OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
October 26-27, 2021
Conference Call with GoToTraining

Ian Jamieson, Chair
Zoe Stewart Lewis, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met by conference call in open and closed session via Citrix GoToTraining on October 26-27, 2021, and discussed the following agenda items:

1. Performance Monitoring Enhancement Project Update
2. Update from SRTR
3. Educational Referrals
4. Individual Member Focused Improvement (IMFI) Pilot Update
5. Patient Safety Events: Data and Case Analysis for Potential Educational Efforts
6. Membership Related Actions
7. Performance Related Actions
8. Compliance Related Actions

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

1. Performance Monitoring Enhancement Project Update

A staff member updated the Committee on the status of the Enhance Transplant Program Performance Monitoring System Proposal. The goals for the Committee were to review the public comment received on the proposal, determine any needed post- public comment revisions, and decide whether to request that the OPTN Board of Directors approve the proposal at its December 6, 2021 meeting. The staff member also noted there would be an update on the implementation and evaluation plans and committee members would have the opportunity to provide feedback.

The staff member summarized the public sentiment on the proposal and reported that overall 74% of respondents either supported or strongly supported the proposal. She summarized the sources of public comment and mentioned the demographics of the respondents. The staff member informed the Committee that the MPSC Performance Monitoring Enhancement Subcommittee met on October 12 to provide initial feedback on the public comment received on the proposal and develop recommendations for the full Committee.

<u>Review of Public Comment</u>
The staff member summarized the main areas of public comment and reported the subcommittee's observations on these topics. The MPSC offered questions and feedback on the main themes of public comment.

- Longer-Term Post-Transplant Outcomes Measure

  Staff reported that in response to the Committee's question about longer-term outcomes in the public comment document, the majority of comments supported the future use of a longer-term post-transplant outcome metric. Most patients noted that one-year survival is not optimal and the OPTN should focus on longer-term graft survival. There was also some debate in the comments between using a 3-year or 5-year measure. A small number of commenters opposed the use of a long-term outcomes measure noting that programs are not primarily responsible for care of recipients long-term. Committee members provided no additional comments at this time.

- Waitlist (Pre-Transplant) Mortality

  The staff member noted that a significant number of comments addressed the waitlist mortality rate metric. Although the comments received supported measuring waiting list management, there were concerns about the use of the waitlist mortality rate ratio to evaluate kidney programs and the possibility that programs will respond with risk-averse behavior. The staff member reported that the subcommittee mentioned that overall consistency across all organs is important even if this metric is not impactful for kidney programs. She mentioned additional subcommittee discussion that focused on a recognition that patients are looking for access to transplant not just to a programs waiting list, noting that programs have a responsibility to take actions that make it more likely a candidate will make it to transplant alive. The subcommittee also noted that risk adjustment accounts for the risks posed by listing sicker patients. In addition, the newer allocation systems favor sicker patients so programs cannot avoid sicker patients if the programs wants to get offers and perform transplants. The subcommittee did not support any changes to the proposal on this topic other than the change to the name of the metric. A committee member asked about the inclusion of high panel reactive antibodies (PRA) in risk adjustment. The SRTR Director responded that high PRA is included in the risk-adjustment model. There were no additional comments made by the committee.

- Offer Acceptance

  Staff described the primary public comment feedback on the organ offer acceptance metric, noting that there was broad support for this metric. The staff member reported that there were concerns raised that the metric may discourage use of broad donor criteria to maximize patient opportunity for transplant, and that more aggressive programs may be disadvantaged. The staff member reported the subcommittee's responses that organ offer acceptance is completely within the control of the program and that it aligns with the Center for Medicaid and Medicare Services (CMS) measures for organ procurement organizations (OPOs). The subcommittee also noted that use of this metric was intended to encourage use of screening criteria and offer filters to reduce organ offers that the program is very unlikely to accept in order to get the organ to the right patient at another program. The subcommittee did not support any changes to this metric. A committee member stated the importance of future education about metrics and risk adjustment, and suggested engaging a professional education consultant. Staff responded that staff is working with Professional Education staff to develop education on the topics.

