OPTN Membership and Professional Standards Committee
Meeting Summary
January 19, 2024
Conference Call

Zoe Stewart Lewis, M.D., Chair
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Introduction

The Membership and Professional Standards Committee (MPSC) met via Webex in both open and closed session on January 19, 2024, to discuss the following agenda items:

1. MPSC Project Review and Prioritization
2. Estimated Glomerular Filtration Rate (eGFR) Update
3. Report of Investigative Activities
4. Membership Related Actions

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

1. MPSC Project Review and Prioritization

OPTN Staff gave an overview of the current MPSC projects, their status, and timelines based on amount of work left in the project from today forward. The projects include:

- Membership Requirements Revision
  - Evidence gathering stage.
  - HRSA has approved resuming work on this project. There is a draft proposal for revisions to general requirements for application and review, OPO membership requirements, and transplant hospital and transplant program membership requirements. Additionally, a Request for Feedback on a framework for revisions to the organ-specific transplant program and key personnel requirements was released for public comment in Winter 2021 and revisions need to be made based on public comment.
- Enhanced OPO Performance Monitoring
  - Postponed release of concept paper for public comment
  - The Workgroup has been working on response to the HRSA request for input on upcoming HHS Secretarial Directive. Likely, there will be additional work in response to the Directive.
- Enhanced Transplant Program Performance Monitoring
  - Implementation stage
  - The last metric, pre-transplant mortality, will be implemented on the last day of the July 2024 MPSC Committee meeting. A program review process and guidance for programs on the new metric is needed. OPTN staff have already done some work by conducting key informant interviews with high performing transplant programs to gather feedback on best practices. A thematic analysis of the feedback gathered has been completed and an effective practice document is included in the meeting packet for the Committee's review. Additional work will be needed in the coming months.
- Require Reporting of Patient Safety Events
  - Implementation stage
  - The proposal was implemented on January 10, 2024

- Allocation Review
    - Operational; work is intermittent when new ideas or issues arise.

OPTN staff then shared feedback given by the OPTN Board of Directors at its December 2023 meeting on the current projects.

- Allocation Review:
  This project may be affected by the initiatives of the Expeditious Taskforce and the OPTN Variance proposal that is currently out for public comment.
- Membership Requirements Revision:
  There is a need to continue work on language to address required reports removed from the required reporting proposal, specifically pertaining to the reporting of sanctions against transplant professionals and attempts to deceive the OPTN and/or HHS. The Board requested that work continue on bylaw revisions for primary physician and primary surgeon requirements, voicing specific concerns about limited currency requirements.
- Transplant Program Performance Monitoring:
  The Board discussed possible changes to the review of post-transplant outcomes to align with taskforce goals and pilot projects.

OPTN staff then addressed each project separately and requested specific feedback on topics related to transplant program performance monitoring and allocations review.

Transplant Program Performance Monitoring

OPTN staff introduced a discussion of post-transplant outcomes monitoring.

The Board of Directors and Expeditious Taskforce requested feedback on potential temporary suspension of monitoring of post-transplant outcome metrics. The Board and Taskforce expressed that there is continued concern in the community that outcomes review disincentivizes programs from accepting lower quality organs and performing riskier transplants and requested that the MPSC discuss how to address this concern. The BOD and Taskforce acknowledged that risk adjustment should address riskier transplants but asked that the MPSC discuss appropriate survival thresholds.

OPTN staff reviewed the current 90-day graft survival and 1-year graft survival conditional on 90-day survival thresholds for pediatric and adult transplants. The MPSC received a high-level snapshot of data on post-transplant outcomes, including the number of programs under review. They reviewed the largest outliers for each organ, as there are programs with three times as many events as expected.

OPTN staff summarized comments from members involving patient safety from different reviews based on these metrics, then turned to the Committee for discussion.

<u>Summary of Discussion:</u>

A Committee member commented that post-transplant outcome metrics are a substantial barrier to programs performing riskier transplants, especially for heart transplants. They noted fear in the community of pushing the limit and transplanting more patients without negatively impacting outcomes. The member did not support suspending review of post-transplant outcome monitoring but suggested that lowering the thresholds that trigger review as a middle ground, citing a past idea to drop

heart thresholds to 80 percent survival. The member suggested that this could alleviate community concern, while still requiring transplant programs to justify negative patient outcomes.

