent periodic reviews of small volume programs, a staff member noted that the proposed evaluation plan includes a periodic review of data for small volume programs to evaluate effectiveness of the criteria to identify potential issues at small volume programs and consider appropriate alternatives, if needed. The staff member asked the subcommittee how it would define "small volume" programs, or should there be a review of randomly selected programs of all volumes.

The staff member presented charts showing pediatric and adult program volumes in the Spring 2020 PSR for heart, kidney, liver, and lung. She also discussed the current, and a potential definition for a small volume program. The subcommittee offered questions and comments.

Subcommittee Feedback:

An SRTR representative asked what the motivation was for randomly selecting to evaluate programs. He stated that the MPSC could just identify more programs for review. The subcommittee chair responded that the MPSC wants to make sure they are not being too liberal with screening. A staff member added that a review of the data would determine if the MPSC would want to request that the program voluntarily provide additional information to help in its analysis.

One subcommittee member stated that he did not support evaluating small volume programs, but would rather evaluate a random selection of programs of all volumes, noting that the subcommittee must take into account staff time, as well as the limited resources at small volume programs. He also stated that evaluating smaller programs only could make it seem like smaller programs are being looked at more closely than larger programs.

Other subcommittee members supported a process to review data and request information from small volume programs in order to answer the question of whether an alternative method for reviewing "small volume" programs should be determined.

The subcommittee participated in a poll to measure support for using the current or a new definition of a small program for the evaluation plan. The majority of the subcommittee (64%) voted to use a new definition (Less than 1 transplant/month or 30 transplants over 2.5 years). There were no other questions or concerns expressed about the evaluation plan.

5. Review of Topic from National Webinar

A staff member described a question posed during the national webinar about multi-organ transplants. The staff member stated that the subcommittee had previously discussed multi-organ transplants in the context of the exclusion and inclusion criteria for the proposed metrics. However, the subcommittee had not specifically focused on whether performance on multi-organ transplants should be evaluated. A member of the SRTR staff stated that multi-organ transplants are not currently included in the post-transplant evaluation cohorts. He also stated that multi-organ transplants are not included in the offer acceptance metric, but are included in the waitlist mortality metric for multi-organ candidates that are listed on a single organ waiting list.

The subcommittee chair brought up a question asked during the national webinar, which was, "Will more metrics mean more programs will be flagged?" He presented a chart that showed the total number of programs flagged for the Spring 2020 PSR through the Fall 2020 PSR for the current performance monitoring criteria. He stated the average number of flags under the current criteria was 68.5 programs. He compared the data to the total number of programs identified under the new criteria

and noted that 62 programs would be identified. He reported that there were also concerns raised about programs being flagged by multiple metrics but the data shows that there are very few programs that would flag for more than one metric in a single cohort. The subcommittee chair encouraged subcommittee members to communicate these concepts to the community.

6. Wrap Up

A staff member thanked the subcommittee and ended the meeting. The subcommittee had no additional questions or concerns at this time.

Upcoming meeting

• June 24, 2021- MPSC Meeting, 1 – 3:00 pm ET

Attendance

• Subcommittee Members

- Richard N. Formica Jr (Subcommittee Chair)
- Sanjeev K. Akkina
- Matthew Cooper
- o Adam M. Frank
- Michael D. Gautreaux
- o Alice L. Gray
- John R. Gutowski
- o lan R. Jamieson
- Christy M. Keahey
- o Jon A. Kobashigawa
- Jules Lin
- Didier Mandelbrot
- Virginia(Ginny) T. McBride
- Wilscott E. Naugler
- o Matthew O'Connor
- Steven R. Potter
- o Lisa M. Stocks

• Other MPSC Members

- Jonathan A. Fridell
- PJ Geraghty
- Edward F. Hollinger
- o Anne M. Krueger
- Saeed Mohammad
- Nicole A. Pilch
- Scott C. Silvestry
- Gebhard Wagener

• HRSA Representatives

- o Marilyn Levi
- Arjun Naik
- o Raelene Skerda

SRTR Staff

- o Ryo Hirose
- Nicholas Salkowski
- o Jon J. Snyder

UNOS Staff

- Sally Aungier
- Nicole Benjamin
- o Tameka Bland

- o Robyn DiSalvo
- o Amanda Gurin
- Danielle Hawkins
- Melissa Koch
- Kay Lagana
- o Ann-Marie Leary
- o Amy Minkler
- o Jacqui O'Keefe
- o Liz Robbins-Callahan
- o Sharon Shepherd
- o Leah Slife
- o Stephon Thelwell
- o Gabe Vece
- Betsy Warnick
- o Karen Wooten

• Other Attendees

o None