OPTN Membership and Professional Standards Committee
Meeting Summary
June 28, 2024
Conference Call

Zoe Stewart Lewis, M.D., Chair
Scott Lindberg, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met via Webex in both open and closed session on June 28, 2024, to discuss the following agenda items:

1. Pre-Transplant Mortality Review Process
2. Performance Monitoring Criteria Changes
3. Evaluation Plan Review
4. Membership Issues
5. Volunteer Acknowledgements

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

1. Pre-Transplant Mortality Review Process

OPTN staff provided data on the number of programs that would have been flagged for the pre-transplant mortality metric based on the January 2024 program specific report (PSR), then reviewed the high-level considerations used for review of performance monitoring cases to provide context for the evaluation of the proposed pre-transplant mortality review process, which include:

- Has the program or OPO demonstrated a patient mix, based on factors not adequately adjusted for in the SRTR model, that affect their outcomes?
- Is there a unique clinical aspect of their program or OPO (for example, clinical trials being conducted) that explains the lower-than-expected outcomes?
- Has the program or OPO evaluated their performance, developed a plan for improvement and implemented the plan?
- Has the program or OPO demonstrated improvement in their outcomes based on recent data, demonstrated ability to sustain?
- Does the OPO or program have the resources needed and processes in place to evaluate their own performance on a regular basis, develop plans for improvement when needed and implement those plans?

Staff gave an overview of the draft questionnaire developed by the Performance Monitoring Enhancement (PME) Subcommittee, providing the context of the Subcommittee's discussions and rationale behind their decision-making. The Subcommittee discussed whether review packets should include summaries for a sample of patients, which would be requested from the flagged program, but was unable to reach a consensus on the usefulness of summaries or, if included, whether the sample should be random or weighted. Staff requested feedback from the Committee on their inclusion, sample method, summary format, and what information should be provided by members in the summaries.

Staff informed the Committee that the PME Subcommittee has also recommended data to be included in review packets. Subcommittee data recommendations include offer acceptance rate ratio overall and

for different categories published in SRTR program specific report and whether the program was flagged for that metric; active vs. inactive numbers and proportion of waiting list at the program compared to regional and national averages; a summary of active vs. inactive time for candidates who died at the program compared to regional and national data with measures of acuity; and a summary of offers received and rejected for candidates prior to death compared to regional and national data with measures of acuity.

The Subcommittee reviewed and provided feedback on a sample format for a report of the recommended data at its last meeting. The report and data will be reviewed in more depth by the full Committee at its July meeting. During a future session, the Committee will also review examples of actual member submissions to facilitate discussion of how to review these cases and promote consistency in review among different reviewers.

Summary of Discussion:

Decision #1: The Committee supports the inclusion of patient summaries in review packets for transplant programs flagged for the pre-transplant mortality metric, utilizing a random sample of 5 patients for pediatric transplant programs and 7 patients for adult transplant programs.

Decision #2: The Committee voted to approve the pre-transplant mortality questionnaire, amended to add the request for patient summaries described during discussion, by a vote of 23 For, 0 Against, and 0 Abstentions.

Decision #1: The Committee supports the inclusion of patient summaries in review packets for transplant programs flagged for the pre-transplant mortality metric, utilizing a random sample of 5 patients for pediatric transplant programs and 7 patients for adult transplant programs.

Members commented that patient summaries would be useful for review and supported their inclusion in review packets, as they will help add context to the data.

Discussion of patient sample size and method focused on consistency, member burden, and ensuring that reviewers could reasonably absorb the amount of information included in review packets. Members noted that too high a sample size would be challenging to digest and supported requesting 5 summaries for pediatric transplant programs and 7 for adult transplant programs, as the Subcommittee had discussed. A member asked whether the sample size would change for programs with different volumes; Staff clarified that the Subcommittee recommended a maximum number of summaries, regardless of volume, and that reviewers would have the ability to request more patient summaries, as needed, based on the initial review. Another member noted that reviewers should keep in mind that the pediatric sample size would likely represent a higher percentage of total patients than the adult sample size.