Another Committee member expressed support for the initiative, but highlighted that while MPSC action is necessary, it is not sufficient without changes to the SRTR, as insurance companies use SRTR data when evaluating transplant programs. For meaningful impact, changes to the SRTR's data output and MPSC monitoring would need to happen in conjunction, and this would require HRSA involvement to drive changes.

A Committee member indicated they disagree with suspending post-transplant outcome monitoring, considering this course of action dangerous and out of line with the direction of the medical community. The member expressed that the bigger problem is flawed algorithms for predicting patient outcomes, as current algorithms underestimate post-transplant mortality risk. They expressed the need for an in-depth review of data analysis utilized to predict outcomes.

Another Committee member remarked that post-transplant outcome monitoring and review can drive change in struggling programs by pushing program administration to increase transplant program support and resource allocation. Lack of review could result in these types of programs falling into a downward spiral in outcomes. The member also pointed to the need for better predictive models for outcomes, as the current models do not account well enough for risks, and suggested that to allow for increased risk, the Committee could provide specific exemptions for extended criteria in desired areas.

A Committee member commented that risk calculators do not account enough for complexity, especially for pediatric programs, and that they overestimate expected survival post-transplantation. When transplant volumes are small, one high risk patient can skew the percentage of survival.

A Committee member serving on the Expeditious Taskforce expressed that the MPSC should not completely suspend all post-transplant monitoring. They also commented on the MPSC's inability to determine SRTR processes, and suggested focusing on what is in the Committee's control to change in terms of supporting and encouraging desired behavior from transplant programs when it comes to taking risks. The member advised that the Committee should work with the SRTR early in the process should changes to post-transplant outcome monitoring proceed, and conduct changes as a study similar to how metric changes were handled during COVID.

Another Committee member voiced that lowering thresholds would be an effective way to motivate programs to take more risk, referencing a previous kidney collaborative that provided a waiver on outcome reviews to participants.

A Committee member highlighted the value of flagging programs for inspiring process changes, increasing resources, and improving outcomes, noting that suspending post-transplant outcome review would not be wise from a patient perspective, progress perceptive, or when considering the public's perception of monitoring, with a potential negative impact to the perception of professionals policing

themselves. The member expressed support for improvement of predictive models and discussion of fair and equitable practices with the SRTR and other stakeholders. The member stated that expedited placement or workload concerns were flawed arguments for suspension of post-transplant outcome monitoring.

Another Committee member indicated agreement with not suspending monitoring, and instead lowering the thresholds, with the caveat that once thresholds are lowered, the Committee will have to find a way to quickly differentiate between programs doing high risk transplants versus programs with underlying problems before conducting full reviews based on changes in outcomes.

SRTR staff expressed willingness to work with the Committee to review the predictive models. They explained that a subcommittee helps with model construction and improvement, and that models are assessed and updated every 6 months. They referenced precedent from the impact of a change in operational rules for reviews on kidney utilization. Based on data, the change did not increase use of high Kidney Donor Profile Index (KDPI) kidneys, likely because models adjust for KDPI. The SRTR is willing to work to get better risk adjusters, and in the past has advocated for more granular adjustment. The SRTR wants to hear from the Committee on what risk factors might not be accounted for, then work with the Committee and the Data Advisory Committee to get them into the models.

OPTN staff summarized the Committee's discussion, stating that the Committee does not at this time support completely suspending review of all post-transplant outcomes, but discussed different options such as changing the thresholds for review, discussing risk adjustment model improvement with the SRTR, and discussing information that is available to the public and how it affects the MPSC's review of members.

Allocations Review

OPTN staff presented a proposed operational change to allocation out of sequence (AOOS) monitoring.

Initially, staff provided an overview of the previous Committee work on allocations review. Staff then updated the Committee on efforts to evaluate ways to decrease case review burden while meeting the Committee's charge to evaluate member policy non-compliance of AOOS cases. While the AOOS case volume has continued to increase, data showed that since 2020 there have been a comparatively small number of Notices of Non-Compliance given to OPOs and transplant hospitals, with most cases closed with no action.

