

OPTN Membership and Professional Standards Committee

Meeting Summary

May 21, 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 May 21, 2024, to discuss the following agenda items:

1. Membership Requirements Revisions
2. Membership Requirements Revisions to Appendix C
3. Performance Monitoring Criteria Changes
4. Membership Issues
5. Investigative Activities

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

1. Membership Requirements Revisions

OPTN staff presented recommendations for revisions to OPTN bylaw language from the Membership Requirements Revision (MRR) subcommittee, the Transplant Administrator Committee, and the Vascular Composite Allograft (VCA) Committee. Staff also provided information and requested decisions from the Committee on an issue that was considered by the MRR subcommittee but was not resolved, a recently arisen issue that could affect the proposal, and additional proposal cleanup items.

Primary Program Administrator Definition

The issue of defining the Primary Program Administrator personnel requirement for transplant programs was previously considered in 2020 by the MPSC, but after discussion, consensus on an appropriate definition was not reached. The MRR Subcommittee Chair presented to the Transplant Administrator Committee (TAC) on April 22, 2024, to solicit input on how to define the role. The TAC recommended the following definition, with non-substantive language changes for verbiage flow made by staff noted with strikethrough and underline:

Each transplant program must have on staff a Primary Program Administrator. The primary program administrator serves as the designated administrator for a program, ~~and serves as a point of contact for OPTN inquiries and communications,~~ ~~Also serves and as a contact person when interventions are needed on behalf of the OPTN.~~

Inclusion of Primary Obstetrician-Gynecologist in Appendix D Key Personnel Requirements

A proposal establishing requirements for uterus transplant programs was implemented in December of 2023. The new requirements include a new key personnel role of primary obstetrician-gynecologist; this new role was not included in the key personnel and program coverage plan provisions in Appendix D. Staff consulted with the VCA committee on April 24, 2024, to solicit feedback on whether the primary obstetrician-gynecologist role should be included in the Appendix D provisions. The VCA committee recommended the following:

- Add primary obstetrician-gynecologist to the list of key personnel in the introductory language in *D.2.B, Transplant Program Key Personnel*
 - Do not add primary obstetrician-gynecologist to paragraph regarding operational role and compliance responsibilities of primary surgeon and primary physician, as the role of the primary obstetrician-gynecologist in uterus transplant programs does not include these responsibilities
- Insert “key personnel” in place of list of primaries where appropriate to reduce complexity
- Add primary obstetrician-gynecologist to *D.2.C. Surgeon and Physician Coverage (Program Coverage Plan)* for uterus transplant programs including a definition of “additional obstetrician-gynecologists.” The definition of additional obstetrician-gynecologist will be finalized after further consultation with the VCA Committee

New issue: Geographically isolated transplant program section

In 2020, the Committee voted to remove the provision for geographically isolated transplant programs in Appendix A.1.F of the bylaws, as it had only been utilized for a transplant program application once since it had been introduced, the transplant hospital for which it was created has had multiple applications since the provision was approved without using the provision, and the plan for the key personnel requirements framework includes the expansion of conditional approval provisions with monitoring, which provides a more balanced approach than an exception.

In the last month, the same program requested use of the provision in order to reactivate their program, and so the Committee was asked to reconsider whether to proceed with removing the provision from the bylaws. Staff noted that the recent reactivation application was for a pancreas program and commented that the Committee has previously noted pervasive issues in the pancreas community in meeting requirements, and these issues are not unique to the geographically isolated transplant program.

MRR Subcommittee Recommendation: Primary Data Coordinator

The OPTN currently requires transplant programs, OPOs, and histocompatibility labs to provide the name of a primary data coordinator. The current proposal adds this as a personnel requirement for transplant programs only. The Subcommittee considered, for consistency, whether to add the requirement for all institutional member types or no member types, with the consideration that the current practice of requiring a primary data coordinator be named would continue if the role is not included in the bylaws.

The Subcommittee recommended including the requirement for all three institutional member types.

MRR Subcommittee Recommendation: Patient and OPTN Notification of Changes to Program Coverage Plan

Staff reviewed the current bylaw language in Appendix D.7.B outlining requirements for patient notification of changes in program coverage, which currently states that patients must be notified of “substantial changes.” The current bylaw does not require notification to the OPTN when changes to the program coverage plan are made. The Committee previously voiced support for the inclusion of a requirement that transplant programs notify the OPTN whenever patients would need to be notified and referred clarification of the definition of “substantial changes” to the Subcommittee. The Subcommittee discussed scenarios based on member questions around what is meant by substantial changes. Feedback from the discussion was used to develop three potential options. The Subcommittee

reviewed the options, eliminated the broadest option, and was split on which of the two remaining options should be used:

- Option 1: Notify patients and the OPTN when changing to/from a single surgeon or single physician only
- Option 2: Notify patients and the OPTN of any changes that result in the inability to provide 24/7/365 coverage

The Subcommittee requested the Committee consider and vote on the two options for notification requirements.