Members expressed support for utilizing a random sample. A member asked for clarification on whether the sample will include both patients who were inactive and active when they died; Staff affirmed that they would. The member recommended the summaries include the reasons for inactivation and time spent in inactive status.

Additional recommendations for information to be provided in summaries include basic patient demographics, date of referral, date of evaluation, date of listing, whether the patient had been delisted or made inactive, cause of organ failure, major comorbidities, cause of death, date of death, last time the team interacted with the patient, whether the patient was inpatient or outpatient, how often they

were seen for assessment of clinical or psychosocial status, and post-death case review; if a post-death review was not completed, or an explanation for the lack of review.

Decision #2: The Committee voted to approve the pre-transplant mortality questionnaire, amended to add the request for patient summaries described during discussion, by a vote of 23 For, 0 Against, and 0 Abstentions.

Staff noted that the questionnaire reviewed by the Committee would be amended to include the request for patient summaries as described by the Committee, and that the vote was to approve the questionnaire with the planned amendment.

2. Performance Monitoring Criteria Changes

OPTN Staff presented an overview of the ways the Committee safeguards patient safety, which include performance monitoring reviews and using tools such as membership application review, site survey, allocation review, and compliance and safety investigations to identify issues at transplant programs. The Committee in part determines performance monitoring metric thresholds through consideration of likelihood of capturing those programs that raise patient safety concerns or have significant opportunities for improvement. During previous discussions, the Committee supported re-examining thresholds at which transplant programs would be flagged for the post-transplant outcome metrics of adult 90-day graft survival and 1-year graft survival conditional on 90-day and offer acceptance.

Staff reviewed the current thresholds for the two metrics being considered, which for both post-transplant outcome metrics are currently a greater than 50% probability that the hazard ratio is greater than 1.75, meaning 75% higher than expected, and for offer acceptance a greater than 50% probability that the rate ratio is lower than 0.30, meaning 70% lower than expected.

Staff provided detailed data to the Committee, which included counts of flagged transplant programs under current thresholds and hypothetical flag counts for potential alternative thresholds for each metric, actions taken after review of flagged programs for previous cycles for post-transplant outcomes, flagged program data including each program's hazard ratios, the number of meeting cycles the program was under review, whether the Committee requested an informal discussion or peer visit, and whether it was likely that those programs would have been flagged under the potential alternative thresholds. SRTR staff demonstrated a tool for exploring the effect of different threshold changes in real time, which was available throughout the Committee's discussion.

Before discussion of the offer acceptance metric began, Staff informed the Committee that since the metric was recently implemented in July of 2023, no review data is available. Staff provided context around the metric, noting that offer acceptance supports efficiency of the system and encourages acceptance of more organs, but also supports patient safety. The increased and broader acceptance of organs results in patients being transplanted faster and reducing likelihood of death prior to transplant.

Summary of Discussion:

Decision #1: The Committee voted to change the flagging threshold for post-transplant outcome metrics from a hazard ratio of 1.75 to 2.25, by a vote of 19 in favor of 2.25, and 7 in favor of 2.0.

Decision #2: The Committee voted to retain the current flagging threshold for the offer acceptance metric by a vote of 17 For, 2 Against, and 1 Abstention.

Decision #1: The Committee voted to change the flagging threshold for post-transplant outcome metrics from a hazard ratio of 1.75 to 2.25, by a vote of 19 in favor of 2.25, and 7 in favor of 2.0.

A member asked for clarification on whether the Committee would be voting on maintaining current thresholds or changing to one of the potential alternatives. Staff clarified that at the last meeting, the Committee voted to change the threshold, but did not decide on what specific threshold to change it to. The alternatives presented were intended as a starting point for Committee discussion. The vote would be on what threshold members decide to include in a proposal. Another member asked about the length of time that programs typically stay under review when flagged with the highest thresholds. Staff answered that the action taken for flagged programs is the same for programs flagged right at the threshold as those high above the threshold.