After reviewing five different monitoring options, the MPSC Allocations Subcommittee suggested a two-fold approach:

- Targeted: Utilize previous MPSC AOOS monitoring decisions as guidelines for what to share in the future. There are some obvious trends for which cases resulted in the highest number of notices:
    - Rerunning a liver match within 8 hours
    - Simultaneous liver kidney (SLK) when kidney was non-eligible
    - Actual vs. intended transplants where a transplant hospital accepts the organ for one candidate and transplants another candidate on the waiting list
    - OPOs not responding to allocation inquiries

    - Other allocations that involve concerns identified by allocation review staff
- Random Sample: Utilize processes from other types of OPTN monitoring
    - Computer-generated random sample of 50% of AOOS reviewed for each OPO
    - OPTN staff will continue to inquiries on every AOOS

Use of these two approaches will result in approximately 5-20 cases per meeting using the specific criteria from the targeted approach and for April cases, 690 cases under the random sample approach.

Additionally, OPTN staff has engaged with IT to collect additional data points at the time of allocation that would reduce member inquiry burden, including why organ was allocated out of sequence, was there a previous primary acceptance that later changed to a decline, and how much cold ischemia time (CIT) had accrued when bypasses were first initiated. OPO allocation review summaries could include non-use trends, AOOS trends, organ yield, and previous MPSC notices. AOOS review documentation could also include potential transplant recipient (PTR) sequence when first bypass was entered and amount of time prior to or after cross clamp when first bypass was entered.

Staff is also researching ways to monitor late turns downs resulting in organ non-use and organs placed out of sequence, in addition to how "recovered for transplant but not transplanted" organs are being defined or labeled as such.

The Committee was asked for feedback on the Allocation Review Subcommittee's recommendation for changes to the MPSC allocation review.

Summary of Discussion:

A Committee member asked whether the proposed review process includes both the targeted and random approaches, or would it be either one approach or the other. Staff confirmed the subcommittee suggested the combination of both approaches, while erring on the side of a 50% threshold for the random sampling with a possibility of decreasing sample size if warranted. The Committee member then asked if the MPSC could vote on each approach separately, i.e., suggesting a lower threshold. Staff confirmed the vote could be separate, but reiterated the threshold could be modified based on data review.

Another Committee member commented on the importance of making data unform across the country and providing member guidance for bypass code data entry and guidance for MPSC reviewers. Staff replied that they plan to provide IT data entry guidance and could also do an educational effort.

The Committee approved the proposed AOOS review process as outlined above, by a vote of 25 Yes, 1 No, 0 Abstentions.

OPO Performance Monitoring

OPTN staff presented an overview of the roadmap for the project, highlighting that the project is divided into two phases. Phase one focuses on data collection for donation referrals and the reasons they do not proceed to donation. The Committee developed a concept paper on this topic. The release of the concept paper for winter 2024 public comment has been postponed at the request of HRSA to avoid confusion with an upcoming HHS Secretarial Directive that will direct the OPTN to collect data that overlaps with the data that would be captured in the draft data capture tool addressed in the concept paper.

Though the concept paper was postponed, the workgroup has been and will continue to work on developing feedback on the data collection that will be reflected in the HHS Secretarial Directive.

Phase two work is on hold until there is sufficient data to develop metrics.

Membership Requirements Revision Project

OPTN staff gave an overview of the history and status of the project, which is not currently active due to a hold placed by HRSA. HRSA has given the OPTN approval to resume work on this project. During the July 2019 meeting, the Committee discussed prioritization of project ideas. Revision of Membership OPTN bylaw requirements were tagged as the top priority, in part due to an OPTN contract task to develop a process for periodic reassessment of OPTN membership status of members.

There were also many inconsistencies and issues that had been identified by OPTN staff and Committee members, so the Committee decided to do a comprehensive review and revision of the membership requirements bylaws in addition to addressing the contract task. The project took a phased approach. A workgroup did extensive work from 2019 to 2021, leading to development of

- A proposal for revisions to the general membership requirements bylaws regarding the membership application and review process, OPO membership requirements and transplant hospital membership and transplant program requirements. The release of this proposal for public comment was put on hold in January 2021.
- A Request for Feedback on a standardized framework for transplant program key personnel requirements that was released for public comment in Winter 2021. The Committee conducted a partial review of the feedback received, but additional review is needed before moving to the phase of applying the framework to organ-specific requirements in collaboration with OPTN organ-specific committees.