No MRR Subcommittee recommendation for changes to proposal: Temporary Leave and Reinstatement

The Subcommittee considered bylaw requirements for temporary leave and reinstatement of key personnel due to the Committee's concern over the 30-day timeframe for temporary leave, especially in the case of medical or parental leave that tends to be longer, and concern over the administrative burden for programs created by the requirement. The Subcommittee discussed potential options to address concerns, including a longer timeframe for temporary leave before an application is required, ways to decrease the administrative burden of an application after a temporary leave, and revising reinstatement requirements.

The Subcommittee recommended retaining the 30-day timeframe, making no changes to reinstatement requirements, and supported consideration of limited requirements for short-term, interim service for key personnel as part of the key personnel training and experience requirements phase of the MRR project.

No MRR Subcommittee recommendation for changes to proposal: Transplant Professional Misconduct

The Board of Directors asked the Committee to discuss ways to consider transplant professional misconduct. The Subcommittee discussed several options and reached the following conclusions:

- Rejected reinserting the certificate of assessment requirement in the proposal based on the previous MPSC conclusion that it did not add value or serve its intended purpose.
- Rejected adding a more detailed requirement for reporting of sanctions against individual transplant professionals to OPTN Policy 18. The MPSC had removed a vague requirement from the Require Reporting of Patient Safety Events proposal last fall. The Subcommittee questioned what actions the MPSC would or could take based on this information and noted the existence of other entities that are better suited to act on individual professional misconduct.
- Rejected requiring that members consult the National Practitioner Data Bank (NPDB) because OPTN transgressions are not being reportable to NPDB and the Subcommittee questioned whether such a requirement is necessary or within the OPTN's purview.
- Rejected OPTN tracking of identified individual misconduct and/or OPTN review of the NPDB for use in evaluation of primaries because of concerns that it would undermine confidential medical peer review and would pose a risk of OPTN liability under employment law. The Subcommittee also noted that the OPTN monitors members, not individuals, and recognized the complexity of patient safety cases which often involve program culture and professionalism and no clear, concrete individual misconduct

The Subcommittee recommended retaining the current proposal language and did not recommend pursuing a new policy requirement for reporting of transplant professional misconduct.

Proposal Clean Up

Staff informed the Committee of general proposal cleanup items, which includes

- Ensuring that “in writing” is consistently included in all places where the member is required to notify the OPTN.
- Removal of language requiring that documentation be “available upon request” because this language was inconsistently used, and removal of this language allows the Committee flexibility in application documentation requirements.
- Striking additional references to program director or to the Board of Director review of applications that were identified in recent review of bylaws.
- Non-substantive revisions to section titles and other non-substantive language (changing use of “shall” to “must”) to ensure consistency between the appendices and clarity in the language.

Staff indicated that the next step would be MRR Subcommittee review of the final proposal. At the May 29, 2024, meeting, the Committee will vote on whether to send the proposal to summer 2024 public comment.

Summary of Discussion:

Decision #1: The Committee voted to approve the inclusion of the definition of Primary Program Administrator as recommended by the TAC and modified by staff by a vote of 19 For, 0 Against, and 0 Abstentions.

Decision #2: The Committee voted to approve the inclusion of primary obstetrician-gynecologist in key personnel and program coverage plan sections as recommended by the VCA committee by a vote of 18 For, 1 Against, and 0 Abstentions.

Decision #3: The Committee voted to approve the removal of section Appendix A.1.F: Geographically Isolated Transplant Program Applicants by a vote of 17 For, 2 Against, and 0 Abstentions.

Decision #4: The Committee voted to approve the addition of primary data coordinator to requirements for OPO, histocompatibility labs, and transplant programs as recommended by the Subcommittee by a vote of 19 For, 1 Against, and 1 Abstention.

Decision #5: The Committee voted to include Option 2 in the proposal by a vote of 11 in favor of Option 2 and 8 in favor of Option 1.

Decision #1: The Committee voted to approve the inclusion of the definition of Primary Program Administrator as recommended by the TAC and modified by staff by a vote of 19 For, 0 Against, and 0 Abstentions.

The Committee expressed no concerns with the proposed language for the definition of primary program administrator.

Decision #2: The Committee voted to approve the inclusion of primary obstetrician-gynecologist in key personnel and program coverage plan sections as recommended by the VCA committee by a vote of 18 For, 1 Against, and 0 Abstentions.