- Risk Adjustment, Criteria, Number of Programs Identified

Staff summarized public comment received on risk adjustment, the criteria, and the number of programs identified. She reported that there was broad support for the use of risk-adjusted metrics. However, there were concerns raised about risk factors not represented in the models. The staff member reported American Society of Transplant Surgeon (ASTS) comment that supported use of an unadjusted fixed floor criteria, and raised concerns about the number of programs being identified under the proposed performance review. Staff explained that the subcommittee addressed these concerns and concluded the lack of a perfect risk adjustment model should not result in rejection of risk adjustment altogether. The subcommittee also discussed the rationale for rejection of a fixed floor, including that a reasonable fixed floor would be more likely to result in risk averse behavior, a fixed floor based on outcomes of alternative therapies is not an option for organs other than kidney, and that use of a fixed floor would likely result in requests for different floors based on differences in patients and donor organs in various parts of the country. The subcommittee acknowledged that the proposal is based on observed to expected outcomes, so there is no predetermined number of programs that would be identified. She reported that the subcommittee did not support any changes to the proposal on this topic. Committee members provided no further comments on this topic.

- AST and ASTS Comments

  The staff member summarized American Society of Transplantation (AST) and ASTS comments. Staff reported that AST expressed neutral sentiment and contained feedback from its communities of practice and a patient advisory committee. The AST response expressed support for many aspects of the proposal but raised concerns that mirrored others concerns about the waitlist mortality metric and that some risk factors were not accounted for in the risk adjustment models. She also noted that ASTS strongly opposed the proposal and had concerns that more metrics may hamper the transplant community's goal to increase transplants. The staff member provided a summary of the comments expressed by ASTS, noting that the ASTS favored continued use of only the one-year post-transplant survival metrics and in the alternative, raised similar concerns as other commenters about the use of waitlist mortality and offer acceptance metrics. As discussed previously, the ASTS suggested use of a fixed floor criteria and raised the concern that too many programs would be identified for review. A SRTR representative stated that a fixed floor with no risk adjustment could potentially increase risk averse behavior. Committee members provided no additional comments on this topic.

<u>Post-Public Comment Revisions</u>

Staff reported that the committee would vote on whether to move forward with two post-public comment revisions. Staff reviewed the post-public comment revisions and requested feedback from the committee.

- <u>Change Waitlist to Pre-Transplant</u> – Staff described a potential change to the title of the waitlist mortality metric to pre-transplant mortality. The SRTR had recently made this change to the title in the SRTR Program Specific Reports (PSRs). The change was made to better reflect that the model includes deaths following removal from waiting list. She reported that the subcommittee supported the change but not unanimously. Some subcommittee members had concerns that pre-transplant might be interpreted as including pre-listing. Staff reviewed the potential proposal language revision. A committee member stated his concern was that changing the

name could result in having to change the bylaws again if a metric was developed in the future that measured pre-listing performance. A few committee members voiced concerns about changing the nomenclature of the metric, while others supported the change.

Committee members supported changing waitlist mortality to pre-transplant mortality in the proposal by a vote of 26 For, 7 Against, 1 Abstention.

- Addition of Metrics Descriptions – Staff explained the rationale for adding metric descriptions. The subcommittee suggested adding metric descriptions to OPTN Bylaws, Appendix N: *Definitions* to provide more clarity and transparency about what each metric is measuring. The potential downside of adding the descriptions is it could reduce the ability to incorporate changes made by SRTR to models without a bylaw change if the descriptions were too detailed. The staff member reviewed the proposed descriptions of the metrics. Some committee members stated concerns with the "Pre-Transplant Mortality Rate Ratio" definition. A committee member noted a discrepancy in the wording and suggested changes to the proposed definition to make it clearer that only deaths during the measurement interval were included. Committee members supported changing the definition to include the term "during the measurement interval". Another committee member suggested adding an asterisk to guide people to look for the new definitions within the bylaws. Staff responded that a footnote may be able to be included that notes that there is a definition in Appendix N for each metric.