The incoming Chair commented on the implementation of the pre-transplant mortality metric scheduled for July of 2024, observing that Committee workload may increase as the review process for the new metric begins, and indicating support for raising the post-transplant metric flagging threshold to a hazard ratio of 2.25 as this will help strike a balance between a manageable workload and ensuring that programs who are true outliers for post-transplant metrics will still be reviewed by the Committee.

A smaller threshold increase to 2.0 was discussed, with members noting the importance of early identification of programs with negative trends in patient outcomes, which allows for intervention and improvement efforts. A member asked about the yellow zone, which identifies programs that are trending towards hitting flagging thresholds, but have not yet reached them, and how it would be impacted by a change in threshold. Staff clarified that the yellow zone is determined by an operational rule, not by the bylaws, so changes to that zone can be made without a proposal that goes through public comment and can be considered at a future Committee meeting. The yellow zone can continue to allow for early identification of programs at risk for flagging.

Members expressed support for raising the threshold to 2.25, the higher end of the potential alternatives, noting that the vast majority of programs with serious issues were not identified through review of post-transplant outcomes, but rather through avenues such as patient safety reports, which will not be affected by a change in threshold. Members noted that monitoring of post-transplant outcomes is important for a holistic evaluation of transplant programs. The Chair observed that flagging for 90-day graft survival is typically a more reliable indicator of surgical problems, rather than 1-year survival conditional upon 90-day, and that based on the data presented, at a threshold of 2.25 there are marginal changes to the 90-day survival flag counts.

SRTR and OPTN staff clarified for members that as hazard ratios are calculated based on the comparison of observed outcomes against expected outcomes, the new threshold would be implemented either as applying retrospectively to the historical data used for the first post-implementation evaluation in January 2025, or by delaying the implementation date.

Members considered whether it is possible to conduct reviews using more recent data, as currently the review is retrospective and based on data from one year prior to the review date, to allow for more agile Committee responses to the sudden development of concerning transplant program behavior. SRTR staff informed the Committee that current timeframes are based on balancing quality and currency of data. There are monthly cumulative sum control charts (CUSUMs) available to transplant programs that provide data on how the program is trending for post-transplant outcomes. Potential Committee review of these reports would require detailed investigation and consideration, as the data in CUSUMs are less reliable due to the lag between occurrence of reportable events and reporting of events. Another potential future option is utilizing a two-year prevalent window, which is a data reporting methodology already under investigation by the SRTR.

Decision #2: The Committee voted to retain the current flagging threshold for the offer acceptance metric by a vote of 17 For, 2 Against, and 1 Abstention.

The Vice Chair highlighted for the Committee that the flagged transplant program counts for potential alternative thresholds were an application of a new threshold to old data. Transplant program behavior changes happen in response to changes in performance monitoring metrics. The actual number of flags under a new threshold is likely to be lower than the number produced by applying the new threshold to old data, as once a new threshold is implemented, transplant programs would work towards meeting that new goal. The goal of changing performance monitoring criteria is to encourage transplant programs to take on risk and increase the number of transplants performed.

SRTR staff emphasized the relevancy of the offer acceptance metric to patient safety issues, noting that research shows that receiving a transplant is highly advantageous to patient survival. This metric has a direct impact on patient survival, as motivating programs to accept offers through performance monitoring could positively influence transplant rates.

A member suggested increasing the flagging threshold for offer acceptance to a rate ratio of .35. Members commented on the positive impact of offer filters on kidney offer acceptance due to the robust filter options available, noting that the filters that have been released for other organs could have the same positive impact once the filter options are expanded. Staff informed the Committee that work to expand filter options is in progress.

Members noted the recency of the implementation of the offer acceptance metric. The Committee is still assessing best practices for reviewing transplant programs flagged for this metric, and data is not yet available for a more in-depth analysis of the effect of a threshold change. The Committee concluded that a change to the offer acceptance threshold would be premature and moved to retain the current criteria.