A member asked for clarification on the experience requirement for primary obstetrician-gynecologists, and whether uterus transplant programs are required to have a primary surgeon and primary physician. Staff confirmed that all three key personnel roles are required and provided a summary of the primary obstetrician-gynecologist requirements.

Another member expressed concern about the lack of specific requirements for some of the VCA primary surgeons, which is not comparable to requirements for other primary transplant surgeons. SRTR

staff clarified that the unique experience requirements are due to the low volume of VCA transplants as it is an emerging field, and it is difficult to get experience performing VCA transplants.

Decision #3: The Committee voted to approve the removal of section Appendix A.1.F: Geographically Isolated Transplant Program Applicants by a vote of 17 For, 2 Against, and 0 Abstentions.

Members expressed concern that allowing an exception based on concerns for the challenges faced by pancreas programs could have implications for other transplant programs since this provision could be used for any transplant program that is geographically isolated and noted that planned future revisions to key personnel training and experience requirements could address the challenges for pancreas programs.

Decision #4: The Committee voted to approve the addition of primary data coordinator to requirements for OPO, histocompatibility labs, and transplant programs as recommended by the Subcommittee by a vote of 19 For, 1 Against, and 1 Abstention.

The Committee expressed no concerns with the proposed language for the definition of primary program administrator.

Decision #5: The Committee voted to include Option 2 in the proposal by a vote of 11 in favor of Option 2 and 8 in favor of Option 1.

A member asked whether Option 2 would conflict with the bylaw provision requiring patient notification of the short-term inactivation of a program's waiting list. Staff clarified that the two provisions are complimentary. This notification requirement applies to changes in the overall plan for coverage while the notification requirement for waiting list inactivation addresses individual instances of short-term inactivation when they occur.

2. Membership Requirements Revisions to Appendix C

The OPTN Histocompatibility Committee Vice Chair presented its Bylaw proposal to Revise Appendix C Membership Requirements. This proposal will be complimentary to the MPSC's Bylaw revisions but sponsored by the Histocompatibility Committee as the subject matter experts. These membership Bylaw revision projects are slated for the Summer 2024 public comment cycle.

Summary of Discussion:

A member inquired if the Appendix C modification intended to permit laboratory directors who are currently approved to retain that approved status in the event they change laboratories. The presenter clarified that oftentimes there are labs with multiple directors but because an individual is not the primary, they may not receive credit for those cases, which could impact their ability to obtain approval if circumstances change, i.e., move institutions or change in lab leadership. An MPSC member noted the applicability to Primary Physicians and Primary Surgeons which could be a point the MPSC considers as they continue to discuss organ-specific membership revisions. A member did note the shift in practice that this would establish from the existing Bylaws. The presenter also noted that the Director credentialing is reviewed as part of the biannual review and accreditation process.

3. Performance Monitoring Criteria Changes

OPTN Staff provided an overview of the Committee's discussion at the April 23, 2024, meeting, and a literature review summary.

During its April meeting, the Committee reviewed the request from the Expeditious Task Force and OPTN Executive Committee to consider potentially making changes to post-transplant outcome and/or offer acceptance metrics criteria for transplant programs. SRTR staff provided data on performance

monitoring reviews, which included the effect of potential threshold changes on the number and characteristics of programs that would be identified. The Committee asked OPTN staff to conduct a literature review focused on determining whether there is evidence that changes to MPSC monitoring criteria affects transplant program behavior. The Committee also expressed a willingness to consider changes to both post-transplant outcomes and offer acceptance metrics criteria.

Staff emphasized that should the Committee decide to move forward with changes, a bylaw change proposal would be required, which would explain the purpose of the proposal, how the proposal will support that purpose, and how the proposal will support the MPSC charge. Staff reviewed the MPSC charge and responsibilities.

Staff reviewed data for the 90-day graft survival, 1-year graft survival conditional on 90-day graft survival, and offer acceptance metrics, noting that the Committee expressed support in April for making changes for adult programs only. The review included the current thresholds, the number of programs identified, number of inquiries sent to programs, the outlier hazard ratios for each organ, actions taken by the MPSC over multiple cycles for programs identified in the July 2022 cycle, and whether programs would have been flagged based on potential threshold changes. Staff commented on the limited availability of data due to the recency of the implementation of the new metrics, particularly the offer acceptance metric. The data review also included metric results for programs that accept the most kidneys allocated out of sequence, which indicated outcomes tend to be either as expected or better than expected performance.