OPTN staff then reviewed the guiding considerations established by the MPSC during the previous project work, which include compliance with the OPTN Final Rule, ability to support a process for periodic reassessment, consistency with current practices and qualifications, and reduction of complexity to simplify membership application submission and review, including stratification of requirements based on application type. Early in the project, HRSA provided feedback that the existing requirements were not entirely consistent with the OPTN Final Rule and the bar for membership as defined in that rule. Proposed changes addressed this feedback.

Staff discussed the status of work completed on specific OPTN bylaw appendices, and referred the Committee to a summary on proposed changes that is available to the Committee in the meeting packet, indicating that a more detailed review is forthcoming pending a committee decision on whether work on this project should resume.

After concluding the overview of all projects, the scheduled meeting time ran short, and so discussion of project prioritization was postponed to a future MPSC meeting. OPTN staff indicated that the Committee members serving on the Expeditious Taskforce may present to the taskforce on Committee projects at a future taskforce meeting.

2. Estimated Glomerular Filtration Rate (eGFR) Update

The MPSC re-reviewed the requirements for kidney programs regarding the review of their waitlists, notification to patients, submission of waiting time modifications, and attestation to the OPTN that the steps have been completed. As of January 4, 2024, one day after the deadline, all kidney programs had submitted their attestations. However, HRSA raised concerns over programs that have submitted an attestation and did not submit or only submitted a few waiting time modifications while having Black or African American candidates on their waiting lists. Due to the concerns raised, the OPTN Executive

Committee discussed potential further action or inquiry for these members to understand their process and try to ensure candidates are not continuing to be disadvantaged due to a race inclusive eGFR calculation. As a next step, the MPSC was tasked with identifying a plan and threshold for further inquiry with kidney programs that may raise these concerns.

The MPSC considered potential options for how to obtain relevant information from identified programs, some of the challenges associated with the current policy, and a meaningful threshold for when to inquire.

Summary of Discussion:

A member noted that the policy as written did not provide granular direction to programs on how they should meet the requirements or how to document their processes, which leaves challenges when the MPSC is asked to further audit these programs. The member suggested that this policy be referred by the MPSC in the future to add a requirement that the protocols be documented so there is something to review. They added that a potential first step with the current request from the Executive Committee would be to inquire with every kidney program and ask for a copy of their protocol to meet the policy requirements and are continuing to use for their patients.

A HRSA Representative acknowledged that the implemented policy has some challenges with compliance monitoring, but reminded the MPSC that OPTN members are required to submit non-fraudulent information to the OPTN so there is a need to verify that they completed the requirements, so candidates are not further disadvantaged. A member replied with their concerns over the policy not requiring documentation, so the MPSC may inquire with a member and the member may verbally say they completed all the steps, which may be all there is without a true way to verify that information. The member asked for HRSA's assistance for how to approach those situations.

Another member clarified that the OPTN Kidney Transplantation Committee specifically did not establish a minimum threshold or percentage or modifications that would reflect good effort by the program because the wait time modification was tied to a prior lab value, which may not exist for every Black or African American candidate. They added that all Black and African American candidates currently listed are potentially eligible for a waiting time modification, not automatically eligible, particularly those candidates who crashed onto dialysis and would not have prior lab values. The member also stated it would be reasonable to count a program that had zero waiting time modifications as a red flag, but programs that did their due diligence should not have to do more work justifying what they have done since it was a large burden for programs. The member suggested understanding the trends in how many modifications were submitted for different programs and using that to identify who to further inquire with instead of reaching out to all programs. Other members agreed that the MPSC should not inquire with all kidney programs and asked who would be tasked with reviewing that information if that was the approach.

A member commented that the guidance here is to trust that programs met requirements, but the MPSC is tasked with verifying that on some level. They added the MPSC should develop some standard criteria around distributions of number of potentially impacted candidates and how many modifications were submitted and determine a threshold (i.e., lower 10% or 20%) on when to ask more questions or have them participate in a remote survey. A member asked if this was something that could or would be reviewed as part of routine site surveys and OPTN Contractor staff clarified that this is a more urgent request and that the site survey team has added an interview question to touch base on how programs are following the policy.