Next Steps:

Staff will draft a public comment document and determine the timeline for special public comment in order to get OPTN Board of Directors consideration in a time frame that will allow incorporation of the new threshold into to the January 2025 SRTR MPSC reports. An update on progress will be provided to the Committee at its July meeting.

3. Evaluation Plan Review

Staff presented updates to the OPTN Evaluation Plan to better encompass all monitoring activities performed and serve as a better tool for the community. These updates included the addition of continuous monitoring, required reporting, organ allocation review, and newly developed monitoring and appendices. The updated version of the OPTN Evaluation Plan is being shared with the MSPC and HRSA and then will be presented to key stakeholders in the Organ Procurement Organization Committee, Transplant Coordinators Committee, and Transplant Administrators Committee before final scheduled release on August 1, 2024. The Committee did not have questions or discussion at this time.

4. Membership Issues

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants and applications are presented to the MPSC members as either a consent or discussion agenda. The Committee reviewed and approved the consent agenda by a vote of 24 For, 0 Against, and 0 Abstentions.

The Committee considered applications and other actions and will ask the Board of Directors to approve the following recommendations during its December 2024 meeting.

- Approve 2 Component Changes from Conditional Approval to Full Approval
- Approve 1 Program Reactivation
- Approve 1 Component Reactivation
- Approve 1 New Business Member
- Approve 1 New Public Organization Member
- Approve 2 New Individual Members
- Approve 1 Individual Membership Renewal

The Committee also reviewed and approved the following program related actions and personnel changes as shown in Exhibit B, hereto entitled "Key Personnel – New and Changed."

- 31 applications for changes in key personnel in Transplant Programs or Components
- 6 applications for new key personnel in Histocompatibility Laboratories

The Committee received notice of member and program inactivation and withdrawals .

5. Volunteer Acknowledgements

At the conclusion of the meeting the members whose terms were ending were recognized for their service.

Upcoming Meetings

- July 23-25, 2024, Detroit
- August 23, 2024, 1-4pm, ET
- September 27, 2024, 2-5pm, ET
- October 9, 2024, 3-6pm, ET
- November 6-8, 2024, times TBD, Virtual
- December 13, 2024, 2-5pm, ET

Attendance

- **Committee Members**
  - Alan Betensley
  - Kristine Browning
  - Anil Chandraker
  - Hannah Copeland
  - Chad Ezzell
  - Robert Fontana
  - Roshan George
  - Darla Granger
  - Robert Harland
  - Rich Hasz
  - Kyle Herber
  - Victoria Hunter
  - Michelle James
  - Peter Lalli
  - Raymond Lee
  - Carolyn Light
  - Scott Lindberg
  - Melinda Locklear
  - Maricar Malinis
  - Amit Mathur
  - Deborah McRann
  - Nancy Metzler
  - Cliff Miles
  - Saeed Mohammad
  - Regina Palke
  - Deidre Sawinski
  - Malay Shah
  - Zoe Stewart Lewis
  - Mark Wakefield
  - Candy Wells
  - James Yun
- **HRSA Representatives**
  - Marilyn Levi
  - Arjun Naik
- **SRTR Staff**
  - Jonathan Miller
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - Anne Ailor
  - Robert Albertson
  - Stephanie Anderson
  - Sally Aungier
  - Elinor Carmona
  - Robyn DiSalvo

    - Laureen Edwards
    - Katie Favaro
    - Liz Friddell
    - Michelle Furjes
    - Houlder Hudgins
    - Elias Khalil
    - Lee Ann Kontos
    - Jessie Kunnamann
    - Krissy Laurie
    - Jon McCue
    - Amy Minkler
    - Heather Neil
    - Rob Patterson
    - Liz Robbins Callahan
    - Melissa Santos
    - Laura Schmitt
    - Erin Schnellinger
    - Sharon Shepherd
    - Stephon Thelwell
    - Marta Waris
    - Betsy Warnick
    - Trevi Wilson
    - Claudia Woisard
    - Emily Womble
    - Hollie Woodcock
    - Karen Wooten
    - Carson Yost
    - Amanda Young
- **Other Attendees**
    - Christopher Curran