OPTN Membership and Professional Standards Committee
Performance Monitoring Enhancement Subcommittee
Meeting Summary
October 12, 2021
Conference Call

Richard Formica, M.D., Chair

Introduction

The Performance Monitoring Enhancement Subcommittee of the Membership and Professional Standards Committee (MPSC) met in open session via Citrix GoToTraining teleconference on October 12, 2021, to discuss the following agenda items:

1. Welcome and Agenda
2. Review of Public Comment Themes
3. Post-public Comment Revisions and Recommendation to MPSC

The meeting was open to all MPSC members, who actively participated in the discussions and voted on recommendations. 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 was for the subcommittee to review the public comment received on the Enhance Transplant Program Performance Monitoring System proposal and to make a recommendation on whether the MPSC should request that the OPTN Board of Directors approve the proposal. She noted that the MPSC would be taking a formal vote during its upcoming October 26-27 meeting on whether to request that the OPTN Board of Directors approve the proposal. The staff member also reviewed the project timeline and stated that there will be an update on the implementation and evaluation monitoring plans during the upcoming MPSC meeting. She mentioned that the subcommittee would also make a recommendation on potential post-public comment revisions.

2. Review of Public Comment Themes

A 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. Subcommittee members provided their initial thoughts on the public comment themes.

<u>Subcommittee Feedback:</u>

The Subcommittee chair stated that he was impressed by the responses received on the proposal and commended the regional representatives for presenting and educating the community about the metrics and proposal. Many subcommittee members stated that regional meetings and public comment went better than expected. However, subcommittee members also reported that some colleagues still struggle with understanding the proposal, which creates skepticism. The subcommittee members discussed the need for more awareness and education about the proposal to help people understand

how the numbers relate to reality, especially during the implementation phase. The subcommittee chair agreed that more education must be provided to help the community get comfortable with the metrics. A staff member responded that the communications and professional education team discussed creating a resource page on the OPTN website for the community to access.

The Subcommittee also discussed feedback for the waitlist mortality and offer acceptance metrics:

- **Waitlist Mortality** – Staff reported the primary feedback received on the waitlist mortality metric. She stated that two of the most prominent themes are the concern about the use of the waitlist mortality rate ratio to evaluate kidney programs and the possibility that programs will respond with risk-averse behavior. Subcommittee members acknowledge that this metric may not be as impactful as it will be for other organs since it is not likely to identify kidney transplant programs. However, the subcommittee members agreed that consistency in the metrics across all organs is important, so kidney programs should not be excluded from monitoring through the waitlist mortality metric. Subcommittee members also noted, as previously discussed during development of the proposal, that transplant programs, by listing a patient for transplant, do have a responsibility for some level waiting list management that makes if more likely that listed patients receive a transplant. Subcommittee members noted that patients ultimately are looking for access to transplant, not just access to a transplant program's waiting list. In response to the concern that programs will respond by not listing sicker patients, subcommittee members noted that an alternative view is that the sicker patients on a program's waiting list are the most likely to get offers and be transplanted so if a transplant program wants to do transplants, the program will need to list sicker patients. The subcommittee also discussed the level of understanding in the community about risk-adjustment and advised that more education is needed in this area to help the community understand that risk adjustment actually allows medical professionals to practice medicine by removing risks based on the characteristics of the patients or donor organs from the calculation of program performance.

- **Offer Acceptance** – Staff described the primary feedback on the organ offer acceptance metric. She stated that the comments were split with some in support of and some raising concerns about the metric. She reported the most prominent concern about the metric was a concern that the metric may discourage use of broad donor criteria to maximize patient opportunity for transplant. The subcommittee discussed that organ offer acceptance is completely within 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 chair noted that as long as programs are honest about the organs that they will use for their patients and set their acceptance criteria accordingly, programs would not be at risk of being identified. Another subcommittee member stated that some larger transplant programs have been able to have high organ acceptance rates and excellent post-transplant outcomes. She noted that these programs could be part of an education effort to share effective practices with the community. The subcommittee supported keeping the offer acceptance metric in the proposal.

- **Longer-term Post-transplant Outcome Metric –** The majority of comments received supported the future use of a longer-term post-transplant outcome metric. Most patients noted the one-year survival is not optimal and the OPTN should focus on longer-term graft survival. Due to the inability of the current 3-year outcomes metric to identify more real-time improvement opportunities, the MPSC has committed to monitor the Scientific Registry of Transplant Recipients (SRTR) development of a longer-term period prevalent metric for future use in performance monitoring.

The subcommittee also discussed public comment responses submitted by the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST). The subcommittee chair noted that the AST actively solicited feedback from all interested parties in the AST so the comment they provided includes feedback from the Communities of Practice and overall AST comments. The AST comments appear to mirror other comments received and previously discussed by the subcommittee. The ASTS comment expressed a concern that more metrics will not help the transplant community to reach its goal of increasing transplants. They were concerned that if the MPSC puts more metrics in place, the opposite may happen. One of the ASTS suggestions is use of a fixed floor to develop criteria. The subcommittee chair noted that the possibility of a fixed floor was suggested and discussed extensively by the Committee during the development of the proposal. The MPSC concluded that a fixed floor was not a viable option for a number of reasons. The MPSC chair noted that a fixed floor based on alternative therapies may be possible for kidney, but is not possible for other organs because there are not comparable alternative therapies for other organs. Additionally, based on education on risk adjustment provided to the MPSC, the Committee concluded that a fixed floor would be more likely to result in risk aversion. Finally, a fixed floor would open up a discussion that the floor should be different for different areas of the country based on representations that the patients and donor organs in a particular area are different from other parts of the country.