  Committee members supported the addition of the descriptions of metrics, as amended during the meeting, to the Bylaws N: *Definitions* by unanimous vote of 34 For, 0 Against, 0 Abstentions.

Sending the Proposal to the Board of Directors for Approval

Following the discussion of public comment, the recommendations from the subcommittee, and the discussion and votes on the post-public comment revisions, Committee members had no further questions or comments on the proposal and proceeded to a vote on whether to send the proposal for approval to the OPTN Board of Directors.

Committee members recommended that the Board of Directors approve the MPSC proposal, as amended post-public comment, by a vote of 32 For, 1 Against, 1 Abstention.

Implementation and Evaluation Plans

Committee members were updated on the recent staff discussions about the implementation and evaluation plans. Staff reminded the Committee that there would be a phased implementation of the metrics, and reviewed the implementation effective dates for each of the four metrics. The staff member provided a detailed implementation plan describing the work of the MPSC on this project over the next three years. The implementation and evaluation plans include staff and MPSC work on education and resources for members, the development of a framework and tools for MPSC performance review, and the monitoring of the effectiveness and any unintended consequences of the proposal.

Staff described the upcoming Performance Monitoring Enhancement Subcommittee work and asked for additional volunteers who would like to join the subcommittee. Committee members participated in a poll to gauge committee member interest in joining the subcommittee.

2. Update from the SRTR

The Director of the Scientific Registry of Transplant Recipients (SRTR) updated the committee on the SRTR Task 5 initiative. The Director explained the charge of the Task 5 initiative, which is to identify metrics to assess national transplantation system performance and support informed decision making by critical audiences. He provided the Committee with an overview of the reporting requirements of the Final Rule and the SRTR's secure site. He highlighted specific requirements of Task 5, which included:

- Identify information of interest to critical audiences
- Develop assessments and metrics

The Director also reviewed the scope of the Task 5 effort and discussed the 5-year process and timeline under Task 5. He introduced the members of the Task 5 Steering Committee and the role of the Steering Committee. The Director provided an overview of the planned patient focus groups to try systematically gathering feedback from the patient population. The Director provided information on where committee members could find information on recruitment for the patient focus groups.

The Director also discussed SRTR's Human Centered Design Initiative, which will help implement conference recommendations from a design and usability standpoint. He stated the SRTR will host a public comment period (Nov-April) leading up to the consensus conference where any interested party can comment. He provided information about the consensus conference meeting date and venue.

The Director provided the Committee with an opportunity to provide feedback and ask questions. A committee member stated he was impressed by the level of conversation that has happened about the metrics and how they should be used. The committee member also mentioned the challenge of tailoring metrics to a specific audience. The SRTR Director responded that it is always critical to ask who the metrics are designed for, and determine the best way to make clear. He used the example of transplant rate and overall survival from listing metrics, which are beneficial metrics for patients. However, those metrics are not beneficial for the MPSC to monitor due to the multiple organizations whose performance contributes to those metrics. The MPSC Vice Chair, who is a Task 5 steering committee member, stated that committee members could reach out with any feedback from stakeholders in the community.

The Director mentioned that he would like to change the conversation surrounding SRTR from being seen as a regulatory body. Another SRTR representative stated the importance of education in the community on the metrics and asked the MPSC to remain as informed as possible. The Committee had no additional questions or comments.

3. Educational Referrals

The purpose of the Educational Referrals session, which is held at the end of every multi-day Committee meeting, is to receive ideas and feedback from committee members regarding any topics for which it would be beneficial to further educate or communicate about to members. Educational recommendations from committee members can take several forms, including but not limited to online courses or modules, online articles, email newsletter articles, and conference presentations.