A member noted that the ask of kidney programs as been well communicated over the course of the year and did not support a blanket approach but rather inquiring with programs that may have a number of candidates on their list but submitted less than what may have been expected. They added that seeing that data would be the first step, then a letter of inquiry, and determine the level of engagement by the MPSC based on the programs' response.

A member commented that a late in the year submission of an attestation should not be a "red flag" for programs since their program started immediately but submitted late in the year and that there was no requirement for when the attestation was submitted other than prior to the deadline. Another member agreed and mentioned the programs that submitted an attestation early may be more of a "red flag."

A member added that pediatric programs were confused by the requirements and urged the MPSC to exclude pediatric programs from inquiry since it is unlikely that they have candidates that were impacted. The MPSC supported excluding pediatric kidney programs.

Next Steps:

The MPSC will need to utilize data (number of potentially impacted candidates and how many modifications were submitted) to determine which kidney programs to further inquire with and would revisit the topic of next steps during their January 29 meeting.

3. Report of Investigative Activities

OPTN Contractor staff supplied a summary of investigative activity from December 2023. 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.

4. Member Related Actions

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 meets in closed session and 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 26 For, 0 Against, and 0 Abstentions. There were no issues discussed during this meeting.

The Committee will ask the Board of Directors to approve the following recommendations during the June 16-18, 2024, meeting.

- Approve 1 New Component
- Approve 1 Program Reactivation
- Approve 2 Business Membership Renewals
- Approve 1 New Business Membership
- Approve 1 Public Organization Membership Renewal

The Committee also reviewed and approved the following program related actions and personnel changes

- 1 Program Inactivation Extension
- 32 applications for changes in key personnel in Transplant Programs or Components

- 1 application for a change in key personnel in Histocompatibility Laboratories

In addition, the Committee received notice of situations where members, programs, or components had inactivated or withdrawn.

Upcoming Meetings

- January 29, 2024, 1-3pm, ET, Conference Call
- February 16, 2024, 2-4pm, ET, Conference Call
- March 5-7, 2024, Detroit
- March 29, 2024, 2-4pm, ET, Conference Call
- Apr 23, 2024, 3-5pm, ET, Conference Call
- May 21, 2024, 2-4pm, ET, Conference Call
- June 28, 2024, 2-4pm, ET, Conference Call
- July 23-25, 2024, Detroit

Attendance

- **Committee Members**
  - Maher Baz
  - Alan Betensley
  - Kristine Browning
  - Chad Ezzell
  - Robert Fontana
  - Roshan George
  - Darla Granger
  - Lafaine Grant
  - Dipankar Gupta
  - Shelley Hall
  - Robert Harland
  - Rich Hasz
  - Kyle Herber
  - Victoria Hunter
  - Catherine Kling
  - Peter Lalli
  - Carolyn Light
  - Scott Lindberg
  - Maricar Malinis
  - Amit Mathur
  - Deborah McRann
  - Nancy Metzler
  - Saeed Mohammad
  - Regina Palke
  - Martha Pavlakis
  - Deidre Sawinski
  - Zoe Stewart Lewis
  - J. David Vega
  - Mark Wakefield
  - Candy Wells
  - James Yun
- **HRSA Representatives**
  - Shannon Dunne
  - Marilyn Levi
  - Chris McLaughlin
  - Arjun Naik
  - Kala Rochelle
- **SRTR Staff**
  - Jonathan Miller
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - Robert Albertson
  - James Alcorn
  - Sally Aungier

    - Matt Belton
    - Linwood Butler
    - Nadine Cahalan
    - Elinor Carmona
    - Robyn DiSalvo
    - Liz Friddell
    - Michelle Furjes
    - Caroline Hales
    - Houlder Hudgins
    - Elias Khalil
    - Lee Ann Kontos
    - Krissy Laurie
    - Jon McCue
    - Amy Minkler
    - Heather Neil
    - Samantha Noreen
    - Rob Patterson
    - Bronson Robertson
    - Laura Schmitt
    - Sharon Shepherd
    - Courtney Skeen
    - Chris Stadolnik
    - Mike Stanley
    - Sarah Stevenson
    - Marta Waris
    - Betsy Warnick
    - Trevi Wilson
    - Claudia Woisard
    - Emily Womble
    - Karen Wooten
    - Amanda Young
- **Other Attendees**
    - None