The ASTS also suggested that pre-transplant metrics should not be included in the proposal. However, the transplant community at large has criticized the use of only post-transplant survival metrics and has requested the inclusion of pre-transplant metrics, noting that the use of only a post-transplant outcomes metric results in disincentivizing transplant of higher risk patients and use of higher risk donor organs. The ASTS' evaluation of the proposed pre-transplant metrics is similar to other comments discussed above.

Finally, the ASTS raised concerns about the number of programs being identified and under performance review. The subcommittee chair noted that under the current system, there have been anywhere from 8% to 12% of heart, kidney, liver, lung and pancreas transplants programs under review at any given time during 2019 and 2020. That includes programs at all stages of review. For each of the two cycles during 2020, newly identified programs were about 4%. No evidence is provided to support the 2.5% suggested by the ASTS. Importantly, the MPSC proposed process is based on the observed to expected, which means there is no predetermined number of programs that would be identified each cycle. It is possible that all programs could perform better, based on their observed to their expected outcomes, and no programs would be identified for review. The subcommittee chair noted that the MPSC's presentation of the proposal might have contributed to the misunderstanding that the MPSC's intent was to identify a certain number of programs each cycle. In fact, the subcommittee was having a difficult time developing the boundaries for the metric so the subcommittee requested that the SRTR provide, as a starting point for discussion, what the criteria could be if no more than the current number of programs were identified and those numbers were divided 50/50 between the pre-transplant metrics and the post-transplant metrics. This was based on a desire by the subcommittee not to identify any more programs than are identified under the current criteria based on a number of reasons. The subcommittee then evaluated the data from each program identified and those that fell just outside the cutoff to determine if the appropriate programs were being identified for review.

3. Post-public Comment Revisions and Recommendation to MPSC

Following the discussion of public comment, the subcommittee did not suggest any changes to the structure, metrics, criteria or review process contained in the proposal. A staff member discussed potential administrative post-public comment changes including replacing the term "waitlist mortality"

with “pre-transplant mortality” and the addition of high level descriptions of the metrics to the definition Appendix in the bylaws.

The purpose of the potential change to waitlist mortality would be to ensure the terminology is consistent with that used on the SRTR website. The SRTR changed the term for waitlist mortality in its July 2021 reports. SRTR staff explained that the change was made to address concerns raised by the community that the term waitlist mortality was somewhat misleading and does not adequately convey that the metric cohort includes some patients that are removed from the waiting list during the observation period. The SRTR believed that the use of the term “pre-transplant” better reflects that the metric includes any mortality that occurs after listing and pre-transplant, even though it might not be perfect. Some Committee members expressed concern that pre-transplant mortality may be interpreted to include pre-listing mortality, particularly if the OPTN begins collecting pre-listing data at some point in the future. Others recognized the value in consistency between the OPTN bylaw language and the term used to describe the metric on the SRTR website. Another recent suggestion that may help if the MPSC decides to change the term used in the bylaw from waitlist mortality to pre-transplant mortality is to add high-level descriptions of the metrics to the bylaw definitions Appendix. On the one hand, a description may provide clarity to members at to what each metric is measuring. However, any description placed in the bylaws would need to be high level to avoid needing to make a change to the bylaws, with the requisite public comment and approval by the Board, when the SRTR tweaks their models for the proposed metrics. Subcommittee members expressed support for the inclusion of high-level descriptions of the metrics in OPTN Bylaws, Appendix N: *Definitions* to provide transparency and clarity for members, as well as address any misunderstandings of the scope of the pre-transplant mortality metric. If the subcommittee supports this addition to the proposal, staff will work on high-level descriptions for review by the MPSC at the October 26-27 meeting.

Thirteen MPSC members responded to polls on the two potential post-public comment changes to the bylaws. The recommendation to change the term “waitlist mortality” to “pre-transplant mortality” in the bylaw proposal was supported by those who participated in the poll by a vote of 8 For, 5 Against, 0 Abstain. The recommendation to add metrics descriptions to OPTN Bylaws, Appendix M: *Definitions* was unanimously supported by poll participants.

Thirteen MPSC members, who participated in the poll, unanimously supported a recommendation that the MPSC request that the OPTN Board of Directors approve the proposal with the described post-public comment changes at its December 2021 meeting.

Upcoming meeting

- October 26-27, 2022: MPSC Meeting, Virtual

Attendance

- **Subcommittee Members**
    - Richard N. Formica (Subcommittee Chair)
    - Nicole Berry
    - Alice L. Gray
    - John R. Gutowski
    - Ian R. Jamieson
    - Mary Killackey
    - Jules Lin
    - Virginia(Ginny) T. McBride
    - Wilscott E. Naugler
    - Michael Pham
    - Steven R. Potter
    - Zoe Stewart Lewis
- **Other MPSC Members**
    - Emily Blumberg
    - Timothy Bunchman
    - Theresa Daly
    - Todd Dardas
    - Kenneth McCurry
    - Jerry McCauley
    - Sara Rasmussen
    - Pooja Singh
    - Jason Smith
    - Parsia Vagefi
    - Gebhard Wagener
- **HRSA Representatives**
    - Arjun Naik
    - Raelene Skerda
- **SRTR Staff**
    - Ryo Hirose
    - Jonathan Miller
    - Jon J. Snyder
    - Bryn Thompson
    - Andrew Wey
- **UNOS Staff**
    - Sally Aungier
    - Matt Belton
    - Tameka Bland
    - Katie Favaro

- Amanda Gurin
- Ann-Marie Leary
- Amy Minkler
- Sharon Shepherd
- Stephon Thelwell
- Gabe Vece
- Betsy Warnick

- **Other Attendees**
  - Matthew Cooper