There was an educational referral submitted ahead of time, so the session started with an open discussion about early cross match on all deceased donor offers. A Committee member led the discussion and asked the Committee to discuss the merits of early, physical cross match, such as less cold ischemic time and increased utilization of organs, as well as the limitations. There was a very robust conversation during which Committee members who use virtual cross match shared their experiences of being able to reap much of the benefit of a physical cross match, but not require tissue typing material to be sent from the procuring OPO. The exception to the use of virtual cross match, according to the discussion, is when a patient has a very high CPRA. The Committee ended its discussion of this topic by suggesting some additional education and sharing of effective practices in the area of virtual cross match utilization and staff agreed to bring it back to a multidisciplinary team that assesses feasibility and next steps for educational referrals.

When asked "From your perspective, on what topics do members need additional education or clarification" and "What education or information would be valuable for the transplant community", there were no responses in addition to the discussion topic mentioned above, however, there were many educational referrals mentioned during some of the other sessions of the Committee meeting. A couple of those referrals include providing guidance around programs having a crisis or disaster plan following a sentinel patient safety event with active engagement from the hospital administration, and technology enhancements that would assist in donor referral and ensuring patient safety by flagging patients in the system with similar names, among other suggestions.

Staff will continue to work on these educational opportunities and will report to the Committee on progress made.

Upcoming Meetings

- December 9, 2021, MPSC Meeting, 1-3pm, ET, Conference Call
- January 20, 2022, 1-3pm, ET, Conference Call
- February 22-24, 2022, Chicago
- March 25, 2022, 1-3pm, ET, Conference Call
- April 22, 2022, 1-3pm, ET, Conference Call
- May 31, 2022, 3-5pm, ET, Conference Call
- June 29, 2022, 1-3pm, ET, Conference Call
- July 12-14, 2022, Chicago

Attendance

- **Committee Members**
  - Mark Barr
  - Nicole Berry
  - Christina Bishop
  - Emily Blumberg
  - Timothy Bunchman
  - Theresa Daly
  - Todd Dardas
  - Richard N. Formica Jr
  - Catherine Frenette
  - Reginald Gohh
  - Barbara Gordon
  - Alice Gray
  - John Gutowski
  - Nicole Hayde
  - Ian R. Jamieson
  - Christopher Jones
  - Christy Keahey
  - Mary Killackey
  - Anne M. Krueger
  - Jules Lin
  - Gabriel Maine
  - Amit Mathur
  - Virginia (Ginny) T. McBride
  - Jerry McCauley
  - Dan Meyer
  - Bhargav Mistry
  - Willscott Naugler
  - Michael Pham
  - Steve Potter
  - Elizabeth Rand
  - Sara Rasmussen
  - Pooja Singh
  - Jason Smith
  - Zoe Stewart Lewis
  - Laura Stillion
  - Parsia Vagefi
  - Gebhard Wagener
- **HRSA Representatives**
  - Marilyn Levi
  - Arjun Naik
  - Raelene Skerda
- **SRTR Staff**
  - Ryu Hirose
  - Jonathan Miller
  - Jon Snyder

- Bryn Thompson

- **UNOS Staff**
  - Sally Aungier
  - Dawn Beasley
  - Matt Belton
  - Dawn Bittler
  - Tameka Bland
  - Tory Boffo
  - Shawn Brown
  - Tommie Dawson
  - Nadine Drumn
  - Demi Emmanouil
  - Katie Favaro
  - Liz Friddell
  - Shavon Goodwyn
  - Lauren Guerra
  - Amanda Gurin
  - Asia Harris
  - Kay Lagana
  - Trung Le
  - Ann-Marie Leary
  - Ellen Litkenhaus
  - Sandy Miller
  - Amy Minkler
  - Steven Moore
  - Sara Moriarty
  - Alan Nicholas
  - Delaney Nilles
  - Jacqui O'Keefe
  - Dina Phelps
  - Michelle Rabold
  - Liz Robbins Callahan
  - Sharon Shepherd
  - Louise Shaia
  - Leah Slife
  - Olivia Taylor
  - Stephon Thelwell
  - Roger Vacovsky
  - Gabe Vece
  - Marta Waris
  - Betsy Warnick
  - Trevi Wilson
  - Emily Womble
  - Karen Wooten
- **Other Attendees**
  - None