Staff gave an overview of the findings from the literature review requested by the Committee. The review included articles spanning 2019 – 2023. Staff noted the limited literature available due to the difficulty in measuring perception and program behavior, and that there are no recent articles evaluating the effect of the recent significant change to post-transplant outcomes metric criteria in July 2022. The review included articles:

- Recommending less restrictive program metric requirements
- Noting a lack of evidence indicating an adverse effect of regulatory metrics on transplant volumes
- Finding that respondents to a perception survey do not believe a change in metrics would change transplant program behavior
- Examining the lack of effect of the Collaborative Innovation and Improvement Network (COIIN) project
- Examining the lack of effect of a committee operational rule that excluded higher risk kidney transplants from post-transplant outcomes flagging
- Supporting the Committee's 2021 performance monitoring enhancement proposal, noting unintended consequences from the previous metrics
- Calling for study of decision making under risk for transplant professionals and commenting on regulatory metrics causing risk averse behavior
- Hypothesizing that the new metrics would increase risk-averse behavior of transplant programs

Summary of Discussion:

Members asked clarifying questions about proper interpretation of the data presented.

A member commented that the literature review suggests that there is not a need to change the metrics criteria and opined that the results of the literature review and the recent change to criteria that resulted in a decrease in the number of flagged programs by about 50% supported maintaining the status quo.

SRTR staff commented that data supports that risk taking programs do better on outcomes, not much has been written that is objective in terms of risk averseness of programs, and there is literature forthcoming that will support the positive effect of risk adjusted metrics in the promotion of risk-taking behavior, and that risk taking programs tend to perform better.

OPTN staff provided information on next steps. SRTR staff will present at the May 29, 2024, Committee meeting and demonstrate a tool that allows exploration of the effects of changes in thresholds, along with additional data for the Committee's consideration.

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 19 For, 0 Against, and 0 Abstentions.

The Committee considered the applications and other actions listed below and will ask the Board of Directors to approve the following recommendations during its June 16-18, 2024, meeting.

- Approve 1 New Transplant Program
- Approve 1 New Pediatric Component

The Committee also reviewed and approved the following personnel changes:

- 27 applications for changes in key personnel for Transplant Programs or Components
- 2 applications for changes in key personnel for Histocompatibility Laboratories

The Committee received notice of inactivation, withdrawal, and OPO changes.

5. Report of Investigative Activities

OPTN Contractor staff supplied a summary of investigative activity from April 2024. The report included the number of reports staff received, modes of receipt, reporting and subject, member type, general classification of the issue, and how many cases staff referred to the MPSC, closed without sending to the MPSC, or are still actively investigating. Most of the report focused on reports that staff did not refer to the full MPSC for review, and the reasons why. Reasons for non-referral included an inability to substantiate the claim, lack of patient safety issue or policy noncompliance

Upcoming Meetings

- May 29, 2024, 4-6pm, ET, Conference Call
- June 28, 2024, 2-5pm, ET, Conference Call
- July 23-25, 2024, Detroit

Attendance

- **Committee Members**
 - Alan Betensley
 - Kristine Browning
 - Hannah Copeland
 - Robert Fontana
 - Roshan George
 - Dipankar Gupta
 - Shelley Hall
 - Robert Harland
 - Rich Hasz
 - Kyle Herber
 - Victoria Hunter
 - Michelle James
 - Raymond Lee
 - Carolyn Light
 - Scott Lindberg
 - Maricar Malinis
 - Nancy Metzler
 - Cliff Miles
 - Saeed Mohammad
 - Regina Palke
 - Martha Pavlakis
 - Deidre Sawinski
 - J. David Vega
 - Mark Wakefield
 - Candy Wells
- **HRSA Representatives**
 - James Bowman
- **SRTR Staff**
 - Ryo Hirose
 - Jon Miller
 - Jon Snyder
 - Bryn Thompson
 - David Zaun
- **UNOS Staff**
 - Anne Ailor
 - Stephanie Anderson
 - Sally Aungier
 - Matt Belton
 - Nadine Cahalan
 - Robyn DiSalvo
 - Elinor Carmona
 - Laureen Edwards
 - Katie Favaro
 - Liz Friddell
 - Michelle Furjes

- Jasmine Gaines
- Houlder Hudgins
- Courtney Jett
- Elias Khalil
- Lee Ann Kontos
- Krissy Laurie
- Jon McCue
- Amy Minkler
- Heather Neil
- Delaney Nilles
- Jacqui O’Keefe
- Rob Patterson
- Liz Robbins Callahan
- Melissa Santos
- Laura Schmitt
- Sharon Shepherd
- Sarah Stevenson
- Juanita Street
- Stephon Thelwell
- Marta Waris
- Trevi Wilson
- Claudia Woisard
- Emily Womble
- Amanda Young
- **Other Attendees**
 - Gerald Morris, OPTN Histocompatibility Committee Chair